Code of Practice update October 2023.

Details about this paper

Area(s) of strategy this paper relates to:	The right information
Meeting:	Authority
Agenda item:	7
Paper number:	HFEA (22/03/2023) 000
Meeting date:	22 March 2023
Author:	Niamh Marren, Regulatory Policy Manager
Annexes	Annex 1: Guidance note 2 - Staff Annex 2: Guidance note 3 - Counselling and patient support Annex 3: Guidance note 4 – Information to be provided prior to consent Annex 4: Guidance note 5 – Consent to treatment, storage, donation, training and disclosure of information Annex 5: Guidance note 6 – Legal parenthood Annex 6: Guidance note 11 – Donor recruitment, assessment and screening Annex 7: Guidance note 12 – Egg sharing arrangements Annex 8: Guidance note 15 – Procuring, processing and transporting gametes and embryos Annex 9: Guidance note 17 – Storage of gametes and embryos Annex 10: Guidance note 19 - Traceability Annex 11: Guidance note 22 – Research and training Annex 12: Guidance note 25 – Premises, practices and facilities Annex 13: Guidance note 26 – Equipment and materials Annex 14: Guidance note 28 - Complaints

Output from this paper

For information or decision?	For decision
Recommendation:	Authority members are asked to: 1. approve the proposed amendments outlined in the Annexes to the Code of Practice, to be introduced in October 2023 subject to sign-off by the Secretary of State for Health and Social Care 2. agree to reviewing and approving any additional necessary guidance changes outside of an Authority meeting as they will need to be incorporated as early as possible to ensure that the guidance we provide to the sector is current and valid
Resource implications:	Within budget
Implementation date:	We are preparing for publication in October 2023, dependent on ministerial and Parliamentary approval. We will keep Authority members and clinics informed in advance of the publication of this update.
Communication(s):	Code of Practice, Chair's letter and Clinic Focus article, LCP
Organisational risk:	Medium

Annex 1

2. Staff

Version 2.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

16 The person responsible

(1) It shall be the duty of the individual under whose supervision the activities authorised by a licence are carried on (referred to in this Act as the "person responsible") to secure -

a) that the other persons to whom the licence applies are of such character, and are so qualified by training and experience, as to be suitable persons to participate in the activities authorised by the licence,

Schedule 3A Supplementary Licence Conditions: Human Application

Requirements for procurement of gametes and embryos

5. Licence conditions shall require all persons to whom a licence applies who are authorised to procure gametes or embryos, or both, to comply with the requirements (including as to staff training, written agreements with staff, standard operating procedures, and appropriate facilities and equipment) laid down in Article 2 (requirements for the procurement of human tissues and cells) of the second Directive.

Licence conditions

T11 The centre must have an organisational chart which clearly defines accountability and reporting relationships.

T12 Personnel in the centre must be available in sufficient number and be qualified and competent for the tasks they perform. The competency of the personnel must be evaluated at appropriate intervals.

T13 All personnel must have job descriptions that accurately reflect their tasks, and responsibilities.

T14 Personnel carrying out licensed activities or other activities carried out for the purposes of providing treatment services that do not require a licence must, where appropriate, be registered in accordance with the appropriate professional and/or statutory bodies, (eg, General Medical Council, Health & Care Professions Council, Nursing and Midwifery Council).

T15 Personnel must be provided with initial/basic training. Training must be updated as required when procedures change or scientific knowledge develops, and adequate opportunity for relevant professional development must be provided. The training programme must ensure and document that each individual:

(a) has demonstrated competence in the performance of their designated tasks

(b) has an adequate knowledge and understanding of the scientific/technical processes and principles relevant to their designated tasks

(c) understands the organisational framework, quality system and Health & Safety rules of the centre in which they work, and

(d) is adequately informed of the broader ethical, legal and regulatory context of their work.

T16 The centre must have access to a nominated registered medical practitioner, within the UK, to advise on and oversee medical activities.

HFEA guidance

Centre staff

2.1 The centre should establish documented procedures for staff management that ensure all staff have:

(a) initial basic training and updated training as required
(b) on-going competence assessment, with audits of this assessment
(c) an annual joint review (with their line manager)
(d) continuing education and professional development
(e) staff records, and
(f) appropriate access to meetings and communications.

2.2 Staff records should include:

(a) job description
(b) terms and conditions of employment
(c) a record of staff induction and orientation
(d) a record of health and safety training
(e) a record of education and training, including continuing professional development
(f) relevant educational and professional qualifications
(g) certificate of registration, if relevant
(h) absence record
(i) accident record
(j) a record of annual joint reviews
(k) occupational health record, and
(l) a record of any disciplinary action.

The centre should ensure that confidentiality of staff records is in line with best practice and relevant legislation.

2.3 All staff should maintain an up-to-date awareness and understanding of legal obligations and support the person responsible in monitoring and improving the performance of the centre.

2.4 All staff should participate in an annual joint review that examines the needs of the centre and of the individual to improve the quality of the service to users and to encourage productive working relationships. Staff performing annual reviews must receive appropriate training.

2.5 The centre should have an effective way of communicating information to, and receiving suggestions from, staff. Centre management should also ensure that the accountabilities and reporting relationships shown in the centre's organisational chart are communicated within the centre.

2.6 Centre management should ensure that staff members who are in contact with patients, donors and their partners (where applicable):

(a) follow the centre's 'patient support policy'
(b) are prepared to offer appropriate emotional support to people suffering distress at any stage before, during and after treatment
(c) understand and can explain the role of counselling, and
(d) know when and how to refer people to the centre's qualified counsellor.

For more detailed guidance on the centre's patient support policy, see paragraph 3.14 of guidance note 3 ('Counselling and patient support").

2.7 Centre management are responsible for delivering the patient support policy and for using intelligence to monitor and evaluate the effectiveness of the policy. Centre management should ensure that the policy addresses the emotional support needs of patients, donors and their partners (where applicable) in order to continuously improve their experience of treatment services.

2.8 Centres should require all prospective and existing staff to report promptly all criminal convictions they have had to the person responsible. In deciding whether or not an individual shall take part in a licensed activity at the centre, the person responsible should take into account relevant previous convictions and breaches of regulations.

Medical staff

2.9 The person responsible should ensure that staff who must be registered with professional bodies are registered, their registration is up to date, and records of this are kept.

2.10 The individual with overall medical responsibility for treatment services involving in vitro fertilisation should:

(a) have completed training recognised by the Royal College of Obstetricians and Gynaecologists (or an equivalent professional body)
(b) be on the General Medical Council's Specialist Register, and
(c) participate in a recognised programme of continuing medical education and professional development.

2.11 If the centre is licensed to provide insemination services only, the individual with overall medical responsibility should:

(a) be a registered medical practitioner, and
(b) have sufficient experience in an established fertility centre to be qualified to take full charge of the centre's treatment services.

2.12 Other medical staff who take part in providing treatment services should be registered medical practitioners with sufficient experience under supervision to qualify them to do so. Medical staff who do laparoscopies should be Fellows or Members of the Royal College of Obstetricians and Gynaecologists (or an equivalent professional body). Medical staff in training should follow relevant training programmes under appropriate supervision.

2.13 New healthcare workers who will perform exposure prone procedures (EPP) are required to demonstrate that they are non-infectious for HIV and Hepatitis C and at low risk of transmitting Hepatitis B. These clearance checks must be completed before confirmation of an appointment to a post that will require performance of EPP.

Nursing staff

Interpretation of mandatory requirements 2A

All nursing staff must be appropriately qualified and registered by the Nursing and Midwifery Council.

2.14 Nurses should be:

(a) working towards competencies set nationally, locally or both, to ensure appropriate standards of clinical competence, and
(b) able to provide evidence of competence in the duties performed (for example, a certificate for a recognised qualification or a written testimonial by another person who is suitably qualified and competent in that discipline or function).

Counselling staff

2.15 Treatment centres should ensure that at least one individual is appointed to fulfil the role of counsellor. All counsellors should have specialist competence in infertility counselling and:

(a) hold a recognised counselling, clinical psychology, counselling psychology or psychotherapy qualification to the level of diploma of higher education or above, and
(b) be accredited under the scheme of the British Infertility Counselling Association (BICA) (or an equivalent body), or show evidence of working towards such accreditation.

2.16 This counsellor should be able to provide evidence of being an accredited member of, or working towards accredited membership of, a recognised professional counselling body. The body should have a complaints/disciplinary procedure, and the individual should have agreed to abide by this organisation's code of conduct or ethics. It is recognised that it may be necessary to appoint a generic counsellor to the role, who is not a fertility specialist. The appointed generic counsellor should be compliant with the requirement to be accredited under the scheme of the British Infertility Counselling Association (BICA) (or an equivalent body) within a period of two years. The BICA Accreditation Board has a list of relevant professional counselling/accreditation schemes.

2.17 Treatment centres carrying out preimplantation genetic testing or mitochondrial donation should ensure that patients have access to counsellors with appropriate knowledge and expertise in these specialisms, including a good understanding of the risks and implications for patients who have treatment involving mitochondrial donation techniques and any children that may be born following such treatment.

See also

Guidance note 3 – Counselling and patient support

Staff engaged in scientific services

2.18 Centre management should ensure that the centre has access to a nominated registered scientist to advise on and oversee scientific activities.

2.19 All healthcare scientists working in licensed centres should be registered or show evidence of working towards registration with the Health & Care Professions Council (HCPC), or other equivalent body where applicable. It is expected that all staff should be registered with the HCPC (or other equivalent body) within one year of their becoming eligible, including those eligible as international applicants after training overseas.

2.20 Healthcare scientists from overseas who are registered in their own country but working in a licensed centre as a visiting scientist, should seek temporary registration with the HCPC.

Healthcare scientists employed in roles not yet requiring state registration (eg, aspirant groups, healthcare science assistants and healthcare science practitioners) should follow an appropriate induction and training programme for the tasks performed. Each individual should maintain proper records of this training.

2.21 The individual responsible for the seminology laboratory should:

(a) possess a degree or higher national diploma in a relevant discipline
(b) have acquired sufficient experience in such a laboratory to supervise and be responsible for one, and
(c) be registered with the HCPC as a clinical scientist or biomedical scientist, or be able to demonstrate equivalent training or expertise.

See also

Association of Biomedical Andrologists: Laboratory andrology guidelines for good practice (third edition, 2012)

2.22 The individual responsible for the clinical embryology laboratory should:

(a) possess an appropriate scientific degree
(b) have had sufficient experience in such a laboratory to be able to supervise and be responsible for one, and
(c) be registered with the HCPC (or other equivalent body) as a clinical scientist with specific expertise in clinical embryology.

See also

Association of Clinical Embryologists: Accreditation standards and guidelines for IVF laboratories (2000)

Association of Clinical Embryologists: Guidelines on good practice in clinical embryology laboratories

Competence and training of ICSI and embryo biopsy practitioners and mitochondrial donation practitioners

2.23 The person responsible should ensure that micromanipulation procedures such as ICSI, embryo biopsy and mitochondrial donation are only carried out by practitioners who have the necessary competence.

2.24 Following training, the competence of each person performing micromanipulation procedures should be evaluated at intervals specified in the quality management system. Retraining should be given when required.

2.25 In the case of mitochondrial donation, only the embryologist(s) practitioner(s) who have been designated as competent by a licence committee ('the designated embryologist(s)') and named on the clinic's licence may carry out maternal spindle transfer (MST) and/or pronuclear transfer (PNT). If the clinic wishes to change the designated embryologist or add to the list of designated embryologists, the clinic will need to apply to the Authority to vary its licence.

Staff involved in genetic testing and mitochondrial donation

2.26 A senior clinical geneticist or mitochondrial disease expert should be involved in the decision-making process when deciding whether a patient should receive treatment involving embryo testing or mitochondrial donation.

2.27 The centre should ensure that a multidisciplinary team is involved in providing the service. Where relevant the team should include reproductive specialists, embryologists, clinical geneticists, genetic counsellors, cytogeneticist, molecular geneticists and mitochondrial disease specialists. It should maintain close contact with the primary care physician or the referring clinician.

2.28 If the centre offers an embryo testing or mitochondrial donation service, the individual responsible for this laboratory should:

(a) hold an appropriate scientific or medical degree
(b) have acquired sufficient experience in an appropriately accredited medical genetics diagnostic laboratory to supervise and be responsible for one, and
(c) be registered with the HCPC (or other equivalent body) as a clinical scientist with specific expertise in clinical genetics.

2.29 If genetic testing of those seeking treatment or considering donation is offered, the centre

should ensure that an individual is available who understands the:

(a) nature of the tests conducted
(b) scope and limitations of the tests
(c) accuracy and implications of the tests, and
(d) meaning of the test results.

2.30 The centre should ensure that people seeking treatment have access to clinical geneticists, mitochondrial donation specialists and genetic counsellors where relevant.

2.31 The centre should work closely with the local genetics or mitochondrial disease team of those seeking treatment.

See also

Guidance note 10 – Embryo testing and sex selection

Guidance note 33 – Mitochondrial donation

Other legislation, professional guidelines and information

Legislation

Clinic Focus article: counselling qualifications and equivalence (April 2022)

Clinic Focus article: Pre-employment health screening for staff (September 2022)

Association of Biomedical Andrologists: Laboratory andrology guidelines for good practice (third edition, 2012)

Association of Clinical Embryologists: Accreditation standards and guidelines for IVF laboratories (2000)

Association of Clinical Embryologists: Guidelines on good practice in clinical embryology laboratories (2012)

British Infertility Counselling Association: Guidelines for good practice in infertility counselling (fourth edition, 2019)

Royal College of Nursing: Representing nurses and nursing, promoting excellence in practice, shaping health policies

BICA Accreditation Board counselling qualifications and equivalence.pdf

BICA Counsellor Accreditation Scheme Guidance Handbook

Risk to healthcare workers - Blood borne viruses (BBV)

Obstetrics and gynaecology: exposure prone procedure categories - GOV.UK

Clinic Focus articles

Clinic Focus article: HCPC professional indemnity guidance (August 2013)

Clinic Focus article: Do your counsellors have the relevant qualifications? (January 2016)

Clinic Focus article: counselling qualifications and equivalence (April 2022)

Clinic Focus article: Pre-employment health screening for staff (September 2022)

Annex 2

3. Counselling and patient support

Version 3.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

13 (6) A woman shall not be provided with treatment services of a kind specified in Part 1 of Schedule 3ZA unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services of that kind, and have been provided with such relevant information as is proper.

13 (6A) A woman shall not be provided with treatment services after the happening of any event falling within any paragraph of Part 2 of Schedule 3ZA unless (before or after the event) she and the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of the woman being provided with treatment services after the happening of that event, and have been provided with such relevant information as is proper.

13A Conditions of licences for non-medical fertility services

(3) A woman shall not be provided with any non-medical fertility services involving the use of sperm other than partner-donated sperm unless the woman being provided with the services has been given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps and has been provided with such relevant information as is proper.

Schedule 3ZA

Part 1: Kinds of treatment in relation to which counselling must be offered

1. The treatment services involve the use of the gametes of any person and that person's consent is required under paragraph 5 of Schedule 3 for the use in question.
2. The treatment services involve the use of any embryo the creation of which was brought about in vitro.
3. The treatment services involve the use of an embryo taken from a woman and the consent of the woman from whom the embryo was taken was required under paragraph 7 of Schedule 3 for the use in question.

Part 2: Events in connection with which counselling must be offered

4. A man gives the person responsible a notice under paragraph (a) of subsection (1) of section 37 of the Human Fertilisation and Embryology Act 2008 (agreed fatherhood conditions) in a case where the woman for whom the treatment services are provided has previously given a notice under paragraph (b) of that subsection referring to the man.

5. The woman for whom the treatment services are provided gives the person responsible a notice under paragraph (b) of that subsection in a case where the man to whom the notice relates has previously given a notice under paragraph (a) of that subsection.
6. A woman gives the person responsible notice under paragraph (a) of subsection (1) of section 44 of that Act (agreed female parenthood conditions) in a case where the woman for whom the treatment services are provided has previously given a notice under paragraph (b) of that subsection referring to her.
7. The woman for whom the treatment services are provided gives the person responsible a notice under paragraph (b) of that subsection in a case where the other woman to whom the notice relates has previously given a notice under paragraph (a) of that subsection.

Schedule 3

3 (1) Before a person gives [or renews] consent under this schedule -

(a) he must be given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and

(b) he must be provided with such relevant information as is proper.

Licence conditions

T60 A woman must not be provided with treatment services using embryos or donated gametes unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services of that kind, and have been provided with such relevant information as is proper.

T61 A woman must not be provided with treatment services where there is an intended second parent unless, either before or after both have consented to the man or woman being the intended second parent, she and the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of the woman being provided with treatment services and have been provided with such relevant information as is proper.

HFEA guidance

The offer of counselling

Interpretation of mandatory requirements 3A

The law requires counselling to be offered when:

(a) a woman or couple seeks treatment with donated gametes or embryos (including mitochondrial donation)

(b) an individual or couple seeks treatment that will create embryos in vitro

(c) an individual or couple seeks to give or renew consent to the storage of their gametes or embryos (for exceptions see Schedule 3 of the HFE Act 1990 (as amended), paragraphs 9 or 10)

(d) an individual or couple seeks to donate their gametes or embryos for the treatment of others (including mitochondrial donation)

(e) an individual seeks to donate their gametes for use in non-medical fertility services

(f) an individual or couple seeks to donate their embryos for research purposes or for training people in embryo biopsy, embryo storage or other embryological purposes

(g) an individual seeks to provide their gametes or cells for the creation of embryos or human admixed embryos for research (for exceptions, see mandatory requirements outlined in guidance note 22 – research and training)

(h) a woman provides embryos (obtained by lavage) for any purpose

(i) written notice is served by a man or woman consenting to the man being treated as the legal father or parent of any child born as a result of the woman's treatment, or

(j) written notice is served by a woman, or her female partner, consenting to the partner being treated as the legal parent of any child born as a result of the woman's treatment.

3.1 The centre should provide a suitable opportunity for counselling after the individual or couple has received oral and written information about the services to be provided and before they consent to treatment or donation, or give or renew consent to the storage or use of gametes or embryos. Counselling should be made as accessible as possible. The timing and frequency of counselling sessions should be agreed between the counsellor and the person or couple concerned in order to best meet their needs.

3.2 The centre should make patients, donors and their partners (where applicable) aware that the offer of counselling is a routine part of the treatment pathway. The offer of counselling should include written information giving the name(s) of the qualified counsellor(s), explaining their role, when they are available and how to access the service. The centre should allow enough time before treatment starts for people to consider the offer and to take up counselling if they wish.

3.3 If the possibility of treatment with donated gametes or embryos arises (including mitochondrial donation), the centre should offer counselling about the implications of treatment with donated material separately from counselling about the implications of treatment in general, and before treatment with donor gametes starts. If the patient is seeking mitochondrial donation treatment, they should be able to access counsellor(s) with the relevant expertise through the centre performing the mitochondrial donation.

3.4 If the possibility of donating gametes or embryos (including mitochondrial donation) for the treatment of others, or donating embryos for research or training arises, the centre should offer counselling about the implications of donation separately from counselling about the implications of treatment before the treatment starts. If treatment has already begun, it should continue only if the potential donor and, if applicable, his or her partner have been offered counselling about the implications of donation.

3.5 The centre should provide proper counselling throughout the treatment, donation or storage processes, and afterwards if requested. Counselling should routinely be offered following adverse events and/or unsuccessful outcomes. If a person who has previously donated gametes or embryos (including mitochondrial donation), or received treatment, requests further counselling at any point, the centre should take all practicable steps to help them obtain it. Group sessions may be offered in addition to individual and couple sessions.

3.6 The centre should offer people the opportunity to take up counselling either with their partner and/or alone, depending on what each person prefers. In the case of counselling on the implications of treatment or donation, if two people are being treated together, then we would recommend they both attend the same counselling session(s).

See also

Guidance note 4 – Information to be provided prior to consent

Guidance note 6 – Legal parenthood

Guidance note 22 – Research and training

The provision of counselling

3.7 The provision of counselling should be clearly distinguished from:

(a) the assessment of a person's suitability to receive treatment, or to store or donate their gametes or embryos (including mitochondrial donation)
(b) the provision of information before obtaining consent or providing treatment, and
(c) the normal relationship between clinical staff and patients or donors.

3.8 The counselling service should comply with current professional guidance on good practice in infertility counselling. Only qualified counsellors should provide counselling.

See also

Guidance note 2 – Staff

3.9 Counselling should be available from a counsellor attached to the centre whose qualifications and experience satisfy the requirements of guidance notes 2.14 to 2.16. If this is not possible or if the patient prefers to seek counselling elsewhere, the centre should provide:

(a) information on local counsellors who have specialist competence in infertility counselling and who meet the requirements of guidance notes 2.14 to 2.16
(b) information on organisations that can provide specialist support.

3.10 The centre should ensure that arrangements are in place to provide, or refer people for, specialist counselling if appropriate, taking account of their duty of confidentiality under the HFE Act. This might include genetic counselling, counselling for patients undergoing treatment involving mitochondrial donation and counselling for oncology patients or others requiring the consenting to longer-term storage of gametes or embryos.

3.11 The centre should ensure that counselling facilities provide quiet and comfortable surroundings for private, confidential and uninterrupted sessions. Where possible, the centre should also make available alternative media for counselling sessions, such as video or audio calls, in order to make counselling as accessible as possible.

Counselling records and confidentiality

3.12 Information obtained during counselling should be confidential (although it may be disclosed in certain circumstances, for example if it gives rise to concerns about the suitability of a person to donate gametes, be a surrogate, or to receive treatment). The written records of the professional counsellor should be kept in a secure place. These written records are confidential and should not be shared with others, including clinic staff. The centre should ensure that their policies on record keeping and data protection include information on when the counselling records form part of the patient's medical record and therefore could be disclosed to the patient

on request.

3.13 The centre should keep a record that it has offered people counselling, even if they choose not to accept this offer.

See also

Guidance note 30 – Confidentiality and privacy

Patient support

3.14 The centre should develop a 'patient support policy' to outline how the centre ensures that patients, donors and their partners (where applicable) receive appropriate psychosocial support from all staff they encounter before, during and after treatment. Psychosocial support is delivered by all members of staff and includes, but is not limited to, access to counselling. All patients, donors and their partners (where applicable) should be treated with sensitivity and respect and supported through all aspects of their treatment and, in particular, if they are suffering distress at any stage. Patient support should be patient-centred and as far as possible centre staff should adapt the support offered to a patient according to their requirements and preferences. Centre staff should be sensitive to any ethnic, religious, societal, cultural or other factors which may influence the kind of support which is appropriate for an individual.

3.15 The policy should include:

a) a definition of patient-centred care and how this will be delivered at the centre
b) a statement regarding each individual staff member's responsibility for supporting patients and managing their expectations
c) a list of written and online information to be provided and how patients will be able to access this
d) where applicable, a list of any patient support events or activities provided by the centre or signposted to by the centre, which may include:
    i) support groups
    ii) forums for patients to engage with each other
    iii) signposting to external groups and forums
    iv) other events/groups etc
e) the expectations about how all staff will communicate with patients, donors and their partners
f) an outline of customised support at different stages of treatment and for different types of patients
g) a list of the training to be provided to centre staff relating to patient support, which may include skills training, information sessions for staff, e-learning courses etc, adapted as appropriate to reflect staff members' roles within the clinic
h) feedback mechanisms for collecting data on the patient/donor experience, and
i) quality indicators for systematically monitoring and evaluating the centre's provision of patient support and patient care as contained in this policy.

3.16 Clinics should offer a chaperone to a patient who is having an intimate examination, including those who are having fertility ultrasound scanning. This applies whether or not the member of staff conducting the examination is the same gender as the patient.

3.17 A chaperone should usually be a health professional and the PR must be satisfied that the chaperone will:

(a) be sensitive and respect the patient's dignity and confidentiality
(b) reassure the patient if they show signs of distress or discomfort
(c) be familiar with the procedures involved in a routine intimate examination
(d) stay for the whole examination and be able to see what the doctor is doing, if practical, and
(e) be prepared to raise concerns if they are concerned about the doctor's behaviour or actions.

3.18 Clinics should also refer to the HFEA's resources on patient support for further information on best practice.

Other legislation, professional guidelines and information

Professional guidelines

British Infertility Counselling Association: Guidelines for good practice in infertility counselling (fourth edition, 2019)

Routine psychosocial care in infertility and medically assisted reproduction – A guide for fertility staff

Intimate examinations and chaperones - ethical guidance - GMC

Clinic Focus articles

Clinic Focus article: Do your counsellors have the relevant qualifications? (January 2016)

Clinic Focus article: Did you know? Do your centre's counsellors have the relevant qualifications? (May 2021)

Clinic Focus article: offer a chaperone to a patient having an intimate examination (October 2021)

Annex 3

4. Information to be provided prior to consent

Version 4.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

12 General Conditions

(1) The following shall be conditions of every licence granted under this Act -

…(c) except in relation to the use of gametes in the course of providing basic partner treatment services, that the provisions of Schedule 3 to this Act shall be complied with,…

13 Conditions of licences for treatment

(6) A woman shall not be provided with treatment services of a kind specified in Part 1 of Schedule 3ZA unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services of that kind, and have been provided with such relevant information as is proper.

(6A) A woman shall not be provided with treatment services after the happening of any event falling within any paragraph of Part 2 of Schedule 3ZA unless (before or after the event) she and the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of the woman being provided with treatment services after the happening of that event, and have been provided with such relevant information as is proper.

13A Conditions of licences for non-medical fertility services

(3) A woman shall not be provided with any non-medical fertility services involving the use of sperm other than partner-donated sperm unless the woman being provided with the services has been given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and has been provided with such relevant information as is proper.

Schedule 3 – Consent to use or storage of gametes, embryos or human admixed embryos etc.

3 (1) Before a person gives [or renews] consent under this Schedule -

(a) he must be given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and

(b) he must be provided with such relevant information as is proper.

Licence conditions

T58 Prior to giving consent gamete providers must be provided with information about:

a. the nature of the treatment

b. its consequences and risks

c. any analytical tests, if they are to be performed

d. the statutory storage period applicable in their circumstances (storage periods will differ depending on whether gamete providers are storing for own use or donating for use in someone else's treatment or whether they are consenting to use for training or research purposes)

e. the requirement, for patients who are storing for use in their own treatment, to renew their consent in writing every 10 years (or at the end of any shorter period they consented to)

f. the legal requirement to remove gametes or embryos from storage and for these to be disposed of once they may no longer lawfully be kept

g. the recording and protection of personal data and confidentiality

h. the right to withdraw or vary their consent, and

i. the availability of counselling.

T59 The information referred to in licence condition T58 must be given by trained personnel in a manner and using terms that are easily understood by the gamete provider.

Note: For the mandatory requirements pertaining to consent, see guidance note 5 – consent to treatment, storage, donation, training and disclosure of information.

Directions

0005 – Collecting and recording information for the HFEA

HFEA guidance

Information to provide

Interpretation of mandatory requirements 4A

The law requires appropriate information to be provided when:

(a) a woman or couple seeks treatment with donated gametes, mitochondria or embryos (including mitochondrial donation)

(b) an individual or couple seeks treatment that will create embryos in vitro

(c) an individual or couple seeks to give or renew consent to the storage of their gametes or embryos (for exceptions, see Schedule 3 of the HFE Act 1990 (as amended), paragraphs 9 or 10)

(d) an individual or couple seeks to donate their gametes, mitochondria or embryos for the treatment of others (including mitochondrial donation)

(e) an individual seeks to donate their gametes for use in non-medical fertility services

(f) an individual or couple seeks to donate their embryos for research purposes, or for training people in embryo biopsy, embryo storage or other embryological techniques

(g) an individual seeks to provide their gametes or cells for the creation of embryos or human admixed embryos for research (for exceptions, see mandatory requirements outlined in guidance note 22 – research and training)

(h) a woman provides embryos (obtained by lavage) for any purpose

(i) written notice is served by a man or a woman consenting to the man being treated as the legal father of any child born as a result of the woman's treatment, or

(j) written notice is served by a woman, or her female partner, consenting to the partner being treated as the legal parent of any child born as a result of the woman's treatment.

Information must always be provided before consent is given to treatment, storage, provision or donation (cases (a) to (h) above) or treatment is provided or continued (cases (i) and (j) above). In the case of donors wishing to donate gametes or embryos for use in mitochondrial donation and patients wishing to undergo treatment involving mitochondrial donation, the above information must be provided by a centre licensed to offer mitochondrial donation.

Preparation for treatment

4.1 Centres should be aware of their obligations under consumer law and should have regard to guidance published by the Competition and Markets Authority (CMA), including that information provided to prospective and current patients is clear, accurate, easy to find, and enables patients to make properly informed decisions. This includes verbal and written information, for example information provided to patients or prospective patients at events and centre open days, in brochures, on centre websites and portals, during consultations and in consultation letters.

4.2 Centres must give prospective and current patients and donors sufficient, accessible and up to-date information to enable them to make informed decisions about their treatment and any consent they provide.

4.3 Centres must provide information and offer counselling for people about the implications of treatment. Centres should ensure that all patients are prepared for treatment. Preparation for treatment includes the provision of information, the discussion of the implications involved, and the offer of counselling.

4.4 Centres should explain the role of counselling for emotional support. Where a person chooses not to take up the offer of counselling, the implications of treatment must be discussed as part of their preparation for treatment. The discussion of implications forms part of the routine provision of information prior to consent, and the person should be given enough time to consider those implications before consenting.

4.5 Centres should ensure that patients have a suitable opportunity to discuss the emotional impact of those implications. Given that emotional issues may surface during the discussion of implications, a qualified counsellor is best suited to having these discussions, even in those cases where the offer of counselling has been declined. Where a qualified counsellor is not available, the PR should be able to assure themselves that the member of staff leading the discussion is sufficiently skilled, knowledgeable and experienced.

4.6 In cases involving third party donation and surrogacy arrangements, our expectation is that the discussion of implications should be delivered by a qualified counsellor.

See also

Guidance note 3 – Counselling and patient support

Information specific to the centre

4.7 Before treatment is offered, the centre should give the woman seeking treatment and her partner, if applicable, information about:

(a) the centre's policy on selecting patients
(b) the centre's statutory duty to take account of the welfare of any resulting or affected child
(c) the expected waiting time for treatment
(d) fertility treatments available, including any treatment add-ons which may be offered and the evidence supporting their use; any information should explain that treatment add-ons refers to the technologies and treatments listed on the treatment add-ons page of the HFEA website www.hfea.gov.uk/treatmentaddons.
(e) the availability of facilities for freezing and storing eggs, sperm and embryos
(f) where patients are freezing and storing eggs, sperm or embryos, the centre should provide information about future use including information about consent to posthumous use, and the duration of storage and renewal of consent
(g) the importance of informing the treatment centre about the eventual outcome of the treatment (including if no live birth results)
(h) the centre's complaints procedure
(i) the availability of emotional support for patients before, during and after treatment.

Information about the treatment

4.8 Before treatment is offered, the centre should give the woman seeking treatment and her partner, if applicable, information about:

(a) the likely outcomes of the proposed treatment (data provided should include the national live birth rate and clinical pregnancy rate and the centre's most recent live birth rate and clinical pregnancy rate; centres are encouraged to provide data per embryo transferred where relevant),
(b) the nature of the proposed treatment and any treatment add-ons, including evidence of effectiveness – the centre should provide information in a lay format with reference to the HFEA website as outlined in 4.7 (d),
(c) the implications of treatment, including for example, the possibility of a negative outcome which could cause distress or a multiple pregnancy, and
(d) why the proposed treatment, including any treatment add-on, is being offered and how it may benefit that patient specifically.

Information about the risks of treatment

4.9 Before treatment is offered, the centre should give the woman seeking treatment and her partner, if applicable, information about:

(a) the potential immediate and longer-term risks of the treatment and any treatment add-ons used, including the risks to the patient and the possibility of any children conceived having developmental and birth defects
(b) the nature and potential risks of any alternative treatment options available so the patient can make an informed decision about their treatment
(c) the possibility of developing ovarian hyperstimulation syndrome (OHSS); any information provided should include the possible symptoms of OHSS, what the woman being treated should do and who to contact if experiencing symptoms of OHSS
(d) the nature and potential risks (immediate and longer term) of using emerging or unproven treatments, including reference to the centre's experience and wider evidence base
(e) the potential risk of emotional distress associated with negative outcomes both during and after treatment.

Information about data and success rates

4.10 In line with the Advertising Standards Authority's (ASA) Code and guidance published by the CMA, the centre should ensure that the information provided on its website complies with the following guidance. This also applies to other relevant marketing communications of the centre and associated satellite and transport centres.

(a) The information should include the most recent data available from the past three years.
(b) Centres are encouraged to display live birth rate data per embryo transferred where relevant and this may be displayed alongside other success rate measures. The information

should not highlight a high success rate that applies only to a small, selected group of patients.

(c) The data should show split by maternal age and, if appropriate, by treatment type.

(d) The information should provide raw numbers rather than just percentages.

(e) The website should provide the national rate and like-for-like comparisons (the same year, maternal age, treatment type, etc.).

(f) The centre's published success rate data should refer to the HFEA as the source of national information through its Choose a Fertility Clinic function.

(g) The information must state clearly that information on success rates is of limited value in comparing centres and choosing where to seek treatment. It should include a link to the HFEA's advice on choosing a clinic: www.hfea.gov.uk/choose-a-clinic/learn-about-choosing-a-clinic/

(h) If the information refers to comparative costs, it should indicate the likely total cost for a typical cycle, based on the actual costs for recent patients, not individual items in tariffs.

Information about the cost of treatment

4.11 Before treatment, storage or both are offered, the centre should also give the person seeking treatment or storage, and their partner (if applicable) a personalised costed treatment plan. The plan should detail the main elements of the treatment proposed (including investigations, tests and treatment add-ons), the cost of that treatment and any possible changes to the plan, including their cost implications. The centre should give patients the opportunity to discuss the plan before treatment begins. Clinics should follow GMC guidance on financial and commercial arrangements and conflicts of interest, and be open, clear and honest about fees and any financial interests.

Information about contracts

4.12 Centres should be aware of their obligations under the Consumer Protection from Unfair Trading Regulations 2008, Consumer Contracts (Information, Cancellation and Additional Charges) Regulations 2013, and Parts I and II of the Consumer Rights Act 2015 and should have regard to guidance published by the CMA.

4.13 Where centres enter into contractual arrangements with patients, these contracts should include the necessary information as required by consumer law and CMA guidance, including:

(a) An explanation of the services that are to be provided to patients under the contract and the price to be paid for them

(b) Any important conditions attached to the service being offered – for example:
  (i) if there is a time limit on completing the treatment, such as if a set number of cycles need to be completed within a specified time
  (ii) the circumstances in which treatment may be delayed, such as if a suitable donor needs to be identified before treatment can commence and/or
  (iii) if patients are required to purchase medication directly from the centre or a chosen supplier.

(c) Information about why and how the treatment (and who provides the treatment) may vary

(d) Information about why and how the agreed price may vary in the future (in circumstances where no changes are made to the agreed treatment). For example, for contracts for egg or embryo storage, which may last a number of years

(e) The name and location(s) of the centres(s) where treatment will be carried out, including, where applicable, whether a partner or third-party business will be carrying out any aspects of the service at a different location

(f) How and when payments are to be made and to whom, including where the centre has arranged for a partner or third party to provide some of the services
(g) Information about any costs involved should the patient wish to use services offered by third parties – for example if patients need to pay a fee to the centre in order to transfer their eggs/embryos/sperm to a third party
(h) Cancellations and refund policies, including where the patient has purchased a multicycle or refund programme, and
(i) Complaints-handling policy.

Further information to provide

4.14 There are different kinds of information centres should give, where appropriate, to patients, patients' partners and donors prior to obtaining consent to treatment, storage or donation. Centre staff should familiarise themselves with all the appropriate information to provide. This information is contained in the following list of guidance notes:

5 – Consent to treatment, storage, donation, and disclosure of information
6 – Legal parenthood
7 – Multiple births
8 – Welfare of the child
9 – Preimplantation genetic testing for aneuploidy (PGT-A)
10 – Embryo testing and sex selection
11 – Donor recruitment, assessment and screening
12 – Egg sharing arrangements
14 – Surrogacy
15 – Procuring, processing and transporting gametes and embryos
17 – Storage of gametes and embryos
20 – Donor assisted conception
21 – Intra-cytoplasmic sperm injection (ICSI)
22 – Research and training
29 – Treating people fairly
30 – Confidentiality and privacy
33 – Mitochondrial donation

Additional information for treating trans patients

4.15 The centre should be aware that there are multiple terms used to refer to trans people and that terminology in this area is evolving. For inclusivity, this Code of Practice uses the term 'trans' to refer to all trans identities, including persons who consider themselves 'non-binary' (ie, identify as somewhere, either fixed or moveable, on the male-female continuum) and 'non-gendered' (ie, neither male, female, nor on the male-female continuum).

4.16 The centre should be aware that under the Gender Recognition Act 2004, a trans person can apply to be legally recognised as their acquired gender and must be so recognised if they have a full gender recognition certificate (GRC) that has been issued by a Gender Recognition Panel (GRP). The centre should be aware that, on occasion, a GRP may issue an interim GRC before a full GRC is issued in certain circumstances, for example where a trans person needs to end their marriage or civil partnership.

A GRP must grant a GRC if satisfied that a person meets the relevant conditions.

4.17 The centre should be aware that under equality legislation, a trans person does not need to undergo gender reassignment or obtain a GRC to have the protection from discrimination onthe

grounds of gender reassignment. For example, if a trans person who was male at birth subsequently identifies as a female and chooses to live in her female identity permanently without any medical intervention, she will have the protection of the Equality Act 2010. The law recognises a person's intention without the person undergoing gender reassignment. Where a trans man seeks services for the purposes of becoming pregnant, whether he has a GRC, interim GRC or neither, the HFE acts apply to that treatment and the centre must comply with all relevant requirements under the legislation. References in the legislation to a woman include a trans man who seeks fertility treatment with the aim of carrying and giving birth to a child.

4.18 Before treatment or storage is offered to a trans person, the centre should (as with all patients) consider the treatment and storage options that are available to the patient, depending on their individual circumstances. For example, if a trans person is visiting the centre prior to gender reassignment they may be seeking options for fertility preservation (ie, storage of either testicular or ovarian tissue, or eggs or sperm depending on whether they have undergone puberty); or if a trans person is visiting the centre after gender reassignment they may be seeking ways to use their preserved tissue, eggs or sperm in treatment with a partner and/or a surrogate. or extend their storage periods due to premature infertility.

4.19 Before treatment, storage or both are offered, the centre should inform a trans person (as with all patients) that they may need to be screened as a donor at the time of egg or sperm collection depending on the treatment options they may wish to pursue in the future and explain the reasons why. For example, they may wish to use their eggs or sperm in treatment with a surrogate.

4.20 Before treatment, storage (including renewing consent to storage) or both are offered to a person who is yet to undergo gender reassignment or who is not yet living in their acquired gender, the centre should inform them that should they change their identity before returning for further treatment (or to renew consent to storage), it will be necessary for them to provide evidence of their acquired identity and to verify that they are the person previously treated.

4.21 The centre should recognise the sensitivities of treating trans patients and have practical ways of accommodating their needs with dignity and respect. For example, rather than making assumptions about how a trans patient would like to be addressed, centres should ask how they would prefer to be addressed. Centres may also need to explain why gender at birth may be noted in medical records and will be determinative in establishing whether the patient is the legal mother, father or second parent of a child. Centres should avoid making assumptions when referring to gender (eg, if a telephone enquiry is received regarding sperm storage, avoid assuming the caller is male), and should take privacy and sensitivity into consideration.

See also

Guidance note 5 – Consent to treatment, storage, donation, training and disclosure of information

Guidance note 6 – Legal parenthood

Guidance note 11 – Donor recruitment, assessment and screening

Guidance note 17 – Storage of gametes and embryos

Guidance note 29 – Treating people fairly

Guidance note 30 – Confidentiality and privacy

Other legislation, professional guidelines and information

Legislation

Gender Recognition Act 2004

The Consumer Protection from Unfair Trading Regulations 2008

Equality Act 2010

The Consumer Contracts (Information, Cancellation and Additional Charges) Regulations 2013

Consumer Rights Act 2015

Data Protection Act 2018

Professional guidelines

Competition and Markets Authority (CMA) guidance on consumer law for the fertility sector

Advertising Standards Authority: UK code of non-broadcast advertising, and direct and promotional marketing (CAP Code)

National Institute for Health and Care Excellence: Fertility problems – assessment and treatment [CG156] (2013)

Our campaign to reduce multiple births

Other information

Competition and Markets Authority (CMA) consumer law compliance review of fertility clinics: findings report 2022

Annex 4

5. Consent to treatment, storage, donation, training and disclosure of information

Version 3.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

12 General Conditions

(1) The following shall be conditions of every licence granted under this Act -

…(c) except in relation to the use of gametes in the course of providing basic partner treatment services, that the provisions of Schedule 3 to this Act shall be complied with…

Schedule 3 – Consent to use or storage of gametes, embryos or human admixed embryos etc.

1 (1) A consent under this Schedule, any renewal of consent, and any notice under paragraph 4 varying or withdrawing a consent under this Schedule, must be in writing and, subject to sub-paragraph (2), must be signed by the person giving it.

(2) A consent under this Schedule by a person who is unable to sign because of illness, injury or physical disability (a "person unable to sign"), any renewal of consent by a person unable to sign, and any notice under paragraph 4 by a person unable to sign varying or withdrawing a consent under this Schedule, is to be taken to comply with the requirement of sub-paragraph (1) as to signature if it is signed at the direction of the person unable to sign, in the presence of the person unable to sign and in the presence of at least one witness who attests the signature.

(3) In this Schedule

(a) "effective consent" means a consent under this Schedule which has not been withdrawn.

(b) References to renewal of consent are to renewal of consent to the storage of any gametes or embryos under paragraph 11A or 11C.

2 (1) A consent to the use of any embryo must specify one or more of the following purposes -

(a) use in providing treatment services to the person giving consent, or that person and another specified person together,

(b) use in providing treatment services to persons not including the person giving consent,

(ba) use for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques, or

(c) use for the purposes of any project of research,

and may specify conditions subject to which the embryo may be so used. …

(1A) A consent to the use of any human admixed embryo must specify use for the purposes of any project of research and may specify conditions subject to which the human admixed embryo

may be so used.

(2) A consent to the storage of any gametes, any embryo or any human admixed embryo must -

(a) specify the maximum period of storage (if less than the statutory storage period for which, by virtue of section 14(3), the gametes, embryo or human admixed embryo may be stored under the licence),

(b) except in a case falling within paragraph (c), state what is to be done with the gametes, embryo or human admixed embryo if the person who gave the consent dies or is unable, because the person lacks capacity to do so, to vary the terms of the consent or to withdraw it, and

(c) where the consent is given by virtue of paragraph 8(2A) or 13(2), state what is to be done with the embryo or human admixed embryo if the person to whom the consent relates dies,

and may (in any case) specify conditions subject to which the gametes, embryo or human admixed embryo may remain in storage.

(2A) A consent to the use of a person's human cells to bring about the creation in vitro of an embryo or human admixed embryo is to be taken unless otherwise stated to include consent to the use of the cells after the person's death.

(2B) In relation to Scotland, the reference in sub-paragraph (2)(b) to the person lacking capacity is to be read as a reference to the person -

(a) lacking capacity within the meaning of the Age of Legal Capacity (Scotland) Act 1991, or

(b) being incapable within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000.

(3) A consent under this Schedule must provide for such other matters as the Authority may specify in directions.

(4) A consent under this Schedule may apply -

(a) to the use or storage of a particular embryo or human admixed embryo, or

(b) in the case of a person providing gametes or human cells, to the use or storage of –

(i) any embryo or human admixed embryo whose creation may be brought about using those gametes or those cells, and

(ii) any embryo or human admixed embryo whose creation may be brought about using such an embryo or human admixed embryo.

(5) In the case of a consent falling within sub-paragraph (4)(b), the terms of the consent may be varied, or the consent may be withdrawn, in accordance with this Schedule either generally or in relation to -

(a) a particular embryo or particular embryos, or

(b) a particular human admixed embryo or particular human admixed embryos.

Procedure for giving consent

3 (1) Before a person gives or renews consent under this Schedule -

(a) he must be given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and

(b) he must be provided with such relevant information as is proper.

(2) Before a person gives consent under this Schedule he must be informed of the effect of paragraph 4 and, if relevant, paragraph 4A below.

Use of gametes for treatment of others

5 (1) A person's gametes must not be used for the purposes of treatment services or non-medical fertility services unless there is an effective consent by that person to their being so used and they are used in accordance with the terms of the consent.

(2) A person's gametes must not be received for use for those purposes unless there is an effective consent by that person to their being so used.

(3) This paragraph does not apply to the use of a person's gametes for the purpose of that person, or that person and another together, receiving treatment services.

In vitro fertilisation and subsequent use of embryo

6 (1) A person's gametes or human cells must not be used to bring about the creation of any embryo in vitro unless there is an effective consent by that person to any embryo, the creation of which may be brought about with the use of those gametes or human cells, being used for one or more of the purposes mentioned in paragraph 2(1)(a), (b) and (c) above.

(2) An embryo the creation of which was brought about in vitro must not be received by any person unless there is an effective consent by each relevant person in relation to the embryo to the use for one or more of the purposes mentioned in paragraph 2(1)(a), (b), (ba) and (c) above of the embryo.

(3) An embryo the creation of which was brought about in vitro must not be used for any purpose unless there is an effective consent by each relevant person in relation to the embryo to the use for that purpose of the embryo and the embryo is used in accordance with those consents. …

(3E) For the purposes of sub-paragraphs (2), (3) and (3B) each of the following is a relevant person in relation to an embryo the creation of which was brought about in vitro ("embryo A")-

(a) each person whose gametes or human cells were used to bring about the creation of embryo A,

(b) each person whose gametes or human cells were used to bring about the creation of any other embryo, the creation of which was brought about in vitro, which was used to bring about the creation of embryo A, and

(c) each person whose gametes or human cells were used to bring about the creation of any human admixed embryo, the creation of which was brought about in vitro, which was used to bring about the creation of embryo A.

(4) Any consent required by this paragraph is in addition to any consent that may be required by paragraph 5 above.

Embryos obtained by lavage, etc.

7 (1) An embryo taken from a woman must not be used for any purpose unless there is an effective consent by her to the use of the embryo for that purpose and it is used in accordance with the consent.

(2) An embryo taken from a woman must not be received by any person for use for any purpose unless there is an effective consent by her to the use of the embryo for that purpose.

(3) Sub-paragraphs (1) and (2) do not apply to the use, for the purpose of providing a woman with treatment services, of an embryo taken from her.

(4) An embryo taken from a woman must not be used to bring about the creation of any embryo in vitro or any human admixed embryo in vitro.

Storage of gametes and embryos

8 (1) A person's gametes must not be kept in storage unless there is an effective consent by that person to their storage and they are stored in accordance with the consent.

(2) An embryo the creation of which was brought about in vitro must not be kept in storage unless there is an effective consent, by each relevant person in relation to the embryo, to the storage of the embryo and the embryo is stored in accordance with those consents…

(2C) For the purposes of sub-paragraphs (2) and (2A) each of the following is a relevant person in relation to an embryo the creation of which was brought about in vitro ("embryo A") -

(a) each person whose gametes or human cells were used to bring about the creation of embryo A,

(b) each person whose gametes or human cells were used to bring about the creation of any other embryo, the creation of which was brought about in vitro, which was used to bring about the creation of embryo A, and

(c) each person whose gametes or human cells were used to bring about the creation of any human admixed embryo, the creation of which was brought about in vitro, which was used to bring about the creation of embryo A.

(3) An embryo taken from a woman must not be kept in storage unless there is an effective consent by her to its storage and it is stored in accordance with the consent.

(4) Sub-paragraph (1) has effect subject to paragraphs 9 and 10; and sub-paragraph (2) has effect subject to paragraphs 4A(4), 16 and 20.

Cases where consent not required for storage

9 (1) The gametes of a person ("C") may be kept in storage without C's consent if the following conditions are met.

(2) Condition A is that the gametes are lawfully taken from or provided by C before C attains the age of 18 years.

(3) Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that C is expected to undergo medical treatment and that in the opinion of the registered medical practitioner -

(a) the treatment is likely to cause a significant impairment of C's fertility, and

(b) the storage of the gametes is in C's best interests.

(4) Condition C is that, at the time when the gametes are first stored, either -

(a) C has not attained the age of 16 years and is not competent to deal with the issue of consent to the storage of the gametes, or

(b) C has attained that age but, although not lacking capacity to consent to the storage of the gametes, is not competent to deal with the issue of consent to their storage.

(5) Condition D is that C has not, since becoming competent to deal with the issue of consent to the storage of the gametes -

(a) given consent under this Schedule to the storage of the gametes, or

(b) given written notice to the person keeping the gametes that C does not wish them to continue to be stored.

(6) In relation to Scotland, sub-paragraphs (1) to (5) are to be read with the following modifications -

(a) for sub-paragraph (4), substitute -

"(4) Condition C is that, at the time when the gametes are first stored, C does not have capacity (within the meaning of section 2(4) of the Age of Legal Capacity (Scotland) Act 1991) to consent to the storage of the gametes.", and

(b) in sub-paragraph (5), for "becoming competent to deal with the issue of consent to the storage of the gametes" substitute "acquiring such capacity".

10 (1) The gametes of a person ("P") may be kept in storage without P's consent if the following conditions are met.

(2) Condition A is that the gametes are lawfully taken from or provided by P after P has attained the age of 16 years.

(3) Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that P is expected to undergo medical treatment and that in the opinion of the registered medical practitioner -

(a) the treatment is likely to cause a significant impairment of P's fertility,

(b) P lacks capacity to consent to the storage of the gametes,

(c) P is likely at some time to have that capacity, and

(d) the storage of the gametes is in P's best interests.

(4) Condition C is that, at the time when the gametes are first stored, P lacks capacity to consent to their storage.

(5) Condition D is that P has not subsequently, at a time when P has capacity to give a consent under this Schedule -

(a) given consent to the storage of the gametes, or

(b) given written notice to the person keeping the gametes that P does not wish them to continue to be stored.

(6) In relation to Scotland -

(a) references in sub-paragraphs (3) and (4) to P lacking capacity to consent are to be read as references to P being incapable, within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000, of giving such consent,

(b) the references in sub-paragraphs (3) and (5) to P having capacity are to be read as references to P not being so incapable, and

(c) that Act applies to the storage of gametes under this paragraph to the extent specified in section 84A of that Act.

11 A person's gametes must not be kept in storage by virtue of paragraph 9 or 10 after the person's death.

Interpretation

22 …(6) References in this Schedule to capacity are, in relation to England and Wales, to be read in accordance with the Mental Capacity Act 2005.

Regulations

The Human Fertilisation and Embryology (Special Exemptions) Regulations 1991

The Human Fertilisation and Embryology (Special Exemptions) Regulations 2009

The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009

Licence conditions

T57 Gametes or embryos must not be used in the provision of treatment services (except in the use of gametes in the course of providing basic partner treatment services or non-medical fertility services) or placed in storage unless effective consent is in place from each gamete provider in accordance with Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as

Directions

0006 – Import and export of gametes and embryos

0007 – Consent

HFEA guidance

Consent to use and storage of gametes and embryos

Interpretation of mandatory requirements 5A

It is unlawful to procure, store or use gametes or embryos without written, effective consent from the gamete provider (or in the case of an embryo, both people who provided the gametes from which the embryo was created). Where the relevant legal requirements can be met prior to storage, it may be possible to store the gametes of someone who is unable to give consent to storage.

These legal requirements that must be met in such cases are set out in paragraphs 9 and 10 of Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended) (see 5G). It is important to note that paragraph 10 of Schedule 3 can only be relied on where the person who lacks capacity and whose gametes are to be stored, is likely at some time to have that capacity to give consent.

Gametes from a person who has died (including cases of brain stem death) cannot be stored or used without that person's written consent. The gametes or embryos of a person who has died can be used but only where they have given consent to posthumous use. While a patient can give consent to the posthumous storage and use of their gametes, storage and use is only possible for the duration of their consent and up to a maximum of 10 years after death.

The provisions of the Human Tissue Act 2004, which allow next of kin, a friend or close relative to give consent to procure, store or use organs and tissues of the deceased do not apply to gametes. No-one can give consent on behalf of a gamete provider.

Anyone who procures, stores or uses gametes without written, effective consent from the gamete provider may be committing a criminal offence.

The use of donor gametes or embryos to create more families than a donor has consented to is a breach of Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended).

The law requires the centre to obtain written, effective consent from a person before it performs the following procedures:

(a) storing that person's gametes (exemptions are outlined in paragraphs 9 or 10 of Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended)

(b) using that person's gametes for the treatment of others or for nonmedical fertility services

(c) creating embryos in vitro with that person's gametes

(d) storing embryos created with that person's gametes

(e) using embryos created with that person's gametes for their own treatment, treatment of a partner or treatment of others

(f) using embryos created with that person's gametes for training people in embryo biopsy, embryo storage or other embryological techniques

(g) using embryos created with that person's gametes for any research project

(h) using that person's cells to create embryos for research, or

(i) creating human admixed embryos with that person's gametes or cells.

If gametes or embryos are to be transferred to a centre outside the UK, the requirements set out in General Direction 0006 must be met. These include that the gamete provider (or in the case of an embryo, both people who provided the gametes from which the embryo was created) has given written, effective consent to the export of the gametes or embryos to the country in which the receiving centre is situated. Such consent must then be provided to the centre receiving the gametes or embryos.

If gametes or embryos are to be transferred into the UK from a centre outside the UK, the requirements set out in General Direction 0006 must be met. These include the requirement that the gamete provider (or in the case of an embryo, both people who provided the gametes from which the embryo was created) has given written, effective consent to the transfer of the gametes or embryos to the UK, and has not withdrawn that consent.

If the provisions of General Direction 0006 cannot be met, the UK centre may need to consider applying for a Special Direction to permit the import or export.

Further requirements regarding consent to the use of gametes, cells and embryos for research (including for the creation of admixed embryos), are outlined in guidance note 22 – research and training.

Requirements regarding consent to legal parenthood are outlined in guidance note 6 – legal parenthood.

5.1 The centre should obtain written, effective consent from a person before it carries out the following procedures:

(a) using their gametes for their own treatment or their partner's treatment, or
(b) using their gametes for research and training.

5.2 When a woman is to undergo an egg or embryo transfer, the centre should:

(a) obtain her consent to the proposed number of eggs or embryos to be transferred, and
(b) record her consent in her medical records.

5.3 The centre should establish and use documented procedures to ensure that no activity involving the handling or processing of gametes or embryos is carried out without the appropriate consent having been given. This should include a documented assurance process to ensure that all relevant consent forms have been properly and correctly completed before treatment.

5.4 If, following treatment, the centre discovers errors in the consent provided by a patient or their partner, the centre should:

(a) take all reasonable steps to notify the affected patient at the earliest opportunity
(b) assess the error(s) and potential impact, and consider the remedial actions that should be taken
(c) take all reasonable steps to support any affected patients (and their partner(s), if relevant) and offer independent legal assistance where necessary, and
(d) report any error(s) as an adverse incident.

Note: Consent to legal parenthood is subject to specific legal requirements. Centres should familiarise themselves with guidance note 6, which contains guidance and mandatory requirements relevant to legal parenthood.

5.5 If the centre becomes involved in a case where a partner or family member of a deceased person intends to make an emergency application to the High Court to permit harvesting of gametes without valid consent, the centre should notify the HFEA as soon as it becomes aware of this.

See also

Guidance note 6 – Legal parenthood

Guidance note 15 – Procuring, processing and transporting gametes and embryos

Procedure for obtaining consent

Interpretation of mandatory requirements 5B

The law requires that before a person gives or renews consents to the procedures outlined in box 5A, they should be given:

(a) enough information to enable them to understand the nature, purpose and implications oftheir treatment or donation

(b) a suitable opportunity to receive proper counselling about the implications of the steps which they are considering taking, and

(c) information about the procedure for varying or withdrawing any consent given, and about the implications of doing so.

5.6 Centres should ensure that, before a person gives consent, they are given the information outlined in guidance note 4.

5.7 The centre should ensure that the person giving consent is able to give their consent freely. The centre may use a patient's first name(s), surname, date of birth and NHS/CHI/HCN/passport number as previously recorded on their electronic medical record (EMR) to pre-complete 'About you' or 'About your partner' sections of HFEA consent forms. These details should be confirmed as correct by the centre and the patient whilst completing consent forms. However, the centre must not pre-complete any other section of consent forms on behalf of the person giving consent. For example, a person giving consent to the storage of their gametes and/or embryos should be free to choose how long to consent to store for, within what is permitted by law.

5.8 The centre should not restrict storage consent to tie in with payment or funding arrangements. Contractual agreements covering payment or funding should be separate to consent, and patients should be given enough information to understand the terms and conditions of the agreement and the steps the centre will take if these terms and conditions are broken while there is still valid consent in place. Further information on storage of gametes or embryos is outlined in guidance note 17.

5.9 The centre should inform anyone providing gametes that they can, if they wish, specify extra conditions for storing or using their gametes (or embryos created using them).

5.10 The centre should give anyone seeking treatment or considering donation or storage enough time to reflect on their decisions before obtaining their consent. The centre should give them an opportunity to ask questions and receive further information, advice and guidance.

5.11 If the possibility of donating gametes or embryos (including mitochondrial donation) for the treatment of others, or donating embryos for research or training purposes, arises during the course of treatment, the centre should allow potential donors enough time to consider the implications and to receive counselling before giving consent.

5.12 The centre should ensure that consent is:

(a) given voluntarily (without pressure to accept treatment or agree to donation)
(b) given by a person who has capacity to do so
(c) overseen by a person authorised by the centre to do so, and
(d) given at the clinic (with both parties present if a couple is being treated) or a documented process should be in place to ensure that consent forms signed outside the clinic, either in a paper or electronic form, are signed by the correct person (i.e. the person whose consent is required), have been correctly completed and the consent is valid.

A child under the age of 16 is only able to provide consent if it has been established that he or she is 'Gillick competent'.

5.13 The centre should ensure that anyone giving consent has been:

(a) given enough information to enable them to understand the nature, purpose and implications of the treatment or donation
(b) given a suitable opportunity to receive proper counselling about the implications of the proposed procedures
(c) given information about the procedure for varying or withdrawing consent, and
(d) given information in writing that is correct and complete.

5.14 Treatment centres should take all reasonable steps to verify the identity of anyone accepted for treatment, including partners who may not visit the centre during treatment. The centre should establish the relationship between a patient and their partner and a record of this should be retained in the patient's notes. If a patient's identity is in doubt, or if a centre has reason to question whether the person is who they claim to be, the centre should take further precautions, including examining photographic evidence such as a passport or a photocard driving licence. The centre should record this evidence in the patient's medical records.

5.15 Centres should have a process in place to verify the identity of a patient (and their partner, if applicable) if they return to the centre for subsequent treatment, to ensure the patient and their partner are the same people they treated initially. The clinic should establish whether the patient and their partner's personal circumstances have changed in the period since their last treatment (for example, whether the couple have divorced or separated since their previous treatment) and consider whether any changes in their personal circumstances impact on consent.

5.16 Where a patient has changed their name (eg, where someone has changed their name by deed poll, has married and taken their partner's surname, or has obtained a gender recognition certificate) or has changed their physical appearance (eg, where someone has undergone gender reassignment or is living in the gender they most closely identify with but which is different from their gender at birth) since their previous consultation, examination or donation, centres should take all reasonable steps to verify the patient's identity. This is to ascertain that a patient presenting for treatment or donation is the same person the centre previously engaged with or treated.

Centres should verify a patient's identity by asking for evidence of their previous name (eg, a passport or photocard driving licence) and verifying details against the person's medical records. This can be a sensitive issue, and centres should take care to address identity issues with consideration. As evidence of their new name, centres should ask the person to provide one of the following:

(a) a marriage certificate, or
(b) evidence of a change in name (such as via deed poll)

For trans patients:

(c) a birth or adoption certificate in an acquired gender
(d) a Gender Recognition Certificate, or
(e) a letter from a doctor or medical consultation confirming that the change of gender is likely to be permanent, and evidence of a change in name (such as via deed poll).

Centres must ensure that a patient's records are updated to accurately reflect their new identity.

5.17 To avoid the possibility of misrepresentation or mistake, the centre should check the identities of patients (and their partners, if applicable) against identifying information in the medical records. This should be done at each consultation, examination, treatment, or donation. If the partner of a patient who is having treatment has not visited the clinic throughout the treatment, or does not return with the patient for subsequent treatment, centres should take reasonable steps to find out whether the patient's partner still consents to the treatment. This may include contacting the partner to confirm that their circumstances have not changed and that their consent is still valid. The centre should not start treatment until it is satisfied that the partner in fact still consents to the treatment.

5.18 The centre should consider the needs of people whose first language is not English and those who face other communication barriers. Where consent is obtained, the centre should record:

(a) any difficulties in communicating the implications of giving consent and providing other information to the person (eg, language barriers or hearing impairment), and
(b) an explanation of how these difficulties were overcome (eg, the use of an independent interpreter). (This guidance is based on a paragraph taken from The Human Tissue Authority's Code of Practice on Consent (2008)).

5.19 The centre should establish and follow documented procedures to obtain written informed consent.

See also

Guidance note 3 – Counselling and patient support
Guidance note 4 – Information to be provided prior to consent
Guidance note 11 – Donor recruitment, assessment and screening
Guidance note 17 – Storage of gametes and embryos
Guidance note 22 – Research and training
Guidance note 23 – The quality management system
Guidance note 29 – Treating people fairly
Guidance note 31 – Record keeping and document control

HFEA consent forms

HFEA consent form guidance

Recording consent and related information

Interpretation of mandatory requirements 5C

The law requires consent, or any subsequent variation or withdrawal of consent, to be in writing and signed by the person giving consent, except in the following situation:

If the person giving consent, or varying or withdrawing consent, has the mental capacity to do so but cannot sign because of illness, injury or physical disability (for example, quadriplegia), they can direct someone to sign on their behalf, provided that:

(a) the person giving consent, or varying or withdrawing consent is present at the time, and

(b) the signature is also witnessed and attested to by at least one other person.

5.20 The centre should keep a copy of a person's signed consent form(s) (either electronically or as a hard copy) so that a copy can be made available to them upon request. Consent forms are subject to the retention requirements outlined in General Direction 0012. Centres must maintain a record relating to the renewal of consent to storage of gametes or embryos as outlined in General Direction 0015.

5.21 The centre should ensure that it documents in the medical records that:

(a) relevant information, as outlined in guidance note 4, has been provided to the person, and
(b) the person has been offered counselling before giving consent.

See also

Guidance note 4 – Information to be provided prior to consent

Guidance note 31 – Record keeping and document control

HFEA consent forms

Additional consent requirements for storing gametes and embryos

Interpretation of mandatory requirements 5D

The law requires the centre to obtain written, informed consent from a person before storing

their gametes or embryos created with their gametes, and gametes or embryos must not be kept in storage unless they are stored in accordance with the consent given. There must be effective consent to storage, and storage in accordance with that consent at all times, without any gaps in consent.

In very limited circumstances, the law allows gametes to be stored without consent. Those circumstances are set out in paragraphs 9 and 10 of Schedule 3 of the HFE Act 1990 (as amended). A person's gametes must not be kept in storage under either paragraph 9 or 10 after their death. Gametes stored by virtue of either of these paragraphs may only be used if the person from whom they were collected gives written, effective consent to their use.

For more information on consent requirements for storing gametes and embryos, see **guidance note 17** on Storage of gametes and embryos.

5.22 The centre should ask patients to give consent to storage at the same time as consent to the use of gametes and embryos. However, the centre should accommodate anyone seeking long- term storage of gametes who may wish to consent to storage separately from consent to use. Any patient who has given consent to storage, but who has not given consent to use, should be informed that their gametes cannot lawfully be used in treatment unless they have given consent to use. This scenario becomes particularly problematic in the case of patients who have died since storing their gametes and whose surviving partner or spouse wishes to use their gametes posthumously but is prevented from doing so because there is no consent to use in place.

5.22 Before the centre obtains consent from anyone wishing to store gametes or embryos for more than 10 years, it should explain that storage can only continue beyond 10 years if a medical practitioner has certified in writing that the gamete provider, their partner, or the person who the gametes or embryos have been allocated to, meet the medical criteria for premature infertility or are likely to become prematurely infertile. This medical opinion must be obtained before the expiry of the statutory 10-year storage period and, in the case of gametes or embryos which are subject to an extended storage period, must be obtained within 10 years from the date of the previous medical opinion. The opinion must be provided in writing and be given by a medical practitioner who is registered with the General Medical Council (GMC).

5.23 The centre should have regard to their obligations to help trans patients. Trans patients, particularly those of a younger age, may be able to store their gametes beyond the statutory 10 years, depending on their individual circumstances and if they can comply with the requirements of the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009. This includes the need to obtain a written opinion from a registered medical practitioner certifying that they are, or are likely to become prematurely infertile. Giving consideration to whether the patient meets the criteria for extended storage will help to ensure that trans patients have viable treatment options in the future.

5.23 The centre should ensure that they discuss the possibility of posthumous use, and the need for consent to posthumous use and named a partner, with all patients, particularly those who are storing gametes before undergoing treatment for serious health conditions which is likely to impair their fertility. Where patients wish to consent to posthumous use, the clinic must take particular care to ensure that all necessary consent forms are properly completed, including consent to posthumous use and posthumous birth registration.

5.24 The gamete provider should be made aware that if they die or become mentally incapacitated, the gametes and embryos cannot be used in treatment unless the necessary consent has been provided and their partner has been named on the relevant consent form. It is therefore important that patients who have previously completed consent forms and not given consent to posthumous use are encouraged to keep in contact with the centre so that they can update their consent forms if their personal circumstances change and they wish to give consent to posthumous use.

See also

Guidance note 6 – Legal parenthood

Guidance note 17 – Storage of gametes and embryos

HFEA consent forms

Interpretation of mandatory requirements 5E

The law requires the centre to ensure that consent to the use of any embryo (not a human admixed embryo) must specify one or more of the following uses for the embryo:

(a) providing treatment for the person giving the consent, or, where applicable, that person and another named person together

(b) providing treatment for others

(c) training centre staff in embryo biopsy, embryo storage or other embryological techniques, or

(d) contributing to a specified research project.

In relation to human admixed embryos, the law requires that consent to their use must specify use for a research project.

The consent may also specify conditions for how the embryo may be used.

5.25 Consent to the use of gametes or embryos for the treatment of others should state the number of families that may have children using the donated gametes or embryos.

5.26 When an individual gives consent to the use of gametes for the treatment of others, the centre need not get consent from the donor's partner or spouse. However, if the donor is married, in a civil partnership or in a long-term relationship, the centre should encourage them to seek their partner's support for the donation of their gametes.

5.27 Men who wish to donate embryos originally created for the treatment of their partner and themselves, and those people considering treatment with such embryos, should be:

(a) informed of the uncertain legal status of men donating embryos created originally for the treatment of their partner and themselves, when the embryos are used in the treatment of a single woman
(b) referred to information on the HFEA's website on this issue, and
(c) advised to seek independent legal advice before consenting to donate their embryos or being treated with the embryos.

See also

Guidance note 20 – Donor assisted conception

Guidance note 22 – Research and training

HFEA consent forms

Additional consent requirements for those participating in a benefits in kind agreement

5.28 The person obtaining consent should ensure that a gamete provider's consent is recorded so that different conditions can be placed on:

(a) the use or storage of the gametes, and the use and storage of embryos created for the gamete provider's own treatment, and
(b) the use of eggs or sperm, and the use and storage of embryos created for the treatment of the recipient(s)

These conditions should be able to be varied independently of each other.

5.29 The person obtaining consent should tell the gamete provider and recipient(s) that the gamete provider may withdraw or vary their consent up to when the gametes or embryo(s) are:

(a) transferred to a woman
(b) used in a research project (defined as being under the control of the researchers and being cultured for use in research)
(c) used for training, or
(d) allowed to perish.

The possible consequences of this should:

(e) be made clear to the gamete provider and the recipient(s) before the treatment begins, and
(f) be set out in the written patient information included with the benefits in kind agreement.

The person obtaining consent should tell the gamete provider and recipient(s) that consent to providing gametes solely for use in mitochondrial donation treatment cannot be withdrawn or varied once the patient's nuclear DNA has been inserted into the egg or embryo.

See also

Guidance note 12 – Egg sharing arrangements

HFEA consent forms

Guidance for centres considering introducing electronic methods of taking consent

5.30 When introducing an electronic consenting platform, the centre should:

(a) evaluate the reliability of the electronic consenting platform, making sure the platform is fully validated, quality assured, and risk assessed. For example, by completing a validation protocol to ensure the correct consent forms are allocated to patients based on factors including the patient's specific treatment, gender, marital status, whether it is the patient's own gametes or donor gametes that will be used in treatment, whether the patient is a patient or a donor, and other aspects that determine which HFEA consent forms need to be completed. The platform should be re-validated after every software update and whenever any new or revised HFEA consent forms are introduced.
(b) consider whether there are any additional IT resources needed, including providing IT support to patients experiencing problems with the electronic consenting platform.
(c) have a documented procedure in place to provide training for staff to ensure they are competent at using the relevant electronic consenting platform and adhere to clinic procedures when taking consent electronically.
(d) retain the capability for taking, varying, and withdrawing consent in a paper form and ensuring that staff are competent to do so.
(e) ensure that the correct version of any HFEA consent forms is in use on their electronic consenting platform.

5.31 Centres that use electronic consent platforms should have processes in place to verify that consent is being given by the correct person. Centres should be able to demonstrate that they have provided patients with relevant information prior to giving consent, as set out in guidance note 4. Any information provided to patients in an electronic format, including informational videos, should not substitute a face to face, video, or phone conversation between the patient

and/or their partner and clinic staff about consent, treatment options and their implications. This conversation must take place prior to patients being asked to complete the consent forms, during which patient concerns can be responded to.

5.32 Where possible, electronic consent forms should be completed at the centre. When completing electronic consent forms remotely centres should have procedures in place to ensure that patients have secure access to clinic staff who can answer additional questions. Clinic staff should have the facilities to have confidential conversations with the patients and establish that the patient is also in an environment where they feel comfortable having a confidential conversation.

5.33 Centres should ensure that any electronic consenting platform used:

(a) has inbuilt security measures that minimise the risk of fraud or forgery
(b) provides an individual account for each person that is required to complete consent forms that cannot be accessed by any other person. The centre must ensure that the platform uses multifactor authentication to enable access to a patient account
(c) provides a person with the information and consent forms that are relevant to their personal circumstances and specific treatment
(d) replicates the current HFEA consent forms and Statutory Notices exactly and in their entirety including the title and the acronym, the wording of the current version, the current HFEA version number and date. Current versions of consent forms and Statutory Notices are published on the HFEA Clinic Portal. HFEA branding should also be replicated on any electronic versions of HFEA consent forms (HFEA branding may not be used on a clinic's internal consent forms)
(e) enables the person giving consent to sign the consent form using an advanced electronic signature and that only the person providing consent can sign the form. It is a requirement under paragraph 1(1) of Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended) that a consent must be signed by the person giving it. An advanced electronic signature is defined in Articles 3 and 26 of the electronic identification and trust services (eIDAS) Regulation as an electronic signature which meets the following requirements:
    i. it is uniquely linked to the signatory,
    ii. it is capable of identifying the signatory,
    iii. it is created using electronic signature creation data that the signatory can, with a high level of confidence, use under their sole control, and
    iv. it is linked to the date signed therewith in such a way that any subsequent change in the data is detectable.
(f) meets the requirements set out in guidance note 30 for confidentiality and privacy, and that clinics have procedures in place for reporting data breaches resulting from the use of, or caused by, the electronic consenting platform, and
(g) enables centres to export and retain copies of completed consent forms such that the centre can comply with the requirements relating to retention of records as set out in General Direction 0012 and General Direction 0015. Centres using electronic consent platforms should carry out staff training and have processes in place to ensure that the requirements of General Direction 0012 and General Direction 0015 are met. Audits of relevant areas of practice (for example consent, retention of records, record keeping) should include electronic consent platforms and provide evidence of compliance with and the robustness of these processes.

5.34 Where consent has been given, varied or withdrawn using a combination of electronic consent forms and paper consent forms, the centre must have procedures in place to ensure that there is a reconciliation of both electronic and paper consent forms and clear record of what the patient has consented to. The centre must ensure consent is effective whether recorded on paper or electronically and where consent has been withdrawn, centres must ensure that this is clear in the patient's record whether it was withdrawn using a paper form or electronically.

5.35 Where possible centres should use secure cloud-based storage systems that are based within the UK to store consent forms.

5.36 In the event of there being a temporary loss of access to the electronic consenting platform, for example due to there being no internet access, the centre should have documented procedures in place to take paper-based consent to prevent disruption or delay to a patient's treatment.

5.37 In the event of errors being identified on electronic consent forms the centre should investigate whether the errors were caused by the electronic consenting platform and report this as an incident as set out in guidance note 27. The centre should take any necessary steps to respond to the incident including informing patients and/or donors affected by the error and where appropriate, ensuring that further consent forms are correctly completed. Centres should also take action to prevent a recurrence of the error, including informing the company that maintains the platform to allow them to take corrective action.

Consent to examination and treatment

5.38 Everyone has the right to withhold or give consent to examination and treatment. Unless there are exceptional circumstances, the centre may not examine, treat or receive gametes from people without first obtaining their consent. The only exceptional circumstance likely to arise during fertility treatment is:

(a) where the procedure is necessary to save the patient's life, and
(b) the treatment cannot be postponed, and
(c) the patient is unconscious or mentally incapacitated so cannot indicate their wishes.

5.39 The centre should comply with current professional guidelines on consent.

Consent to the presence of observers

5.40 If a member of the centre's team wishes an observer to be present when a patient is being examined, treated or counselled, they should explain why beforehand and state who the observer is. The centre should give the patient appropriate information about the proposed observation and ask them whether they consent to the observer's presence.

Consent to disclose identifying information

Interpretation of mandatory requirements 5F

Patients have the right to decide what identifying information should be disclosed and to whom. Centres should obtain a patient's written consent before disclosing information relating to their treatment (or providing gametes for a partner's treatment), or the storage of gametes or embryos.

In addition, consent is needed from any person who could be identified through disclosure of information about a person's treatment or gamete/embryo storage. For example, consent would be needed from a patient's partner if they could be identified through disclosure of information about the patient's treatment.

If a child born as a result of treatment could be identified, consent must be obtained from the parent(s), unless identification is necessary in disclosing information about the patient's treatment. Once a child born as a result of treatment is considered competent to consent, then their consent (if given) will override the consent of the parent(s).

5.41 Before obtaining consent to disclose information, the centre should give the person enough information for them to make a properly informed decision, including:

(a) precisely what information is to be disclosed
(b) the terms on which it is to be disclosed
(c) the reasons for disclosure (eg, to keep the person's GP informed about the fertility treatment)
(d) the implications of disclosure, in particular the fact that, once it is disclosed, the information will be subject no longer to the special provisions of the HFE Act 1990 (as amended) but only to the general law of confidentiality, and
(e) the categories of people to whom the information is to be disclosed.

5.42 The centre should seek consent to disclosure to the following categories of people:

(a) the patient's GP or the patient's partner's GP
(b) other healthcare professionals outside the centre (so they can provide the patient or the patient's partner with the best possible medical care)
(c) auditors or administrative staff outside of the centre (so they can perform their functions in connection with the centre's licensable activities), and
(d) medical or other researchers (so they can contact the patient about specific research projects or carry out non-contact research).

5.43 The UK General Data Protection Regulation (UK GDPR) includes the concept of 'special category data' which is broadly similar to sensitive personal data under the Data Protection 1998. Special category data is personal data which in GDPR terms, requires a greater degree of protection because it is more sensitive than any other personal data. Under UK GDPR and the Data Protection Act 2018 (DPA 2018), the definition of 'special category data' includes information about a person's genetics, biometrics (where used for identification purposes), health, sex life, sexual orientation, race, ethnic origin, politics or trade union membership. Information about a person's gender reassignment, gender confirmation and information relating to a person's gender history would fall within the scope of special category data.

5.44 Due to the sensitive nature of 'special category data' centres must take particular care to protect it and must have a lawful basis for processing the data. The legal bases for processing special category data are set out in Article 6 and Article 9 of the UK GDPR and clinics must identify a lawful basis under both for processing to be lawful. Centres may be asked to disclose patient information for various purposes. When considering how to respond to a request for disclosure, centres may need to seek the input of specialists including lawyers who are familiar with the HFE Act 1990, all current data protection legislation and the common law duty of confidentiality. When considering disclosure of special category data as well as considering the requirements of the HFE Act 1990, UK GDPR and DPA 2018, centres should be aware that it is an offence under the Gender Recognition Act 2004 (GRA 2004) to disclose 'protected information' that centres have obtained in an official capacity about a person who has applied for a gender recognition certificate (GRC) or the gender history of someone who has obtained a full GRC, unless consent has been obtained from that person or an exemption to disclosure under the GRA 2004 applies.

5.45 The centre should consider circumstances where they may need to disclose a person's gender history (eg, to those within the centre who need to know of a trans patient's previous identity to deliver safe and appropriate care) to determine whether they need to obtain the person's consent to disclosure of this information. This should be discussed in detail with the person and any consent obtained should be filed with their medical records. Centres dealing with requests for disclosure of this information may wish to seek advice from information law specialists before disclosing any information.

5.46 The centre should renew consent to disclosure if the nature of treatment changes after initial consent has been given (eg, if during treatment, it is proposed that donor gametes are used

instead of the patient's own, or if the patient moves from unlicensed to licensed fertility treatment).

5.47 The centre should ensure that people to whom they disclose identifying information know that the information remains protected by the existing common law on confidentiality. Those receiving information should also be told:

(a) the precise terms upon which it was disclosed and for which consent has been given, and
(b) that if they disclose the information they have received, a child might learn in an inappropriate way that they were born as a result of fertility treatment.

See also

Guidance note 30 – Confidentiality and privacy

HFEA consent forms

Cases where consent is not required for storage

Interpretation of mandatory requirements 5G

Cases where consent is not required for storage:

Gametes may be stored without consent if the conditions in paragraph 9 or 10, of Schedule 3

of the HFE Act 1990 (as amended) are met.

Paragraph 9 sets out the conditions that must be met before the gametes of a person who is **under the age of 18** can be stored without their consent.

Condition A is that the gametes are lawfully taken from the person before they reach the age of 18 years.

Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that the person is expected to undergo medical treatment and that in the opinion of the registered medical practitioner:

(a) the treatment is likely to cause a significant impairment of their fertility, and

(b) the storage of the gametes is in the person's best interests.

Condition C is that, at the time when the gametes are first stored, either:

(a) the person has not reached the age of 16 years and is not competent to deal with the issue of consent to the storage of the gametes, or

(b) the person is 16 years old but, although not lacking capacity to consent to the storage of the gametes, is not competent to deal with the issue of consent to storage. A registered medical practitioner must actively establish that the person is not competent to deal with the issues arising in relation to consent to the storage of their gametes.

Note: In relation to Scotland for Condition C, the test is whether, at the time the gametes were first stored, the person has capacity within the meaning of section 2(4) of the Age of Legal Capacity (Scotland) Act 1991.

Condition D is that the person has not, since becoming competent to deal with the issue of consent to the storage of the gametes:

(a) given consent to the storage of the gametes, or

(b) given written notice to the centre that they do not wish their gametes to continue to be stored.

Paragraph 10 sets out the conditions that must be met before the gametes of a person who is **16 years or over** may be stored without their consent.

Condition A is that the gametes are lawfully taken from or provided by the person after they have reached the age of 16 years.

Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that the person is expected to undergo medical treatment and that in the opinion of the registered medical practitioner:

(a) the treatment is likely to cause a significant impairment of their fertility,

(b) the person lacks capacity to consent to the storage of the gametes,

(c) the person is likely at some time to have that capacity, and

(d) the storage of the gametes is in their best interests.

Condition C is that, at the time when the gametes are first stored, the person lacks capacity to consent to their storage.

Condition D is that the person has not subsequently, at a time when he or she has capacity to give a consent:

(a) given consent to the storage of the gametes, or

(b) given written notice to the centre that they do not wish their gametes to continue to be stored.

Gametes stored in compliance with these paragraphs may be used in treatment if the person from whom they were collected gives written effective consent to their use. A person's gametes must not be kept in storage by virtue of either paragraph 9 or 10 after the person's death.

5.48 Before a centre can store a patient's gametes without their consent, the centre must ensure that each of the conditions set out in either paragraph 9 or 10 of Schedule 3 of the 1990 Act (whichever is applicable in the circumstances) are met. The centre should ensure that it documents its decision to store the patient's gametes in the absence of consent and records the evidence relied upon to establish that each of the conditions have been met.

5.49 When assessing a patient's competence to consent, the centre should follow current guidance produced by the Department of Health, the General Medical Council and other professional bodies.

5.50 When assessing whether it is in a child's best interests to store their gametes, the centre should refer to applicable General Medical Council guidance and consider the child's short- and long- term best interests. When the child is competent to give consent, the centre should seek their consent to the continued storage of the gametes.

5.51 The centre should provide written information about the proposed procedures that children and young people can read and understand easily. This information should be given by a member of staff experienced in communicating with children.

5.52 The conditions outlined in 5G are situations where consent to storage is not required by anyone. Therefore, no one needs to sign a consent to storage on behalf the patient.

Competence

5.53 If the centre's staff doubt someone's competence to consent to a proposed procedure, or to the storage or use of gametes or embryos, they should:

(a) refer to the Mental Capacity Act 2005 (England and Wales), or the Age of Legal Capacity (Scotland) Act 1991 and the Adults with Incapacity (Scotland) Act 2000, and
(b) follow the current guidelines of professional bodies. If they remain in any doubt, the centre should seek legal advice.

Variation and withdrawal of consent

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Schedule 3

Variation and withdrawal of consent

4 (1) The terms of any consent under this Schedule may from time to time be varied, and the consent may be withdrawn, by notice given by the person who gave the consent to the person keeping the gametes, human cells, embryo or human admixed embryo to which the consent is relevant.

(1A) Sub-paragraph (1B) applies to a case where an egg is used in the process set out in regulation 4 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 (and "egg A" and "egg B" have the same meanings in this paragraph as in that regulation).

(1B) The terms of the consent to that use of egg A or egg B cannot be varied, and such consent cannot be withdrawn, once all the nuclear DNA of egg B which is not polar body nuclear DNA is inserted into egg A.

(2) Subject to sub-paragraph (3) to (3B), the terms of any consent to the use of any embryo cannot be varied, and such consent cannot be withdrawn, once the embryo has been used -

(a) in providing treatment services,

(aa) in training persons in embryo biopsy, embryo storage or other embryological techniques, or

(b) for the purposes of any project of research.

(3) Where the terms of any consent to the use of an embryo ("embryo A") include consent to the use of an embryo or human admixed embryo whose creation may be brought about in vitro using embryo A, that consent to the use of that subsequent embryo or human admixed embryo cannot be varied or withdrawn once embryo A has been used for one or more of the purposes mentioned in sub-paragraph (2)(a) or (b).

(3A) Sub-paragraph (3B) applies to a case where an embryo is used in the process set out in regulation 7 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 (and "embryo A" and "embryo B" have the same meanings in sub-paragraph (3B) as in that regulation).

(3B) The terms of the consent to that use of embryo A or embryo B cannot be varied, and such consent cannot be withdrawn, once all the nuclear DNA of embryo B which is not polar body nuclear DNA is inserted into embryo A.

4A (1) This paragraph applies where -

(a) a permitted embryo, the creation of which was brought about in vitro, is in storage,

(b) it was created for use in providing treatment services,

(c) before it is used in providing treatment services, one of the persons whose gametes were used to bring about its creation("P") gives the person keeping the embryo notice withdrawing P's consent to the storage of the embryo, and

(d) the embryo was not to be used in providing treatment services to P alone.

(2) The person keeping the embryo must as soon as possible take all reasonable steps to notify each interested person in relation to the embryo of P's withdrawal of consent.

(3) For the purposes of sub-paragraph (2), a person is an interested person in relation to an embryo if the embryo was to be used in providing treatment services to that person.

(4) Storage of the embryo remains lawful until -

(a) the end of the period of 12 months beginning with the day on which the notice mentioned in sub-paragraph (1) was received from P, or

(b) if, before the end of that period, the person keeping the embryo receives a notice from each person notified of P's withdrawal under sub-paragraph (2) stating that the person consents to the destruction of the embryo, the time at which the last of those notices is received.

(5) The reference in sub-paragraph (1)(a) to a permitted embryo is to be read in accordance with section 3ZA.

Renewal of consent to storage of embryos

11C (14) Storage of the embryo remains lawful until—

(a) the end of the period of 6 months beginning with the day on which P's consent is taken as withdrawn under this paragraph, or

(b) if, before the end of that period, K receives a notice from each person notified under sub-paragraph (13) stating that the person consents to the disposal of the embryo, the time at which the last of those notices was received.

Interpretation of mandatory requirements 5H

The law allows consent to be varied or withdrawn at any point until gametes or embryos (other than human admixed embryos) are used to provide treatment services, or used for a research project or for training.

Consent to providing eggs, embryos or sperm solely for use in mitochondrial donation treatment cannot be withdrawn or varied once the patient's nuclear DNA has been inserted into the egg or embryo.

Consent to the use of any human admixed embryo can be varied or withdrawn until the embryo has been used for a research project.

If someone wishes to withdraw consent to the storage or use of gametes, embryos or human admixed embryos, they must do so in writing, except if they are unable to do so because of illness, injury or incapacity. In these cases, they can direct someone to sign on their behalf, provided that the person

withdrawing consent is present at the time, and that the signature is also witnessed and attested to by at least one other person.

If one of the gamete providers withdraws consent to the continued storage of embryos intended for treatment (created from their gametes), the law requires the centre to take all reasonable steps to notify the intended recipient(s).

When (only) one gamete provider has withdrawn their consent to storage of embryos, ongoing storage for up to 12-months from the date on which consent was withdrawn is lawful, unless or until the point at which each interested person has also withdrawn their consent. After the 12-month 'cooling off' period the centre must remove the embryos from storage and dispose of them. However, if the period to which effective consent to storage was previously given expires before the 12 months, embryos must be removed from storage and disposed of by that date. For guidance about the withdrawal of consent see guidance note 5 – Consent to treatment, storage, donation, and disclosure of information.

When (only) one gamete provider has failed to renew their consent to storage of embryos before the end of the Renewal Period and their consent is taken as having been withdrawn, ongoing storage for a further 6-month period from the end of the Renewal Period is lawful unless, before the end of that period, the centre receives a notice from each gamete provider confirming their consent to the disposal of the embryo. After this 6-month period the centre must remove the embryos from storage and dispose of them. For guidance about what to do when consent is taken as having been withdrawn, see guidance note 17 – Storage of gametes and embryos.

The law allows embryos to be stored for 12 months from the date that the centre receives written withdrawal of consent, or less if the centre receives written signed consent from all intended recipients for the embryos to be destroyed.

This 12-month 'cooling off' period must not extend beyond the end of the period for which valid consent exists.

5.54 The centre should check the identity of anyone withdrawing or varying consent against identifying information held in the medical records. The centre should also ensure that the person withdrawing or varying consent has been given sufficient information to enable them to make an informed decision about doing so. If a patient wishes to withdraw or vary their consent using an electronic form outside of a centre, the centre must contact the patient to confirm that they wish to withdraw or vary their consent and ensure all implications of withdrawing or varying consent have been fully explained to the patient.

5.55 The centre should have procedures for dealing with disputes that may arise when one gamete provider withdraws their consent to the use or storage of gametes or embryos in treatment. In this situation the centre should stop treatment and notify all relevant parties. Centres should provide information about counselling or mediation services as appropriate.

See also

HFEA consent forms

HFEA consent form guidance

Other legislation, professional guidelines and information

Legislation

Age of Legal Capacity (Scotland) Act 1991

Adults with Incapacity (Scotland) Act 2000

Data Protection Act 2018

General Data Protection Regulation (EU) 2016/679 (GDPR)

European (Withdrawal) Act 2018

The Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019

Equality Act 2010

Gender Recognition Act 2004

Mental Capacity Act 2005

Regulation (EU) 910/2014 on electronic identification and trust services for electronic transactions in the internal market

The Electronic Identification and Trust Services for Electronic Transactions (Amendment etc.) (EU Exit) Regulations 2019

Consent to examination and treatment

Department of Health: Reference guide to consent for examination or treatment (second edition, 2009)

General Medicines Council: Consent – patients and doctors making decisions together (2008)

Human Tissue Authority: Code of Practice – A: Guiding Principles and the Fundamental Principle of Consent (2017)

Office of the Public Guardian: Code of Practice – Mental Capacity Act (2013)

Royal College of Obstetrics and Gynaecologists: Obtaining valid consent [Clinical Governance Advice No.6] (third edition, 2015)

General information

Department of Health: Best practice guidance for doctors and other health professionals on the provision of advice and treatment to young people under 16 on contraception, sexual and reproductive health (2004)

Competition and Markets Authority (CMA) guidance on consumer law for the fertility sector

Chief Executive's letters

Chief Executive's letter CE(12)02: Extension of storage of gametes and embryos where one of the gamete providers is deceased

Chief Executive's letter CE(16)02(a): Changes to the interpretation of several regulations

Chair's letters

Chair's letter CH(19)01: Electronic methods of taking consent

Chair's letter CH(21)01 - Women providing eggs or embryos created with their eggs for their partner's treatment

Clinic Focus articles

Clinic Focus article: Electronic consent (February 2022)

Annex 5
6. Legal parenthood

Version 4.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 2008

Part 2: Parenthood in cases involving assisted reproduction

Meaning of "mother"

33 Meaning of "mother"

(1) The woman who is carrying or has carried a child as a result of the placing in her of an embryo or of sperm and eggs, and no other woman, is to be treated as the mother of the child.

(2) Subsection (1) does not apply to any child to the extent that the child is treated by virtue of adoption as not being the woman's child.

(3) Subsection (1) applies whether the woman was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or the sperm and eggs.

Application of sections 35 to 47

34 Applications of sections 35 to 47

(1) Sections 35 to 47 apply, in the case of a child who is being or has been carried by a woman (referred to in those sections as "W") as a result of the placing in her of an embryo or of sperm and eggs or her artificial insemination, to determine who is to be treated as the other parent of the child.

(2) Subsection (1) has effect subject to the provisions of sections 39, 40 and 46 limiting the purposes for which a person is treated as the child's other parent by virtue of those sections.

Meaning of "father"

35 Women married [to, or civil partner of, a man] at time of treatment

(1) If -

(a) at the time of the placing in her of the embryo or of the sperm and eggs or of her artificial insemination, W was a party to a marriage [with a man or a civil partnership with a man], and

(b) the creation of the embryo carried by her was not brought about with the sperm of the other party to the marriage [or civil partnership],

then, subject to section 38(2) to (4), the other party to the marriage [or civil partnership] is to be treated as the father of the child unless it is shown that he did not consent to the placing in her of the embryo or the sperm and eggs or to her artificial insemination (as the case may be).

(2) This section applies whether W was in the United Kingdom or elsewhere at the time mentioned in subsection (1)(a).

36 Treatment provided to woman where agreed fatherhood conditions apply

If no man is treated by virtue of section 35 as the father of the child and no woman is treated by virtue of section 42 as a parent of the child but -

(a) the embryo or the sperm and eggs were placed in W, or W was artificially inseminated, in the course of treatment services provided in the United Kingdom by a person to whom a licence applies,

(b) at the time when the embryo or the sperm and eggs were placed in W, or W was artificially inseminated, the agreed fatherhood conditions (as set out in section 37) were satisfied in relation to a man, in relation to treatment provided to W under the licence,

(c) the man remained alive at that time, and

(d) the creation of the embryo carried by W was not brought about with the man's sperm,

then, subject to section 38(2) to (4), the man is to be treated as the father of the child.

37 The agreed fatherhood conditions

(1) The agreed fatherhood conditions referred to in section 36(b) are met in relation to a man ("M") in relation to treatment provided to W under a licence if, but only if, -

(a) M has given the person responsible a notice stating that he consents to being treated as the father of any child resulting from treatment provided to W under the licence,

(b) W has given the person responsible a notice stating that she consents to M being so treated,

(c) neither M nor W has, since giving notice under paragraph (a) or (b), given the person responsible notice of the withdrawal of M's or W's consent to M being so treated,

(d) W has not, since the giving of the notice under paragraph (b), given the person responsible -

(i) a further notice under that paragraph stating that she consents to another man being treated as the father of any resulting child, or

(ii) a notice under section 44(1)(b) stating that she consents to a woman being treated as a parent of any resulting child, and

(e) W and M are not within prohibited degrees of relationship in relation to each other.

(2) A notice under subsection (1)(a), (b) or (c) must be in writing and must be signed by the person giving it.

(3) A notice under subsection (1)(a), (b) or (c) by a person ("S") who is unable to sign because of illness, injury or physical disability is to be taken to comply with the requirement of subsection (2) as to signature if it is signed at the direction of S, in the presence of S and in the presence of at least one witness who attests the signature.

38 Further provision relating to sections 35 and 36

(1) Where a person is to be treated as the father of the child by virtue of section 35 or 36, no other person is to be treated as the father of the child.

(2) In England and Wales and Northern Ireland, sections 35 and 36 do not affect any presumption, applying by virtue of the rules of common law, that a child is the legitimate child of the parties to a marriage.

(3) In Scotland, sections 35 and 36 do not apply in relation to any child who, by virtue of any enactment or other rule of law, is treated as the child of the parties to a marriage.

(4) Sections 35 and 36 do not apply to any child to the extent that the child is treated by virtue of adoption as not being the man's child.

39 Use of sperm, or transfer of embryo, after death of man providing sperm

(1) If -

(a) the child has been carried by W as a result of the placing in her of an embryo or of sperm and eggs or her artificial insemination,

(b) the creation of the embryo carried by W was brought about by using the sperm of a man after his death, or the creation of the embryo was brought about using the sperm of a man before his death but the embryo was placed in W after his death,

(c) the man consented in writing (and did not withdraw the consent) -

(i) to the use of his sperm after his death which brought about the creation of the embryo carried by W or (as the case may be) to the placing in W after his death of the embryo which was brought about using his sperm before his death, and

(ii) to being treated for the purpose mentioned in subsection (3) as the father of any resulting child,

(d) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the man to be treated for the purpose mentioned in subsection (3) as the father of the child, and

(e) no-one else is to be treated -

(i) as the father of the child by virtue of section 35 or 36 or by virtue of section 38(2) or (3), or

(ii) as a parent of the child by virtue of section 42 or 43 or by virtue of adoption,

then the man is to be treated for the purpose mentioned in subsection (3) as the father of the child.

(2) Subsection (1) applies whether W was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or of the sperm and eggs or of her artificial insemination.

(3) The purpose referred to in subsection (1) is the purpose of enabling the man's particulars to be entered as the particulars of the child's father in a relevant register of births.

(4) In the application of this section to Scotland, for any reference to a period of 42 days there is substituted a reference to a period of 21 days.

40 Embryo transferred after death of [male spouse, civil partner or intended parent] etc. who did not provide sperm

(1) If -

(a) the child has been carried by W as a result of the placing in her of an embryo,

(b) the embryo was created at a time when W was a party to a marriage [with a man or a civil partnership with a man],

(c) the creation of the embryo was not brought about with the sperm of the other party to the marriage [or civil partnership],

(d) the other party to the marriage [or civil partnership] died before the placing of the embryo in W,

(e) the other party to the marriage [or civil partnership] consented in writing (and did not withdraw the consent) -

(i) to the placing of the embryo in W after his death, and

(ii) to being treated for the purpose mentioned in subsection (4) as the father of any resulting child,

(f) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the man to be treated for the purpose mentioned in subsection (4) as the father of the child, and

(g) no-one else is to be treated -

(i) as the father of the child by virtue of section 35 or 36 or by virtue of section 38(2) or (3), or

(ii) as a parent of the child by virtue of section 42 or 43 or by virtue of adoption,

then the man is to be treated for the purpose mentioned in subsection (4) as the father of the child.

(2) If -

(a) the child has been carried by W as a result of the placing in her of an embryo,

(b) the embryo was not created at a time when W was a party to a marriage or a civil partnership but was created in the course of treatment services provided to W in the United Kingdom by a person to whom a licence applies,

(c) a man consented in writing (and did not withdraw the consent) -

(i) to the placing of the embryo in W after his death, and

(ii) to being treated for the purpose mentioned in subsection (4) as the father of any resulting child,

(d) the creation of the embryo was not brought about with the sperm of that man,

(e) the man died before the placing of the embryo in W,

(f) immediately before the man's death, the agreed fatherhood conditions set out in section 37 were met in relation to the man in relation to treatment proposed to be provided to W in the United Kingdom by a person to whom a licence applies,

(g) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the man to be treated for the purpose mentioned in subsection (4) as the father of the child, and

(h) no-one else is to be treated -

(i) as the father of the child by virtue of section 35 or 36 or by virtue of section 38(2) or (3), or

(ii) as a parent of the child by virtue of section 42 or 43 or by virtue of adoption,

then the man is to be treated for the purpose mentioned in subsection (4) as the father of the child.

(3) Subsections (1) and (2) apply whether W was in the United Kingdom or elsewhere at the time of the placing in her of the embryo.

(4) The purpose referred to in subsections (1) and (2) is the purpose of enabling the man's particulars to be entered as the particulars of the child's father in a relevant register of births.

(5) In the application of this section to Scotland, for any reference to a period of 42 days there is substituted a reference to a period of 21 days.

Cases in which woman to be other parent

42 Woman in civil partnership [or marriage to a woman] at time of treatment

(1) If at the time of the placing in her of the embryo or the sperm and eggs or of her artificial insemination, W was a party to a civil partnership [with another woman or a marriage with another woman], then subject to section 45(2) to (4), the other party to the civil partnership [or marriage] is to be treated as a parent of the child unless it is shown that she did not consent to the placing in W of the embryo or the sperm and eggs or to her artificial insemination (as the case may be).

(2) This section applies whether W was in the United Kingdom or elsewhere at the time mentioned in subsection (1).

43 Treatment provided to woman who agrees that second woman to be parent

If no man is treated by virtue of section 35 as the father of the child and no woman is treated by virtue of section 42 as a parent of the child but -

(a) the embryo or the sperm and eggs were placed in W, or she was artificially inseminated, in the course of treatment services provided in the United Kingdom by a person to whom a licence applies,

(b) at the time when the embryo or the sperm and eggs were placed in W, or W was artificially inseminated, the agreed female parenthood conditions (as set out in section 44) were met in relation to another woman, in relation to treatment provided to W under that licence, and

(c) the other woman remained alive at that time,

then, subject to section 45(2) to (4), the other woman is to be treated as a parent of the child.

44 The agreed female parenthood conditions

(1) The agreed female parenthood conditions referred to in section 43(b) are met in relation to another woman ("P") in relation to treatment provided to W under a licence if, but only if, -

(a) P has given the person responsible a notice stating that P consents to P being treated as a parent of any child resulting from treatment provided to W under the licence,

(b) W has given the person responsible a notice stating that W agrees to P being so treated,

(c) neither W nor P has, since giving notice under paragraph (a) or (b), given the person responsible notice of the withdrawal of P's or W's consent to P being so treated,

(d) W has not, since the giving of the notice under paragraph (b), given the person responsible -

(i) a further notice under that paragraph stating that W consents to a woman other than P being treated as a parent of any resulting child, or

(ii) a notice under section 37(1)(b) stating that W consents to a man being treated as the father of any resulting child, and

(e) W and P are not within prohibited degrees of relationship in relation to each other.

(2) A notice under subsection (1)(a), (b) or (c) must be in writing and must be signed by the person giving it.

(3) A notice under subsection (1)(a), (b) or (c) by a person ("S") who is unable to sign because of illness, injury or physical disability is to be taken to comply with the requirement of subsection (2) as to signature if it is signed at the direction of S, in the presence of S and in the presence of at least one witness who attests the signature.

45 Further provision relating to sections 42 and 43

(1) Where a woman is treated by virtue of section 42 or 43 as a parent of the child, no man is to be treated as the father of the child.

(2) In England and Wales and Northern Ireland, sections 42 and 43 do not affect any presumption, applying by virtue of the rules of common law [or section A1(2) of the Legitimacy Act 1976] [or section 2(1)(a) of the Family Law Act (Northern Ireland) 2001], that a child is the legitimate child of the parties to a marriage [or civil partnership].

(3) In Scotland, sections 42 and 43 do not apply in relation to any child who, by virtue of any enactment or other rule of law, is treated as the child of the parties to a marriage.

(4) Sections 42 and 43 do not apply to any child to the extent that the child is treated by virtue of adoption as not being the woman's child.

46 Embryo transferred after death of [female spouse, civil partner or intended parent

(1) If -

(a) the child has been carried by W as the result of the placing in her of an embryo,

(b) the embryo was created at a time when W was a party to a civil partnership [with a woman or a marriage with a woman],

(c) the other party to the civil partnership [or marriage] died before the placing of the embryo in W,

(d) the other party to the civil partnership [or marriage] consented in writing (and did not withdraw the consent) -

(i) to the placing of the embryo in W after the death of the other party, and

(ii) to being treated for the purpose mentioned in subsection (4) as the parent of any resulting child,

(e) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the other party to the civil partnership [or marriage] to be treated for the purpose mentioned in subsection (4) as the parent of the child, and

(f) no one else is to be treated -

(i) as the father of the child by virtue of section 35 or 36 or by virtue of section 45(2) or (3), or

(ii) as a parent of the child by virtue of section 42 or 43 or by virtue of adoption,

then the other party to the civil partnership [or marriage] is to be treated for the purpose mentioned in subsection (4) as a parent of the child.

(2) If -

(a) the child has been carried by W as the result of the placing in her of an embryo,

(b) the embryo was not created at a time when W was a party to a marriage or a civil partnership, but was created in the course of treatment services provided to W in the United Kingdom by a person to whom a licence applies,

(c) another woman consented in writing (and did not withdraw the consent) -

(i) to the placing of the embryo in W after the death of the other woman, and

(ii) to being treated for the purpose mentioned in subsection (4) as the parent of any resulting child,

(d) the other woman died before the placing of the embryo in W,

(e) immediately before the other woman's death, the agreed female parenthood conditions set out in section 44 were met in relation to the other woman in relation to treatment proposed to be provided to W in the United Kingdom by a person to whom a licence applies,

(f) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the other woman to be treated for the purpose mentioned in subsection (4) as the parent of the child, and

(g) no one else is to be treated -

(i) as the father of the child by virtue of section 35 or 36 or by virtue of section 45(2) or (3), or

(ii) as a parent of the child by virtue of section 42 or 43 or by virtue of adoption,

then the other woman is to be treated for the purpose mentioned in subsection (4) as a parent of the child.

(3) Subsections (1) and (2) apply whether W was in the United Kingdom or elsewhere at the time of the placing in her of the embryo.

(4) The purpose referred to in subsections (1) and (2) is the purpose of enabling the deceased woman's particulars to be entered as the particulars of the child's other parent in a relevant register of births.

(5) In the application of subsections (1) and (2) to Scotland, for any reference to a period of 42 days there is substituted a reference to a period of 21 days.

48 Effect of sections 33 to 47

(1) Where by virtue of section 33, 35, 36, 42 or 43 a person is to be treated as the mother, father or parent of a child, that person is to be treated in law as the mother, father or parent (as the case may be) of the child for all purposes.

(2) Where by virtue of section 33, 38, 41, 45 or 47 a person is not to be treated as a parent of the child, that person is to be treated in law as not being a parent of the child for any purpose.

(3) Where section 39(1) or 40(1) or (2) applies, the deceased man -

(a) is to be treated in law as the father of the child for the purpose mentioned in section 39(3) or 40(4), but

(b) is to be treated in law as not being the father of the child for any other purpose.

(4) Where section 46(1) or (2) applies, the deceased woman -

(a) is to be treated in law as a parent of the child for the purpose mentioned in section 46(4), but

(b) is to be treated in law as not being a parent of the child for any other purpose.

(5) Where any of subsections (1) to (4) has effect, references to any relationship between two people in any enactment, deed or other instrument or document (whenever passed or made) are to be read accordingly.

(6) In relation to England and Wales and Northern Ireland, a child who -

(a) has a parent by virtue of section 42, or

(b) has a parent by virtue of section 43 who is at any time during the period beginning with the time mentioned in section 43(b) and ending with the time of the child's birth a party to a marriage or civil partnership with the child's mother,

is the legitimate child of the child's parents.

(7) In relation to England and Wales and Northern Ireland, nothing in the provisions of section 33(1) or sections 35 to 47, read with this section -

(a) affects the succession to any dignity or title of honour or renders any person capable of succeeding to or transmitting a right to succeed to any such dignity or title, or

(b) affects the devolution of any property limited (expressly or not) to devolve (as nearly as the law permits) along with any dignity or title of honour.

(8) In relation to Scotland -

(a) those provisions do not apply to any title, coat of arms, honour or dignity transmissible on the death of its holder or affect the succession to any such title, coat of arms or dignity or its devolution, and

(b) where the terms of any deed provide that any property or interest in property is to devolve along with a title, coat of arms, honour or dignity, nothing in those provisions is to prevent that property or interest from so devolving.

References to parties to marriage or civil partnership

49 Meaning of references to parties to a marriage

(1) The references in sections 35 to 47 to the parties to a marriage at any time there referred to -

(a) are to the parties to a marriage subsisting at that time, unless a judicial separation was then in force, but

(b) include the parties to a void marriage if either or both of them reasonably believed at that time that the marriage was valid; and for the purposes of those sections it is to be presumed, unless the contrary is shown, that one of them reasonably believed at that time that the marriage was valid.

(2) In subsection (1)(a) "judicial separation" includes a legal separation obtained in a country outside the British Islands and recognised in the United Kingdom.

50 Meaning of references to parties to a civil partnership

(1) The references in sections 35 to 47 to the parties to a civil partnership at the time there referred to -

(a) are to the parties to a civil partnership subsisting at that time, unless a separation order was then in force, but

(b) include the parties to a void civil partnership if either or both of them reasonably believed at that time that the civil partnership was valid; and for the purposes of those sections it is to be presumed, unless the contrary is shown, that one of them reasonably believed at that time that the civil partnership was valid.

(3) In subsection (1)(a), "separation order" means -

(a) a separation order under section 37(1)(d) or 161(1)(d) of the Civil Partnership Act 2004 (c. 33),

(b) a decree of separation under section 120(2) of that Act, or

(c) a legal separation obtained in a country outside the United Kingdom and recognised in the United Kingdom.

Further provision about registration by virtue of section 39, 40 or 46

51 Meaning of "relevant register of births"

For the purposes of this Part a "relevant register of births", in relation to a birth, is whichever of the following is relevant -

(a) a register of live-births or still-births kept under the Births and Deaths Registration Act 1953 (c. 20),

(b) a register of births or still-births kept under the Registration of Births, Deaths and Marriages (Scotland) Act 1965 (c. 49), or

(c) a register of live-births or still-births kept under the Births and Deaths Registration (Northern Ireland) Order 1976 (S.I. 1976/1041 (N.I.14)).

52 Late election by mother with consent of Registrar General

(1) The requirement under section 39(1), 40(1) or (2) or 46(1) or (2) as to the making of an election (which requires an election to be made either on or before the day on which the child was born or within the period of 42 or, as the case may be, 21 days from that day) is nevertheless to be treated as satisfied if the required election is made after the end of that period but with the consent of the Registrar General under subsection (2).

(2) The Registrar General may at any time consent to the making of an election after the end of the period mentioned in subsection (1) if, on an application made to him in accordance with such requirements as he may specify, he is satisfied that there is a compelling reason for giving his consent to the making of such an election.

(3) In this section "the Registrar General" means the Registrar General for England and Wales, the Registrar General of Births, Deaths and Marriages for Scotland or (as the case may be) the Registrar General for Northern Ireland.

Interpretation of references to father etc. where woman is other parent

53 Interpretation of references to father etc.

(1) Subsections (2) and (3) have effect, subject to subsections (4) and (6), for the interpretation of any enactment, deed or any other instrument or document (whenever passed or made).

(2) Any reference (however expressed) to the father of a child who has a parent by virtue of section 42 or 43 is to be read as a reference to the woman who is a parent of the child by virtue of that section.

(3) Any reference (however expressed) to evidence of paternity is, in relation to a woman who is a parent by virtue of section 42 or 43, to be read as a reference to evidence of parentage.

(4) This section does not affect the interpretation of the enactments specified in subsection (5) (which make express provision for the case where a child has a parent by virtue of section 42 or 43).

(5) Those enactments are -

(a) the Legitimacy Act (Northern Ireland) 1928 (c. 5 (N.I.)),

(b) the Schedule to the Population (Statistics) Act 1938 (c. 12),

(c) the Births and Deaths Registration Act 1953 (c. 20),

(d) the Registration of Births, Deaths and Marriages (Special Provisions) Act 1957 (c. 58),

(e) Part 2 of the Registration of Births, Deaths and Marriages (Scotland) Act 1965 (c. 49),

(f) the Congenital Disabilities (Civil Liability) Act 1976 (c. 28),

(g) the Legitimacy Act 1976 (c. 31),

(h) the Births and Deaths Registration (Northern Ireland) Order 1976 (S.I. 1976/1041 (N.I. 14)),

(i) the British Nationality Act 1981 (c. 61),

(j) the Family Law Reform Act 1987 (c. 42),

(k) Parts 1 and 2 of the Children Act 1989 (c. 41),

(l) Part 1 of the Children (Scotland) Act 1995 (c. 36),

(m) section 1 of the Criminal Law (Consolidation) (Scotland) Act 1995 (c. 39), and

(n) Parts 2, 3 and 14 of the Children (Northern Ireland) Order 1995 (S.I. 1995/755 (N.I. 2)).

(6) This section does not affect the interpretation of references that fall to be read in accordance with section 1(2)(a) or (b) of the Family Law Reform Act 1987 or Article 155(2)(a) or (b) of the Children (Northern Ireland) Order 1995 (references to a person whose father and mother were, or were not, married to each other at the time of the person's birth).

58 Interpretation of Part 2

(2) For the purposes of this Part, two persons are within prohibited degrees of relationship if one is the other's parent, grandparent, sister, brother, aunt or uncle; and in this subsection references to relationships -

(a) are to relationships of the full blood or half blood or, in the case of an adopted person, such of those relationships as would subsist but for adoption, and

(b) include the relationship of a child with his adoptive, or former adoptive, parents, but do not include any other adoptive relationships.

Licence conditions

T58 Prior to giving consent gamete providers must be provided with information about:

a. the nature of the treatment

b. its consequences and risks

c. any analytical tests, if they are to be performed

d. the statutory storage period applicable in their circumstances (storage periods will differ depending on whether gamete providers are storing for own use or donating for use in someone else's treatment or whether they are consenting to use for training or research purposes)

e. the requirement, for patients who are storing for use in their own treatment, to renew their consent in writing every 10 years (or at the end of any shorter period they consented to)

f. the legal requirement to remove gametes or embryos from storage and for these to be disposed of once they may no longer lawfully be kept

g. the recording and protection of personal data and confidentiality

h. the right to withdraw or vary their consent, and

i. the availability of counselling.

T59 The information referred to in licence condition T58 must be given by trained personnel in a manner and using terms that are easily understood by the gamete provider.

T60 A woman must not be provided with treatment services using embryos or donated gametes unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services of that kind, and have been provided with such relevant information as is proper.

T61 A woman must not be provided with treatment services where there is an intended second parent unless, either before or after both have consented to the man or woman being the intended second parent, she and the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of the woman being provided with treatment services and have been provided with such relevant information as is proper.

T62 The reference in licence conditions T60 and T61 above to the intended second parent is a reference to:

a. any man with respect to whom the agreed fatherhood conditions in Section 37 of the Human Fertilisation and Embryology Act 2008 ("the 2008 Act") are for the time being satisfied in relation to treatment provided to the woman mentioned in licence conditions T60 and T61, and

b. any woman with respect to whom the agreed female parenthood conditions in Section 44 of the 2008 Act are for the time being satisfied in relation to treatment provided to the woman mentioned in licence conditions T60 and T61.

T63 In the case of treatment services using donated gametes, or embryos created using donated gametes, the person receiving treatment and any intended second parent, must be provided with information about:

a. the importance of informing any resulting child at an early age that they were born as a result of such treatment, and

b. suitable methods of informing such a child of that fact.

T64 In cases where the nominated second parent withdraws their consent to be treated as the parent of any child born to a named woman, the PR must:

a. notify the woman in writing of the receipt of the notice from the second parent, and

b. ensure that no treatment services are provided to the named woman until she has been notified of the second parent's withdrawal of consent.

T65 If a woman withdraws her consent to her nominated second parent being treated as the legal parent, or consents to a different person being the legal parent of any child resulting from treatment, the PR must notify the original nominated second parent in writing of this.

Directions

0007 – Consent

HFEA guidance

Legal parenthood and parental responsibility

6.1 The centre should provide information to people seeking treatment about legal parenthood, or should direct those people to suitable sources of information. This information should include who will be the child's legal parent(s) under the HFE Act 2008 and other relevant legislation. Nationals or residents of other countries, or individuals treated with gametes obtained from nationals or residents of other countries, should be informed that the law in other countries may be different from that in the United Kingdom. In particular, if people are seeking treatment as part of a surrogacy arrangement that involves nationals or residents of other countries, the centre should:

(a) make clear to those involved that the legal and immigration implications are complex; and
(b) advise them to seek their own legal advice.

6.2 The centre should seek to ensure that people seeking treatment understand:

(a) the difference in law between legal parenthood and parental responsibility; and
(b) the implications of this for themselves and any child born as a result of treatment.

6.3 A person recognised as the legal parent of a child may not automatically have parental responsibility. Legal parenthood gives a lifelong connection between a parent and a child, and affects things like nationality, inheritance and financial responsibility. A person with parental responsibility has the authority to decide about the care of the child while the latter is young, for example for medical treatment and education.

6.4 A woman who carries and gives birth to a child as a result of treatment will be the legal mother of that child. Where the woman is married to or in a civil partnership with a man and they are seeking treatment together using the spouse or civil partner's sperm (or embryos created using the partner's sperm), the partner will automatically be the legal father of any resulting child. However, there are cases where the woman's partner may not automatically be the legal parent of the resulting child.

If the woman is married or in a civil partnership at the time of the treatment (and a judicial separation order or separation order is not in force), her spouse or civil partner will be treated as a legal parent unless it is shown that the spouse or civil partner did not consent to the placing in the woman of the embryo or the sperm and eggs or to her artificial insemination, as the case may be.

If the woman is not married or in a civil partnership with her partner, and the woman is being treated using donor sperm (or embryos created using donor sperm), the consent of both the woman and her partner is needed for the partner to be recognised as the child's legal parent.

For further details about establishing legal parenthood, see below.

6.5 A child's legal mother automatically has parental responsibility. The position of the father or other legal parent depends on factors including their marital status, what is recorded on the birth certificate, and whether the family court has made an order.

6.6 In any case in which people seeking treatment have any doubts or concerns about legal parenthood or parental responsibility for a child born as a result of treatment services, or where a centre has concerns about the understanding of the people seeking treatment, the centre should advise them to seek their own legal advice.

See also

HFEA consent forms

HFEA consent form guidance

Guidance note 27 – Adverse incidents

Human Fertilisation and Embryology Act 2008 explanatory notes

General procedures for obtaining consent

6.7 The centre should record whether a person receiving treatment is married or in a civil partnership in their notes, and should explain to the person that this is relevant because relationship status is an important factor in determining the legal parenthood of any child that may be born, and is relevant when considering what consent forms need to be completed prior to treatment. If a person is having treatment with a partner, the centre should record whether they are married or in a civil partnership with one another (or with someone else). This may affect who will be the second legal parent of any child born following treatment and whether consent is required to make the partner (with whom treatment is being sought) the child's legal parent.

6.8 If a person is seeking treatment on their own i.e. without a partner, but is still married or in a civil partnership, the centre should record this in their notes, as this may affect who will be the second legal parent of any child born following treatment.

For more guidance on what to do if a woman who is married or in a civil partnership returns for subsequent treatment without her spouse or civil partner present, see paragraphs 6.23 and 6.28.

6.9 Where consent is required for the partner to be the child's legal parent, the centre should establish and use documented procedures to obtain written, effective consent to legal parenthood. Failure to carry out the following steps could mean that the partner is not legally recognised as the child's legal parent and it may be necessary for the partner to apply for a declaration of parentage through the Courts.

6.10 Consent to the partner being the legal parent must be obtained from **both** the woman receiving treatment and her partner.

6.11 Consent to legal parenthood must be obtained (either electronically or as a hard copy) from the woman receiving treatment and her partner before sperm and egg transfer, embryo transfer, or insemination takes place.

6.12 Consent should be obtained and recorded using the correct HFEA consent forms. The woman must complete the form that pertains to her, and her partner must complete the form that pertains to them.

For more information on which consent to legal parenthood forms should be used and what you should do to make sure consent is taken properly, see the HFEA guide to consent.

6.13 The consent forms must be correctly completed, signed and dated. The centre should keep a copy of a person's signed consent form(s) (either electronically or as a hard copy) so that a copy can be made available to them upon request. All consent forms are subject to the retention requirements outlined in General Direction 0012.

6.14 The centre should ensure that there is documented evidence in the medical records that information about legal parenthood and an offer of counselling must be provided to the person giving consent before consent is obtained. The centre should ensure that there is documented evidence in the medical records that this has happened.

6.15 The centre should ensure that consent to legal parenthood is:

(a) given voluntarily

(b) given by a person who has the capacity to do so, and

(c) taken by a person authorised by the centre to do so.

If the person giving consent is unable to complete the consent form because of physical illness, injury or disability they may direct someone else to complete and sign it for them. However, if the person is consenting to being registered as the legal parent of any child born as a result of treatment after their death, only they can sign that part of the form.

6.16 The centre should ensure that any person giving consent declares that:

(a) they were given enough information to understand the nature, purpose and implications of receiving treatment (or their partner receiving treatment) following consent

(b) they were given a suitable opportunity to receive proper counselling about the implications of receiving treatment (or their partner receiving treatment) following consent

(c) they were given information about the implications and procedure for varying or withdrawing consent, and

(d) the information they have given in writing is correct and complete.

6.17 When obtaining consent to register the partner posthumously as the parent, the centre should ensure that the partner consents to their details and identifying information about treatment being disclosed to either the Registrar General for England and Wales, the Registrar General for Scotland or the Registrar for Northern Ireland, as appropriate.

6.18 If the woman receiving treatment withdraws or varies her consent to her partner being the child's legal parent (either electronically or as a hard copy), the partner must be notified of this in writing. If the woman's partner withdraws or varies their consent to being the child's legal parent, the woman must be notified of this in writing.

6.19 A woman can only withdraw consent to her partner being the child's legal parent if donor sperm or embryos are used in the treatment and the woman and her partner are not married or in a civil partnership and only before the sperm or embryo(s) are placed in the woman.

6.20 When anyone gives, withdraws or varies consent to legal parenthood, the centre should check their identity against identifying information held in the medical records. If there is doubt about a patient's identity, the centre should take steps to verify this, including examining photo identification such as a photocard driving licence or passport. The centre should record this evidence in the medical records.

6.21 There are very serious implications for patients, their partners and resulting children if consent to legal parenthood is not obtained properly, not recorded accurately or not recorded at all. Inaccuracies or errors on consent to legal parenthood forms may cause doubt about the parental status of the patient's partner, which may only be determined by the partner applying for a declaration of parentage in the courts.

For more information on how to avoid making mistakes when obtaining consent to legal parenthood, see the HFEA guide to consent.

6.22 In cases where a centre identifies anomalies in legal parenthood consent that may have an impact on the legal parenthood of any child born as a result of treatment, the centre should:

(a) take all reasonable steps to notify the affected patient at the earliest opportunity

(b) assess the error(s) and potential impact, and consider the remedial actions that should be taken, and

(c) take all reasonable steps to support any affected patients (and their partner(s), if relevant) and offer independent legal assistance where necessary.

The centre should also seek independent legal advice and must inform the HFEA in writing of any anomalies or deficiencies in legal parenthood consent that it discovers by sending a completed adverse incident form within the incident reporting timescales set out at guidance note 27.

See also

Guidance note 4 – Information to be provided prior to consent

Guidance note 5 – Consent to treatment, storage, donation, training and disclosure of information

HFEA consent forms

HFEA consent form guidance

Legal parenthood when the woman has a male civil partner or husband

Interpretation of mandatory requirements 6A

Where a woman is married to, or in a civil partnership with a man, and is seeking treatment using her husband's or civil partner's sperm or embryos created using her husband's or civil partner's sperm, the husband or civil partner will automatically be the legal father of any child born as a result of the treatment, and will have parental responsibility.

Where a woman is married to, or in a civil partnership with a man, and is seeking treatment using sperm other than that of her husband or civil partner, or an embryo created using sperm other than that of her husband or civil partner, her husband or civil partner will be treated as the father of any child born as a result of that treatment (and will have parental responsibility) unless:

(a) at the time the sperm and eggs or embryos were placed in her, or she was inseminated, a judicial separation or separation order was in force, or

(b) it is shown that the husband or civil partner did not consent to the placing in her of the sperm and eggs or embryos, or to her insemination.

For more information on what legal parenthood consent forms must be used and on how to ensure consent is taken properly, see the HFEA guide to consent.

6.23 The law relating to legal parenthood can be complex and have lifelong implications for patients, it is therefore important that centres, and patients, take independent legal advice where necessary to ensure that patients and partners understand how the law on legal parenthood applies in their particular situation and, if applicable, that all necessary actions are taken to enable the partner to be the second legal parent.

6.24 When a woman who is married to or in a civil partnership with a man returns for subsequent treatment without her husband or civil partner present, the centre should establish whether the couple are still seeking treatment together or have separated or divorced. Even if they have separated, if the marriage or civil partnership is still in existence, there will be a presumption under section 35 of the (HFE) Act 2008, as amended, that the husband or civil partner will be the father of any child born as a result of further treatment unless an order for judicial separation (in the case of marriage) or an order for separation (in the case of a civil partnership) has been obtained. If no such order has been obtained, the husband or civil partner will be treated as the father of any child unless it can be shown that he does not consent to the proposed treatment.

6.25 Where appropriate, and taking account of confidentiality, centres should attempt to contact the husband or civil partner and ask him to provide written confirmation as to whether or not he consents

to the proposed treatment. In seeking such clarification, a centre should inform the husband or civil partner of the effect of section 35. Where a woman and her husband or civil partner still intend on having treatment together, the centre should ensure that the original consent forms completed during their first treatment are still valid and effective.

For more information on what a centre should consider when a patient returns for subsequent treatment, see the HFEA guide to consent.

6.26 If a woman married to or in a civil partnership with a man is seeking treatment using donor sperm, or embryos created using donor sperm, the centre should take all practical steps to:

(a) ascertain whether the husband or civil partner consents to the treatment 'as a question of fact' (see box 6B), taking into account the duty of confidentiality to the woman (it may not be appropriate to contact him if he is unaware his wife or civil partner is having treatment), and
(b) obtain a written record of the husband or civil partner's position. If the husband or civil partner consents, he should complete the relevant centre consent form. If he does not consent 'as a question of fact' (see box 6B), the centre should take all practical steps to obtain evidence of this.

6.27 If the centre cannot obtain a written record of the husband or civil partner's consent or lack of consent, it should record the steps taken to establish whether he consents to the treatment in the medical records. The centre could consider not providing treatment until an order for judicial separation has been obtained or the divorce has been finalised or, in the case of a civil partnership, an order for separation or dissolution has been obtained.

6.28 A woman who is still married or in a civil partnership may wish to be treated with a new partner (with her new partner's sperm or with donor sperm or a donor embryo). If she wishes her new partner to be registered as the legal parent of any child born from this treatment, then prior to any transfer of sperm or embryos, evidence to show that her husband or civil partner does not consent to the treatment must be obtained in order for the woman's new partner to be the legal parent of any child born as a result of the treatment. It should not be assumed that the woman's new partner, even if he is the biological father, will necessarily be the second legal parent if the patient is still married or in a civil partnership with another person.

6.29 The centre should explain to patients seeking treatment together using embryos created with donor sperm that if they subsequently separate or divorce, any embryos in storage may only be stored and used in accordance with the consent of the egg and sperm providers whose gametes were used to create the embryos.

Interpretation of mandatory requirements 6B

Establishing lack of consent by the husband or male civil partner 'as a question of fact'

To prove that the husband or male civil partner of a woman undergoing treatment does not consent to this treatment, their lack of consent requires a basis in fact (for example, if the patient and her husband or civil partner are separated – but there is no judicial separation or separation order in force – and the latter is unaware of the treatment). The patient's husband or civil partner may be considered the legal father of the child if they support the treatment in any way, for instance if they help the patient to attend appointments to receive treatment. Any form declaring their lack of consent may not by itself remove their status as the legal father if they do consent 'as a question of fact'. If there is a factual basis for the husband not consenting, centres should obtain evidence of this, for instance evidence that the couple are about to start divorce proceedings.

Parenthood in these circumstances can be complex and is case-specific and any dispute is ultimately for the family court or births registrar (or both) to determine. Centres and couples may need to seek their own independent legal advice before proceeding with treatment.

See also

HFEA consent forms

HFEA consent form guidance

Legal parenthood when the woman has a civil partner or wife

Interpretation of mandatory requirements 6C

Where a woman who is married to or in a civil partnership with a woman is seeking treatment using donor sperm, or embryos created using donor sperm, the woman's wife or civil partner will be treated as a legal parent of any resulting child unless, at the time of placing the embryo or sperm and eggs in the woman, or of her insemination:

(a) a judicial separation or separation order was in force, or

(b) it is shown that the wife or civil partner did not consent to the placing in her of the sperm and eggs, or embryos, or to the insemination.

For more information on what legal parenthood consent forms must be used and on how to ensure consent is taken properly, see the HFEA guide to consent.

6.30 The law relating to legal parenthood can be complex and have lifelong implications for patients, it is therefore important that centres where necessary, and patients, take independent legal advice to ensure that patients and partners understand how the law on legal parenthood applies in their particular situation and, if applicable, that all necessary actions are taken to enable the partner to be the second legal parent.

6.31 When a woman who is married to or in a civil partnership with a woman returns for subsequent treatment without her wife or civil partner present, the centre should establish whether the couple are still seeking treatment together or have separated or divorced. Even if they have separated, if the marriage or civil partnership is still in existence, there will be a presumption under section 42 of the (HFE) Act 2008, as amended, that the wife or civil partner will be a legal parent of any child born as a result of further treatment unless an order for judicial separation (in the case of marriage) or an order for separation (in the case of a civil partnership) has been obtained. If no such order has been obtained, the wife or civil partner will be treated as a legal parent of any child unless it can be shown that she does not consent to the proposed treatment.

6.32 Where appropriate and taking account of confidentiality, centres should attempt to contact the wife or civil partner and ask her to provide written confirmation about whether or not she consents to the proposed treatment. In seeking such clarification, the centre should inform the wife or civil partner of the effect of section 42. Where a woman and her wife or civil partner still intend on having treatment together, the centre should ensure that the original consent forms completed during the first treatment are still valid and effective.

For more information on what a centre should consider when a patient returns for subsequent treatment, see the HFEA guide to consent.

6.33 If a woman married to or in a civil partnership with a woman is seeking treatment using donor sperm, or embryos created using donor sperm, the centre should take all practical steps to:

(a) ascertain whether the wife or civil partner consents to the treatment 'as a question of fact' (see box 6D), taking into account the duty of confidentiality to the woman seeking treatment (it may not be appropriate to contact her if she is unaware her wife or civil partner is having treatment), and

(b) obtain a written record of the position of the wife or civil partner. If the wife or civil partner consents, she should complete the relevant centre consent form. If the civil partner or wife does not consent 'as a question of fact' (see box 6D), the centre should take all practical

steps to obtain evidence of this.

6.34 If the centre cannot obtain a written record of the civil partner or wife's consent or lack of consent, it should record the steps taken to establish whether the civil partner or wife consents to the treatment in the medical records. The centre could consider not providing treatment until an order for judicial separation has been obtained or the divorce has been finalised or, in the case of a civil partnership, an order for separation or dissolution has been obtained.

6.35 A woman who is still married to or in a civil partnership with a woman may wish to be treated with a new partner (with donor sperm or a donor embryo). If she wishes her new partner to be registered as the legal parent of any child born from this treatment, then prior to any transfer of sperm or embryos, evidence to show that her wife or civil partner does not consent to the treatment must be obtained in order for the woman's new partner to be the legal parent of any child born as a result of the treatment. It should not be assumed that the woman's new partner will necessarily be the second legal parent if the woman being treated is still married or in a civil partnership with another woman.

6.36 The centre should explain to patients seeking treatment together using one of the female partner's eggs and donor sperm that if they store embryos and subsequently separate or divorce, any embryos in storage may only be stored and used in accordance with the consent of the egg and sperm providers whose gametes were used to create the embryos. This is the case regardless of who the eggs were intended for, if the egg provider initially wished for her former partner to carry the pregnancy.

Interpretation of mandatory requirements 6D

Establishing lack of consent by wife or civil partner 'as a question of fact'

To prove that the wife, or civil partner of a woman undergoing treatment does not consent to this treatment, their lack of consent requires a basis in fact (for example, if the patient and her wife, or civil partner are separated – but there is no judicial separation or separation order in force – and the latter is unaware of the treatment). The patient's wife, or civil partner may be considered a legal parent of the child if they support the treatment in any way, for instance if they help the patient to attend appointments to receive treatment. Any form declaring their lack of consent may not by itself remove their status as the legal parent if they do consent 'as a question of fact'. If there is a factual basis for the wife, or civil partner not consenting, centres should obtain evidence of this, for instance evidence that the couple are about to start divorce proceedings.

Parenthood in these circumstances can be complex and is case-specific and any dispute is ultimately for the family court or births registrar (or both) to determine. Centres and couples may need to seek their own independent legal advice before proceeding with treatment.

See also

HFEA consent forms

HFEA consent form guidance

Legal parenthood: male partner who is not a civil partner or husband

Interpretation of mandatory requirements 6E

The following rules apply only if the woman having treatment:

(a) is neither married nor in a civil partnership, or

(b) is married to or in a civil partnership with a man but there is a judicial separation or separation order in force.

Where a woman is seeking treatment using her unmarried male partner's sperm, or embryos created using her partner's sperm, her male partner will automatically be the legal father of any child born as a result of the treatment.

Where a woman is seeking treatment using donor sperm, or embryos created with donor sperm, her male partner will be the legal father of any resulting child if, at the time the eggs and sperm, or embryos, are placed in the woman or she is inseminated, all the following conditions apply:

(a) both the woman and the male partner have given a written, signed notice (subject to the exemption for illness, injury or physical disability) to the centre consenting to the male partner being treated as the legal father

(b) neither consent was withdrawn (or superseded with a subsequent written notice) before insemination/transfer, and

(c) the patient and male partner are not close relatives (within prohibited degrees of relationship to each other, as defined in section 58(2), HFE Act 2008).

For more information on what legal parenthood consent forms must be used and on how to ensure consent is taken properly, see the HFEA guide to consent.

6.37 The law relating to legal parenthood can be complex and have lifelong implications for patients, it is therefore important that centres where necessary, and patients, take independent legal advice to ensure that patients and partners understand how the law on legal parenthood applies in their particular situation and, if applicable, that all necessary actions are taken to enable the partner to be the second legal parent.

6.38 When a woman with an unmarried male partner returns for subsequent treatment without her partner present, the centre should establish whether the couple are still seeking treatment together or have split up. Where appropriate and taking account of confidentiality, centres should attempt to contact the partner and ask them to provide written confirmation about whether or not they consent to the proposed treatment. In seeking such clarification, the centre should inform the unmarried male partner of the effect of sections 36 and 37 of the (HFE) Act 2008. Where the patient and her unmarried partner still intend having treatment together, the centre should ensure that the original consent forms completed during the first treatment are still valid and effective.

6.39 Where subsequent treatment involves the use of donor sperm, the centre should establish whether the male partner wishes to continue to be recognised as the legal parent of any future child born from the treatment. If they have split up and the male partner no longer wishes to be recognised as the legal parent, it is recommended that he withdraw his consent to being the legal parent. The woman receiving treatment should also complete the relevant consent form to withdraw her consent to her former partner being the legal parent of any child born as a result of her treatment.

6.40 If the centre cannot obtain a written record of the male partner's consent or lack of consent, it should record the steps taken to establish whether the partner consents to the treatment in the medical records.

6.41 If a woman returns for treatment with a new male partner and wishes to use embryos in storage (which were created with donor sperm), then prior to any transfer of sperm or embryos both the woman and her new partner must complete the relevant legal parenthood consent forms consenting

to the new partner being treated as the parent of any resulting child. The previous partner should complete the relevant consent form to withdraw his consent to being the legal parent of any child born as a result of his previous partner's treatment. The woman should also complete the relevant consent form to withdraw her consent to her previous partner being the legal parent of any child born as a result of her treatment.

6.42 The centre should explain to patients seeking treatment together using donor sperm that if they store embryos and subsequently separate, any embryos in storage may only be stored and used in accordance with the consent of the egg and sperm providers whose gametes were used to create the embryos.

See also

HFEA consent forms

HFEA consent form guidance

Legal parenthood: female partner who is not a civil partner or wife

Interpretation of mandatory requirements 6F

The following rules apply only if the woman having treatment:

(a) is neither married nor in a civil partnership, or

(b) is married to or in a civil partnership with a woman but there is a judicial separation or separation order in force.

Where a woman is being treated together with a female partner using donor sperm, or embryos created with donor sperm, the female partner will be the other legal parent of any resulting child if, at the time the eggs and sperm, or embryos, are placed in the woman or she is inseminated, all the following conditions apply:

(a) both the woman and her female partner have given a written, signed notice (subject to the exemption for illness, injury or physical disability) to the centre consenting to the female partner being treated as the parent of any resulting child

(b) neither consent was withdrawn (or superseded with a subsequent written note) before insemination/transfer, and

(c) the patient and female partner are not close relatives (within prohibited degrees of relationship to each other as defined in section 58(2), part 2, HFE Act 2008).

For more information on what legal parenthood consent forms must be used and on how to ensure consent is taken properly, see the HFEA guide to consent.

6.43 The law relating to legal parenthood can be complex and have lifelong implications for patients, it is therefore important that centres where necessary, and patients, take independent legal advice to ensure that patients and partners understand how the law on legal parenthood applies in their particular situation and, if applicable, that all necessary actions are taken to enable the partner to be the second legal parent.

6.44 When a woman with a female partner returns for subsequent treatment without her partner present, the centre should establish whether the couple are still seeking treatment together or have split up. Where appropriate and taking account of confidentiality, centres should attempt to contact the partner and ask them to provide written confirmation about whether or not they consent to the proposed treatment. In seeking such clarification, the centre should inform the unmarried female partner of the effect of sections 43 and 44 of the (HFE) Act 2008.Where the patient and her unmarried partner still intend having treatment together, the centre should also ensure that the original consent forms completed during the first treatment are still valid and effective.

6.45 Where subsequent treatment involves the use of donor sperm, the centre should establish whether the female partner wishes to continue to be recognised as the legal parent of any future child born from the treatment. If they have split up and the female partner no longer wishes to be recognised as the legal parent, it is recommended that she withdraw her consent to being the legal parent. The woman receiving treatment should also complete the relevant consent form to withdraw her consent to her former partner being the legal parent of any child born as a result of her treatment.

6.46 If the centre cannot obtain a written record of the female partner's consent or lack of consent, it should record the steps taken to establish whether the partner consents to the treatment in the medical records.

6.47 If a woman returns for treatment with a new female partner and wishes to use embryos in storage that were created with her eggs and donor sperm, then prior to any transfer of sperm or embryos both the patient and her new partner must complete the relevant legal parenthood consent forms consenting to the new partner being treated as the parent of any resulting child. The previous partner should complete the relevant consent form to withdraw her consent to being the legal parent of any child born as a result of her previous partner's treatment. The egg provider should also complete the relevant consent form to withdraw her consent to her previous partner being the legal parent of any child born as a result of her treatment.

6.48 The centre should explain to patients seeking treatment together using one of the female partner's eggs and donor sperm that if they store embryos and subsequently separate, any embryos in storage may only be stored and used in accordance with the consent of the egg and sperm providers whose gametes were used to create the embryos. This is the case regardless of who the eggs were intended for, and if the egg provider initially wished for her former partner to carry the pregnancy.

See also

HFEA consent forms

HFEA consent form guidance

Parenthood after death of a man providing sperm

Interpretation of mandatory requirements 6G

A husband or male partner who has provided sperm for the treatment of their wife or female

partner can be registered as the father of any child born as a result of treatment after their death, if the following conditions are met:

(a) the man had given written consent for his sperm, or embryos created using his sperm, to be used after his death in the treatment of his wife or partner

(b) the man had given written consent to being registered as the father of any resulting child

(c) the woman elected in writing, within 42 days (21 days in Scotland) after the child's birth, for the man's details to be entered in the relevant register of births, and

(d) no-one else is to be treated as the father or parent of the child.

The treatment can involve insemination of sperm, transfer of sperm and eggs, or transfer of embryos created before or after the man's death. The centre must ensure that partners are given an opportunity to consent to this.

See also

HFEA consent forms

HFEA consent form guidance

Parenthood after death of a partner who has not provided sperm

Interpretation of mandatory requirements 6H

A partner (husband, wife, civil partner or other partner) who has not provided sperm for

the treatment of their wife, civil partner or female partner can be registered as the father or parent of any child born as a result of treatment after their death, if the following conditions are met:

(a) the treatment involved the transfer to the woman of an embryo after the death of the partner

(b) the embryo was created when the partner was alive,

(c) the partner had given written consent for the embryo to be placed in the woman after their death

(d) the partner had given written consent to being registered as the father or parent of any resulting child

(e) the woman elected in writing, within 42 days (21 days in Scotland) after the child's birth, for the partner's details to be entered in the relevant register of births, and

(f) no-one else is to be treated as the father or parent of the child.

The centre must ensure that partners are given an opportunity to consent to this.

Legal parenthood: surrogacy

Interpretation of mandatory requirements 6I

Surrogate

The woman who gives birth to the child (in this case the surrogate) is the legal mother when the child is born. She will also have parental responsibility.

Husband, wife or civil partner of the surrogate

If the surrogate is married or in a civil partnership at the time of insemination/transfer, her husband, wife or civil partner will be the legal father or parent of any child born as a result of her treatment (and will have parental responsibility), unless:

(c) there is a judicial separation or a separation order in force, or

(d) it is shown that her husband, wife or civil partner did not consent to the placing of the sperm and eggs, or embryos, in her, or to her insemination.

Establishing lack of consent 'as a question of fact'

For these purposes, lack of consent requires a basis in fact (for example, if the surrogate and her husband, wife or civil partner are separated and the latter is unaware of the treatment). The surrogate's husband, wife or civil partner will be the legal father or parent of the child if they support the surrogacy arrangement. Any consent form declaring their lack of consent may not by itself remove their status as the legal father or parent if they do consent, 'as a question of fact'. If there is a factual basis for the husband, wife or civil partner not consenting, centres should obtain evidence of this.

Parenthood in these circumstances can be complex and case-specific, and any dispute is ultimately for the family court or births registrar (or both) to determine.

Intended parent(s)

The intended parent(s) is/are the individual or couple who intend to raise the child following a surrogacy arrangement.

If both the surrogate and her spouse/civil partner are the legal parents of the child, neither intended parent will be a legal parent when the child is born (and neither will have parental responsibility).

If the surrogate:

is neither married nor in a civil partnership, and

is judicially separated from her spouse or civil partner, or

has a spouse or civil partner that does not consent to her treatment

Then one of the intended parents (where the intended parents are a couple), or the intended parent (where the intended parent is not one of a couple) may be the legal parent when the child is born. Options for which intended parent is the legal parent at birth are as follows:

(a) if the intended father provides his sperm for the surrogacy arrangement, he will be the legal father at common law when the child is born, if no one else is nominated.

(b) an intended father who is not the biological father (ie, an intended father using donor sperm or, in a male same-sex couple, the partner of the biological father) will be the legal father when the child is born if, at the time the eggs and sperm, or embryos, are placed in the surrogate or she is inseminated, all the following conditions apply:

(i) both the surrogate and the intended father nominated as a parent have given a written, signed notice (subject to the exemption for illness, injury or physical disability) to the centre consenting to him being the legal father

(ii) neither consent has been withdrawn (or superseded by a subsequent written consent) before the insemination/transfer, and

(iii) the surrogate and intended father nominated are not close relatives (within prohibited degrees of relationship to each other, as defined in section 58(2), HFE Act 2008).

(c) the intended female parent (or one of them if the intended parents are a female same-sex couple) will be the other legal parent when the child is born if, at the time the eggs and sperm, or embryos, are placed in the surrogate or she is inseminated, all the following conditions apply:

(i) both the surrogate and the intended female parent have given a written, signed notice (subject to the exemption for illness, injury or physical disability) to the centre consenting to her being the other legal parent of any resulting child

(ii) neither consent has been withdrawn (or superseded by a subsequent written consent) before the insemination/transfer, and

(iii) the surrogate and intended female parent are not close relatives (within prohibited degrees of relationship to each other as defined in section 58(2), HFE Act 2008).

Parental orders

The intended parent(s) are expected to apply to the family court for a parental order after the child is born. A parental order will make the intended parent (in the case of one person making an application alone) or both intended parents (in the case of a couple making an application) the legal parent(s) (with parental responsibility) and will permanently extinguish the surrogate's legal motherhood. It will also trigger the re-issue of the child's birth certificate, showing the intended parent(s) as the legal parent(s).

For a couple (married, civil partners or living together as partners) to be able to apply for a parental order, one or both of the intended parents must be a gamete provider for the child. Where the intended parent is applying for a parental order alone, the intended parent must be a gamete provider for the child. Other conditions also apply, and centres should advise those involved in a surrogacy arrangement to seek their own legal advice to ensure they will be able to secure their family's legal status after the child is born.

For more information on what legal parenthood consent forms must be used in surrogacy arrangements and on how to ensure consent is taken properly, see the HFEA guide to consent.

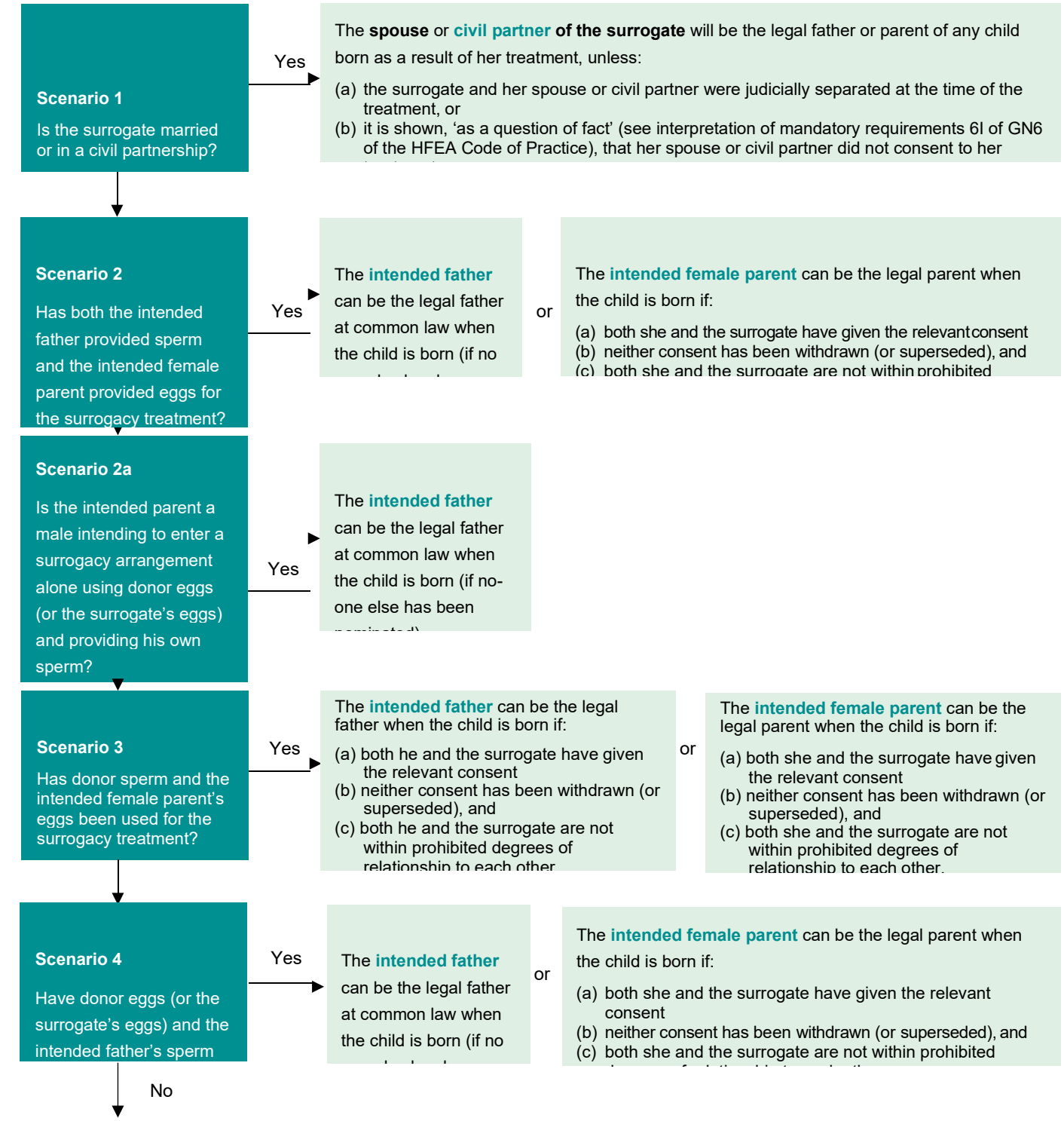
See also

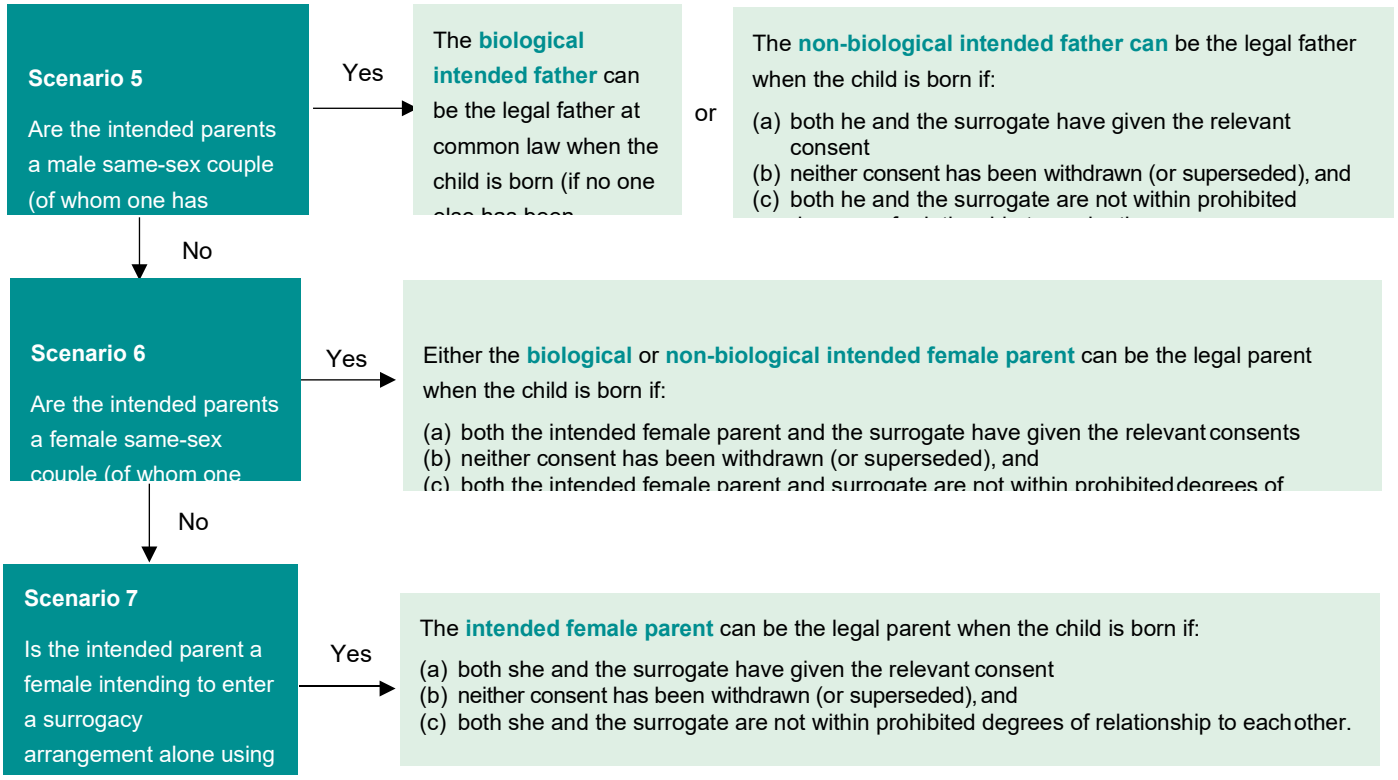
HFEA consent forms

HFEA consent form guidance

6.49 The decision tree on the following page provides a guide to some aspects of legal parenthood and surrogacy. It summarises some of the relevant legal positions but is not intended to replace advice on the individual facts of a specific surrogacy arrangement. Centres should advise people involved in surrogacy arrangements to seek their own legal advice.

Decision tree: Legal parenthood in surrogacy arrangements





See also

Guidance note 14 – Surrogacy

Legal parenthood: trans patients

6.50 The Gender Recognition Act 2004 sets out the circumstances in which a gender recognition certificate (GRC) will be issued and provides trans people with a formal mechanism by which they can be legally recognised in their acquired gender.

The centre should be aware that obtaining a GRC (or an interim GRC) does not affect the status of the person as the legal mother, father or second parent of a child. What is relevant in determining legal parenthood is the birth gender of the trans patient. For example:

- a woman who has had a child and subsequently transitions to become a trans man remains the mother of his existing child
- a trans man who gives birth to a child will also be recorded on the birth certificate as that child's mother
- a trans woman who uses her sperm in her female partner's treatment will be the father of the child
- a trans man whose partner gives birth to a child will be recorded as that child's second parent.

See also

Guidance note 4 – Information to be provided prior to consent

Guidance note 5 – Consent to treatment, storage, donation, training and disclosure of information

HFEA consent forms

HFEA consent form guidance

People not to be treated as parents

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 2008

Part 2

41 Persons not to be treated as father

(1) Where the sperm of a man who had given such consent as is required by paragraph 5 of Schedule 3 to the 1990 Act (consent to use of gametes for purposes of treatment services or non-medical fertility services) was used for a purpose for which such consent was required, he is not to be treated as the father of the child.

(2) Where the sperm of a man, or an embryo the creation of which was brought about with his sperm, was used after his death, he is not, subject to section 39, to be treated as the father of the child.

(3) Subsection (2) applies whether W was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or of the sperm and eggs or of her artificial insemination.

47 Woman not to be other parent merely because of egg donation

A woman is not to be treated as the parent of a child whom she is not carrying and has not carried, except where she is so treated -

(a) by virtue of section 42 or 43, or

(b) by virtue of section 46 (for the purpose mentioned in subsection (4) of that section), or

(c) by virtue of adoption.

34 Application of sections 35 to 47

(1) Sections 35 to 47 apply, in the case of a child who is being or has been carried by a woman (referred to in those sections as “W”) as a result of the placing in her of an embryo or of sperm and eggs or her artificial insemination, to determine who is to be treated as the other parent of the child.

54 Parental orders[: two applicants]

(1) On an application made by two people ("the applicants"), the court may make an order providing for a child to be treated in law as the child of the applicants if:

(a) the child has been carried by a woman who is not one of the applicants, as a result of the placing in her of an embryo or sperm and eggs or her artificial insemination

(b) the gametes of at least one of the applicants were used to bring about the creation of the embryo, and

(c) the conditions in subsections (2) to [(8A)] are satisfied.

(2) The applicants must be:

(a) husband and wife,

(b) civil partners of each other, or

(c) two persons who are living as partners in an enduring family relationship and are not within prohibited degrees of relationship in relation to each other.

(3) Except in a case falling within subsection (11), the applicants must apply for the order during the period of 6 months beginning with the day on which the child is born.

(4) At the time of the application and the making of the order:

(a) the child's home must be with the applicants, and

(b) either or both of the applicants must be domiciled in the United Kingdom or in the Channel Islands or the Isle of Man.

(5) At the time of the making of the order both the applicants must have attained the age of 18.

(6) The court must be satisfied that both:

(a) the woman who carried the child, and

(b) any other person who is a parent of the child but is not one of the applicants (including any man who is the father by virtue of section 35 or 36 or any woman who is a parent by virtue of section 42 or 43),

have freely, and with full understanding of what is involved, agreed unconditionally to the making of the order.

(7) Subsection (6) does not require the agreement of a person who cannot be found or is incapable of giving agreement; and the agreement of the woman who carried the child is ineffective for the purpose of that subsection if given by her less than six weeks after the child's birth.

(8) The court must be satisfied that no money or other benefit (other than for expenses reasonably incurred) has been given or received by either of the applicants for or in consideration of:

(a) the making of the order

(b) any agreement required by subsection (6)

(c) the handing over of the child to the applicants, or

(d) the making of arrangements with a view to the making of the order,

unless authorised by the court.

[(8A) An order relating to the child must not previously have been made under this section or section 54A, unless the order has been quashed or an appeal against the order has been allowed.

(9) For the purposes of an application under this section:

(a) in relation to England and Wales:

(i) “the court" means the High Court or the family court, and

(ii) proceedings on the application are to be "family proceedings" for the purposes of the Children Act 1989],

(b) in relation to Scotland, "the court" means the Court of Session or the sheriff court of the sheriffdom within which the child is, and

(c) in relation to Northern Ireland, "the court" means the High Court or any county court within whose division the child is.

(10) Subsection (1)(a) applies whether the woman was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or the sperm and eggs or her artificial insemination.

(11) An application which:

(a) relates to a child born before the coming into force of this section, and

(b) is made by two persons who, throughout the period applicable under subsection (2) of section 30 of the 1990 Act, were not eligible to apply for an order under that section in relation to the child as husband and wife,

may be made within the period of six months beginning with the day on which this section comes into force.

[54A Parental orders: one applicant]

[(1) On an application made by one person ("the applicant"), the court may make an order providing for a child to be treated in law as the child of the applicant if:

(a) the child has been carried by a woman who is not the applicant, as a result of the placing in her of an embryo or sperm and eggs or her artificial insemination

(b) the gametes of the applicant were used to bring about the creation of the embryo, and

(c) the conditions in subsections (2) to (8) are satisfied.

(2) Except in a case falling within subsection (11), the applicant must apply for the order within the period of 6 months beginning with the day on which the child is born.

(3) At the time of the application and the making of the order:

(a) the child's home must be with the applicant, and

(b) the applicant must be domiciled in the United Kingdom or in the Channel Islands or the Isle of Man.

(4) At the time of the making of the order the applicant must have attained the age of 18.

(5) The court must be satisfied that both:

(a) the woman who carried the child, and

(b) any other person who is a parent of the child but is not the applicant (including any man who is the father by virtue of section 35 or 36 or any woman who is a parent by virtue of section 42 or 43),

have freely, and with full understanding of what is involved, agreed unconditionally to the making of the order.

(6) Subsection (5) does not require the agreement of a person who cannot be found or is incapable of giving agreement; and the agreement of the woman who carried the child is ineffective for the purpose of that subsection if given by her less than six weeks after the child's birth.

(7) The court must be satisfied that no money or other benefit (other than for expenses reasonably incurred) has been given or received by the applicant for or in consideration of:

(a) the making of the order

(b) any agreement required by subsection (5)

(c) the handing over of the child to the applicant, or

(d) the making of arrangements with a view to the making of the order,

unless authorised by the court.

(8) An order relating to the child must not previously have been made under section 54 or this section, unless the order has been quashed or an appeal against the order has been allowed.

(9) Section 54(9) applies for the purposes of an application under this section.

(10) Subsection (1)(a) applies whether the woman was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or the sperm and eggs or her artificial insemination.

(11) An application which relates to a child born before the coming into force of this section may be made within the period of six months beginning with the day on which this section comes into force.]

Interpretation of mandatory requirements 6J

A sperm donor is not to be treated as the father of any child resulting from the use of his sperm in the treatment of others.

An egg donor is not to be treated as the parent of any child resulting from the use of her egg(s) unless her egg(s), or embryos created from her egg(s), are used in treating a civil partner or other female partner (subject to the requirements in sections 42, 43 or 46 of the HFE Act 2008, where relevant) or the resulting child is adopted by the egg donor.

Section 54 of the HFE Act 2008 is amended by the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 to provide that, where a child has been born following treatment involving mitochondrial donation, a person who donated the mitochondria is not eligible to apply for a parental order on the basis of that donation alone.

Information provision and counselling

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Section 13

Conditions of licences for treatment

(6) A woman shall not be provided with treatment services of a kind specified in Part 1 of Schedule 3ZA unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services of that kind, and have been provided with such relevant information as is proper.

(6A) A woman shall not be provided with treatment services after the happening of any event falling within any paragraph of Part 2 of Schedule 3ZA unless (before or after the event) she and the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of the woman being provided with treatment services after the happening of that event, and have been provided with such relevant information as is proper.

(6B) The reference in subsection (6A) to the intended second parent is a reference to -

(a) any man as respects whom the agreed fatherhood conditions in section 37 of the Human Fertilisation and Embryology Act 2008 ("the 2008 Act") are for the time being satisfied in relation to treatment provided to the woman being treated, and

(b) any woman as respects whom the agreed female parenthood conditions in section 44 of the 2008 Act are for the time being satisfied in relation to treatment provided to the woman to be treated.

(6C) In the case of treatment services falling within paragraph 1 of Schedule 3ZA (use of gametes of a person not receiving those services) or paragraph 3 of that Schedule (use of embryo taken from a woman not receiving those services), the information provided by virtue of subsection (6) or (6A) must include such information as is proper about -

(a) the importance of informing any resulting child at an early age that the child results from the gametes of a person who is not a parent of the child, and

(b) suitable methods of informing such a child of that fact.

Schedule 3ZA: Circumstances in which offer of counselling required as condition of licence for treatment

Part 2: Events in connection with which counselling must be offered

4. A man gives the person responsible a notice under paragraph (a) of subsection (1) of section 37 of the Human Fertilisation and Embryology Act 2008 (agreed fatherhood conditions) in a case where the woman for whom the treatment services are provided has previously given a notice under paragraph (b) of that subsection referring to the man.

5. The woman for whom the treatment services are provided gives the person responsible a notice under paragraph (b) of that subsection in a case where the man to whom the notice relates has previously given a notice under paragraph (a) of that subsection.

6. A woman gives the person responsible notice under paragraph (a) of subsection (1) of section 44 of that Act (agreed female parenthood conditions) in a case where the woman for whom the treatment services are provided has previously given a notice under paragraph (b) of that subsection referring to her.

7. The woman for whom the treatment services are provided gives the person responsible a notice under paragraph (b) of that subsection in a case where the other woman to whom the notice relates has previously given a notice under paragraph (a) of that subsection.

Interpretation of mandatory requirements 6K

The law states that, where a woman who has consented to her male or female partner being

treated as the legal parent of any child born as a result of her treatment, and the partner has consented to being the legal parent, treatment may continue after the point at which consent is given only if the woman and her partner:

(a) have had a suitable opportunity to receive proper counselling about the implications of treatment in these circumstances, and

(b) have been given proper information.

When people seek treatment using donor gametes or embryos, they must be given information about:

(a) the importance of informing any resulting child, at an early age, that they were conceived using the gametes of a person who is not their parent, and

(b) suitable methods of telling the child this.

See also

Guidance note 3 – Counselling and patient support

Guidance note 4 – Information to be provided prior to consent

Notification of withdrawal of consent to parenthood

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Section 13

Conditions of licences for treatment

(6D) Where the person responsible receives from a person ("X") notice under section 37(1)(c) or 44(1)(c) of the 2008 Act of X's withdrawal of consent to X being treated as the parent of any child resulting from the provision of treatment services to a woman ("W"), the person responsible -

(a) must notify W in writing of the receipt of the notice from X, and

(b) no person to whom the licence applies may place an embryo or sperm and eggs in W, or artificially inseminate W, until W has been so notified.

(6E) Where the person responsible receives from a woman ("W") who has previously given notice under section 37(1)(b) or 44(1)(b) of the 2008 Act that she consents to another person ("X") being treated as a parent of any child resulting from the provision of treatment services to W -

(a) notice under section 37(1)(c) or 44(1)(c) of the 2008 Act of the withdrawal of W's consent, or

(b) a notice under section 37(1)(b) or 44(1)(b) of the 2008 Act in respect of a person other than X, the person responsible must take reasonable steps to notify X in writing of the receipt of the notice mentioned in paragraph (a) or (b).

Interpretation of mandatory requirements 6L

If a person withdraws their consent to being treated as the legal parent of any child resulting

from the treatment of their partner, the person responsible (PR) must notify the partner in writing of this. The partner must not be treated with sperm and eggs, or with embryos, or be inseminated, until she has been notified in this way.

If a woman withdraws her consent to her partner being treated as the legal parent of any child resulting from the woman's treatment, or notifies the centre that she wishes a different person to be treated as the legal parent of any child resulting from her treatment, the PR must notify the partner in writing of this.

Consent can be withdrawn only before sperm and egg or embryo transfer, or insemination.

6.51 The PR should ensure that the written notification they issue explains and refers to the relevant parts of the legislation regarding legal parenthood and withdrawal of consent.

See also

HFEA consent forms

HFEA consent form guidance

Other legislation, professional guidelines and information

Legislation

Equality Act 2010

Gender Recognition Act 2004

Chief Executive's letter

Chief Executive's letter CE(14)01: Ensuring consent to legal parenthood is properly taken

Chief Executive's letter CE(14)02: Follow up on legal parenthood audit

Chair's letters

Chair's letter CH(21)01: Women providing eggs or embryos for their partner's treatment

Clinic Focus articles

Clinic Focus Article: Legal parenthood (April 2021)

Annex 6

11. Donor recruitment, assessment and screening

Version 4.0

The United Kingdom (UK) left the European Union (EU) on 31 January 2020, and the Implementation Period (IP) ended at 11pm on 31 December 2020. The Human Fertilisation and Embryology Act 1990 (HF&E Act) continues to apply UK wide, with some amendments resulting in certain provisions applying to centres in Northern Ireland (NI) only and other amendments applying to centres in Great Britain (England, Wales and Scotland) only.

Where there are distinct Licence Conditions or guidance for centres NI, the NI guidance has been highlighted below, within a light grey box.

Except in those cases where different requirements are highlighted, requirements and guidance in the Code apply to clinics in both NI and GB.

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Schedule 3 – Consent to use or storage of gametes, embryos or human admixed embryos etc.

Use of gametes for treatment of others

5 (1) A person's gametes must not be used for the purposes of treatment services or non-medical fertility services unless there is an effective consent by that person to their being so used and they are used in accordance with the terms of the consent.

(2) A person's gametes must not be received for use for those purposes unless there is an effective consent by that person to their being so used.

(3) This paragraph does not apply to the use of a person's gametes for the purpose of that person, or that person and another together, receiving treatment services.

31ZD Provision to donor of information about resulting children

(1) This section applies where a person ("the donor") has consented under Schedule 3 (whether before or after the coming into force of this section) to -

(a) the use of the donor's gametes, or an embryo the creation of which was brought about using the donor's gametes, for the purposes of treatment services provided under a licence, or

(b) the use of the donor's gametes for the purposes of non-medical fertility services provided under a licence.

(2) In subsection (1) -

(a) "treatment services" do not include treatment services provided to the donor, or to the donor and another person together, and

(b) "non-medical fertility services" do not include any services involving partner-donated sperm.

(3) The donor may by notice request the appropriate person to give the donor notice stating -

(a) the number of persons of whom the donor is not a parent but would or might, but for the relevant statutory provisions, be a parent by virtue of the use of the gametes or embryos to which the consent relates,

(ab) the number of persons in respect of whom the donor is a mitochondrial donor,

(b) the sex of each of those persons, and

(c) the year of birth of each of those persons.

(4) Subject to subsections (5) and (7), the appropriate person shall notify the donor whether the appropriate person holds the information mentioned in subsection (3) and, if the appropriate person does so, shall comply with the request.

(5) The appropriate person need not comply with a request under subsection (3) if the appropriate person considers that special circumstances exist which increase the likelihood that compliance with the request would enable the donor to identify any of the persons falling within paragraphs (a) to (c) of subsection (3).

(6) In the case of a donor who consented as described in subsection (1)(a), the Authority need not comply with a request made to it under subsection (3) where the person who held the licence referred to in subsection (1)(a) continues to hold a licence under paragraph 1 of Schedule 2, unless the donor has previously made a request under subsection (3) to the person responsible and the person responsible -

(a) has notified the donor that the information concerned is not held, or

(b) has failed to comply with the request within a reasonable period.

(7) In the case of a donor who consented as described in subsection (1)(b), the Authority need not comply with a request made to it under subsection (3) where the person who held the licence referred to in subsection (1)(b) continues to hold a licence under paragraph 1A of Schedule 2, unless the donor has previously made a request under subsection (3) to the person responsible and the person responsible -

(a) has notified the donor that the information concerned is not held, or

(b) has failed to comply with the request within a reasonable period.

(8) In this section "the appropriate person" means -

(a) in the case of a donor who consented as described in paragraph (a) of subsection (1) -

(i) where the person who held the licence referred to in that paragraph continues to hold a licence under paragraph 1 of Schedule 2, the person responsible, or

(ii) the Authority, and

(b) in the case of a donor who consented as described in paragraph (b) of subsection (1) -

(i) where the person who held the licence referred to in that paragraph continues to hold a licence under paragraph 1A of Schedule 2, the person responsible, or

(ii) the Authority.

(9) In this section "the relevant statutory provisions" has the same meaning as in section 31ZA.

Conditions of licences for treatment

13 (9) Persons or embryos that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop -

(a) a serious physical or mental disability,

(b) a serious illness, or

(c) any other serious medical condition,

must not be preferred to those that are not known to have such an abnormality.

Regulations

Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004

Licence conditions

T52 Prior to the use and/or storage of donor gametes and/or embryos created with donor gametes the centre must comply with the selection criteria for donors and the requirements for laboratory tests and storage set out below, namely:

a. donors must be selected on the basis of their age, health and medical history, provided on a questionnaire and through a personal interview performed by a qualified and trained healthcare professional. This assessment must include relevant factors that may assist in identifying and screening out persons whose donations could present a health risk to others, such as the possibility of transmitting diseases, (such as sexually transmitted infections) or health risks to themselves (eg superovulation, sedation or the risks associated with the egg collection procedure or the psychological consequences of being a donor)

b. the donors must be negative for HIV1 and 2, HCV, HBV and syphilis on a serum or plasma sample tested as follows, namely:

- HIV 1 and 2: Anti-HIV – 1, 2
- Hepatitis B: HBsAg and Anti-HBc
- Hepatitis C: Anti-HCV-Ab
- Syphilis: see (d) below

c. the centre must devise a system of storage which clearly separates:

- quarantined/unscreened gametes and embryos,
- gametes and embryos which have tested negative, and
- gametes and embryos which have tested positive

d. a validated testing algorithm must be applied to exclude the presence of active infection with Treponema pallidum. The non-reactive test, specific or non-specific, can allow gametes to be released. When a non-specific test is performed, a reactive result will not prevent procurement or release if a specific Treponema confirmatory test is non-reactive. The donor whose specimen test reacted on a Treponema-specific test will require a thorough risk assessment to determine eligibility for clinical use

e. in addition to the requirements in (b) and (d) above, sperm donors must be negative for chlamydia on a urine sample tested by the nucleic acid amplification technique (NAT)

f. This requirement has been removed.

g. HTLV-1 antibody testing must be performed for donors living in or originating from high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas

h. in certain circumstances, additional testing may be required depending on the donor's history and the characteristics of the gametes donated (eg, RhD, Malaria, T.cruzi), and

i. genetic screening for autosomal recessive genes known to be prevalent, according to international scientific evidence, in the donor's ethnic background and an assessment of the risk of transmission of inherited conditions known to be present in the family must be carried out, after consent is obtained. Complete information on the associated risk and on the

measures undertaken for its mitigation must be communicated and clearly explained to the recipient.

T53 for centres in Great Britain

T53 The centre must ensure that the laboratory tests required by licence condition T52 meet the following requirements, namely:

a. The test must be carried out by a laboratory which is accredited to conduct that test by UKAS, the national accreditation body for the UK or another body accrediting to an equivalent standard, using CE marked, CE and UK(NI) marked, or UKCA marked testing kits where appropriate.

b. Blood samples must be obtained within a timeframe specified by the Authority, and.

c. Donor sperm must be quarantined for a minimum of 180 days, after which repeat serological testing is required. If the blood donation sample is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, the donor sperm must be quarantined for a minimum of three months, after which a further donor blood sample should be taken and subjected to repeat serological and NAT testing.

NOTE: CE marked medical devices (including testing kits) will continue to be accepted on the UK market until 30 June 2023. Medical devices placed on the GB market after 30 June 2023 must be UKCA marked rather than CE marked, as set out in the Medical Devices Regulations 2002 (as amended). This requirement does not prevent centres from continuing (after 30 June 2023) to use CE marked medical devices which were on the market prior to 1 July 2023. The UK Government has guaranteed unfettered access for NI businesses to the rest of the UK internal market. This means that any conformity mark held by a NI business which validates a medical device for sale on the NI market is valid for the whole of the UK. Accordingly, NI businesses can continue to place CE marked and CE and UK(NI) marked devices on the GB market after 30 June 2023.

NOTE: The Government has announced that the deadline for manufacturers placing CE marked devices on the GB market will be extended beyond 30 June 2023.

This means that, despite the wording of the notes under Standard Licence Conditions T30, T51, T53, R59 and R67 centres can continue to use CE marked devices placed on the GB market after 30 June 2023. See February 2023 Clinic Focus.

T53 for centres in Northern Ireland

T53 The centre must ensure that the laboratory tests required by licence condition T52 meet the following requirements, namely:

a. The test must be carried out by a laboratory which is accredited to conduct that test by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard, using CE marked or CE and UK(NI) marked testing kits where appropriate.

b. Blood samples must be obtained within a timeframe specified by the Authority, and

c. Donor sperm must be quarantined for a minimum of 180 days, after which repeat serological testing is required. If the blood sample taken at the time of donation is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, the donor sperm must be quarantined for a minimum of three months, after which a further donor blood sample should be taken and subjected to repeat serological and NAT testing.

NOTE: The UKCA mark is not available for devices placed on the NI market. Medical devices (including testing kits) used in Northern Ireland should be CE marked if certified by a notified body in the European Union. Medical devices certified for the market in Northern Ireland by a UK notified body should be both CE and UK(NI) marked as set out in the Medical Devices Regulations 2002 (as amended).

T55 Potential donors that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop:

a. a serious physical or mental disability

b. a serious illness, or

c. any other serious medical condition,

must not be preferred to those that are not known to have such an abnormality.

Directions

0001 – Gametes and embryo donation

0005 – Collecting and recording information for the HFEA

HFEA guidance

Advertising

11.1 Advertising and publicity materials should be designed and written with regard to the sensitive issues involved in recruiting donors.

See also

Guidance note 13 – Payments for donors

Age of prospective donors

11.2 Centres should refer to the relevant professional guidelines on age limits before accepting gametes for the treatment of others.

Note: Current professional guidelines state that eggs should not be taken from donors aged 36 or over, and sperm should not be taken from donors aged 46 or over.

11.3 For donated eggs, the relevant age limit should be observed unless there are exceptional reasons not to do so. The centre should record any such reasons in the patient's medical records.

11.4 For donated sperm, the relevant age limit should normally be observed. However, due to less substantial evidence on age limits for sperm donors, centres should assess the possible effect of the donor's age on a case-by-case basis. The centre should record in the patient's medical records the reasons for using a donor above the recommended age limit.

11.5 For donated embryos, the guidance above applies to both gamete providers.

11.6 Gametes for the treatment of others should not be taken from anyone under the age of 18.

General enquiries to be made

11.7 The recruiting centre should take reasonable steps to verify the identity of the prospective donor by asking for appropriate identification (eg, passport or photocard driving licence). Failure to obtain satisfactory evidence of identity should be taken into account in deciding whether to accept their gametes or embryos for treatment.

11.8 Where a donor has changed their name (eg, where someone has changed their name by deed poll, has married and taken their partner's surname, or has obtained a gender recognition certificate) or has changed their physical appearance (eg, where someone has undergone gender

reassignment or is living in the gender they most closely identify with but which is different from their gender at birth) since their previous consultation, examination or donation, centres should take all reasonable steps to verify the donor's identity. This is to ascertain that a donor presenting or donation is the same person the centre previously engaged with or treated.

Centres should verify a donor's identity by asking for evidence of their previous name (eg, a passport or photocard driving licence) and verifying details against the donor's medical records. This can be a sensitive issue for donors and centres should take care to address identity issues with consideration. As evidence of their new name, centres should ask donors to provide one of the following:

(a) a marriage certificate, or
(b) evidence of a change in name (such as via deed poll)

For trans donors:

(c) a birth or adoption certificate in their acquired gender
(d) a Gender Recognition Certificate, or
(e) a letter from a doctor or medical consultation confirming that the change of gender is likely to be permanent, and evidence of a change in name (such as via deed poll).

Centres must ensure that a donor's records are updated to accurately reflect their new identity.

11.9 When obtaining gametes or embryos for the treatment of others (whether directly from a donor, from another licensed centre or from a foreign supplier), the centre should take appropriate steps to discover whether gametes from that donor have been obtained for use in licensed treatment before and, if so:

(a) establish which centre is the primary centre for that donor
(b) notify that centre that it proposes to use that donor's gametes
(c) seek authorisation to do so, if appropriate, and
(d) ensure that the limit of 10 families per donor will not be exceeded.

Family and other relevant history

11.10 Before a prospective donor provides gametes, the recruiting centre should take their medical and family histories, and details of previous donations. The centre should encourage prospective donors to provide as much other non-identifying biographical information as possible, so that it may be available to prospective recipients, parents and resulting children. If a prospective donor cannot give a full and accurate family history, the centre should record this fact and take it into account in deciding whether or not to accept their gametes or embryos for treatment.

11.11 The centre should seek the prospective donor's consent to approach their GP for further factual information if it suspects the donor might be unsuitable. The centre should always seek further information if:

(a) information provided by the patient suggests there are risk factors that may affect anyone treated using their gametes or any child born as a result
(b) the prospective donor has failed to provide any information requested
(c) the information provided by the prospective donor is inconsistent, or
(d) there is evidence of deception.

11.12 If the prospective donor refuses to give such consent, the centre should take this into consideration when deciding whether to accept that donor. Such refusal should not in itself be grounds for not accepting the donor. The centre should discuss with the prospective donor their reason for refusing.

See also

HFEA consent forms

Suitability as a donor

Interpretation of mandatory requirements 11A

A donor must not be selected because they are known to have a particular gene, chromosome or mitochondrial abnormality that, if inherited by any child born as a result of the donation, may result in that child having or developing:

(a) a serious physical or mental disability

(b) a serious illness, or

(c) any other serious medical condition.

11.13 The use of gametes from a donor known to have an abnormality as described above, should be subject to consideration of the welfare of any resulting child and should normally have approval from a clinical ethics committee.

11.14 If a centre determines that it is appropriate to provide treatment services for a woman using a donor known to have an abnormality as described above, it should document the reason for the use of that donor.

See also

Guidance note 10 – Embryo testing and sex selection

11.15 Before accepting gametes for the treatment of others, the recruiting centre should consider the suitability of the prospective donor. In particular, the centre should consider:

(a) personal or family history of heritable disorders
(b) personal history of transmissible infection (as outlined in Department of Health guidance, there should be no specific restrictions on donations from men who have sex with men (MSM), the centre should assess the risks and benefits of accepting donations from each such individual – ie, document MSM behaviour)
(c) the level of potential fertility indicated by semen analysis (where appropriate)
(d) the implications of the donation for the prospective donor and their family, especially for any children they may have at the time of donation or in the future, and
(e) the implications for any children born as a result of the donation, in the short and long term.

11.16 Centres are not expected to match the ethnic background of the recipient to that of the donor. Where a prospective recipient is happy to accept a donor from a different ethnic background, the centre can offer treatment, subject to the normal welfare of the child assessment.

11.17 A centre should not perform treatment that involves mixing gametes (eg, through insemination, IVF or ICSI) of close relatives who are genetically related, including between:

(a) grandfather and granddaughter
(b) grandmother and grandson
(c) father and daughter
(d) mother and son
(e) brother and sister
(f) half-brother and half-sister
(g) uncle and niece
(h) aunt and nephew
(i) uncle and half-niece
(j) aunt and half-nephew.

11.18 The restriction described in 11.17 does not include treatment that involves replacing the gametes of close relatives who are genetically related (eg, sister-to-sister egg donation).

See also

Guidance note 8 – Welfare of the child

Guidance note 20 – Donor assisted conception

11.19 The centre should ensure that its procedures for recruiting donors are fair and non-discriminatory.

See also

Guidance note 29 – Treating people fairly

Conditions placed on a donation

11.20 The centre should inform anyone providing gametes that they can, if they wish, specify extra conditions for storing or using their gametes (or embryos created using them).

11.21 However, some conditions imposed by donors may be incompatible with the Equality Act 2010. The Equality Act prohibits service providers (such as clinics) from discriminating by treating people less favourably because of various protected characteristics. The protected characteristics are:

(a) age
(b) disability
(c) gender reassignment
(d) marriage and civil partnership
(e) pregnancy and maternity
(f) race
(g) religion or belief
(h) sex
(i) sexual orientation.

11.22 When deciding whether or not to recruit donors who place conditions on the use of their gametes or embryos, the centre should judge whether this will result in less favourable treatment because of a protected characteristic (eg, if it will reduce the choice of donors for a particular person by virtue of a protected characteristic).

See also

Guidance note 29 – Treating people fairly

Medical and laboratory tests

11.23 In addition to meeting the requirements set out in licence conditions, donors of gametes and embryos should be screened in accordance with screening guidelines and timeframes set out in current professional guidance produced by the relevant professional bodies and the Advisory Committee on the Safety of Blood, Tissues, and Organs (SaBTO).

11.24 Where a centre has determined that an individual donor does not meet the criteria for any additional testing a robust risk assessment must be undertaken and documented. Any risks identified and decisions made must be clearly communicated and explained to the patient and documented within the patient records.

11.25 Centres should take a blood sample and screen potential donors both before accepting them as donors, and before using the donated gametes and embryos in treatment. In line with the addendum to the SaBTO Donor Selection Criteria Report 2017, centres should screen all egg donors by NAT testing in addition to serology.

11.26 In addition to meeting the mandatory requirements outlined in this guidance note, the centre should quarantine donated gametes and embryos in line with guidance from the relevant professional bodies. Where NAT testing is used in addition to serology, centres should quarantine donor sperm for a minimum of three months in line with the addendum to the SaBTO Donor Selection Criteria report 2017.

11.27 Patients using donor sperm in treatment which were first stored in, or imported to, the UK before 19 October 2018, and were thus screened under the previous version of SLC T53, should be advised regarding:

(a) the introduction of more stringent screening requirements since the sperm to be used in their treatment was first imported and/or stored
(b) the risks, if any, associated with the use of such sperm relative to sperm screened as per the revised version of SLC T53
(c) if the donor sperm to be used in treatment was subjected to serological and NAT testing at the time of donation but not to quarantine and re-testing thereafter.

People considered unsuitable as donors

11.28 A prospective donor should not be accepted if the centre:

(a) concludes that a recipient or any child born as a result of treatment using the donor's gametes is likely to experience serious physical, psychological or medical harm, or
(b) cannot get enough further information to conclude there is no significant risk.

11.29 Equality legislation prohibits service providers (such as clinics) from discriminating by treating people less favourably because of various protected characteristics or statuses. The protected characteristics set out in the Equality Act 2010 are listed at paragraph 11.21. Centres that consider a person unsuitable to donate due to one or more of these protected characteristics, or the person's status, are likely to be in breach of equality legislation and exposing themselves to liability.

See also

Guidance note 8 – Welfare of the child
Guidance note 29 – Treating people fairly
Guidance note 30 – Confidentiality and privacy

11.30 When the centre decides that a prospective donor is unsuitable to donate, it should record the reasons and explain them to the prospective donor. The centre should present the reasons for the decision sensitively and answer any questions in a straightforward and comprehensive way.

11.31 The centre should offer counselling to all prospective donors who are considered unsuitable for any reason. When the centre refuses to accept a prospective gamete donor because of physical or psychological problems that require separate treatment or specialist counselling, the centre should provide reasonable assistance to the individual to obtain relevant treatment or counselling.

11.32 If information affecting the suitability of a prospective donor becomes known after the selection process, the centre should review the prospective donor's suitability and take appropriate action.

Unsuspected heritable conditions in donors

11.33 At registration, donors should indicate whether or not they wish to be notified if the centre learns (eg, through the birth of an affected child) that they have a previously unsuspected genetic disease or they are a carrier of a harmful inherited condition. They should also be asked whether or not they would like their primary care physician to be informed. Their wishes should be recorded in the donors' medical records.

11.34 If a centre learns that a donor has a previously unsuspected genetic disease or is a carrier of a harmful inherited condition, the centre should:

(a) notify the primary centre (where there is one) and the HFEA immediately (the primary centre should immediately notify other centres who have received gametes obtained from that donor)
(b) inform patients who have had a live birth as a result of treatment with gametes from that donor, and offer these patients appropriate counselling
(c) carefully consider when and how a woman who is pregnant, as a result of treatment with gametes from that donor, is given this information, and
(d) refer to the donor's medical records to establish whether, and in what way, they would like to be given the information. If the donor has indicated that they would like to be given such information, the centre should notify their primary care physician, so that the donor can be referred for the appropriate medical care and counselling. If the donor has indicated that they would not like their primary care physician to be informed, the centre should contact the donor directly.

11.35 The centre should tell gamete donors that they should inform the centre if, after the donation:

(a) they discover they are affected by an unsuspected genetic disease, or
(b) they find they are a carrier of a harmful recessively inherited condition (eg, through the birth of an affected child).

The centre should then proceed as indicated above.

See also

Guidance note 15 – Procuring, processing and transporting gametes and embryos

Information for prospective donors

11.36 Before any consents or samples are obtained from a prospective donor, the recruiting centre should provide information about:

(a) the screening that will be done, and why it is necessary,
(b) the possibility that the screening may reveal unsuspected conditions (eg, low sperm count, genetic anomalies or HIV infection) and the practical implications,
(c) the scope and limitations of the genetic testing that will be done and the implications for the donor and their family,
(d) the importance of informing the recruiting centre of any medical information that may come to light after donation that may have health implications for any woman who receives treatment with those gametes or for any child born as a result of such treatment,
(e) the procedure used to collect gametes, including any discomfort, pain and risk to the donor (eg, from the use of superovulatory drugs),
(f) the legal parenthood of any child born as a result of their donation,
(g) the restriction on using gametes and embryos from an individual donor when the number of families that have already had children as a result of treatment using such gametes or embryos has reached 10 (or any lower figure specified by the donor), including how a family is defined under this limit as set out in 11.56 to 11.59 under this limit,
(h) what information about the donor must be collected by the centre and held on the HFEA Register,
(i) the fact that the centre or the HFEA (or both) may disclose non-identifying information about the donor, for example to prospective recipients or to the parents of donor-conceived children,
(j) the HFEA's obligation to disclose non-identifying information and identifying information if donation took place after 31 March 2005, to someone who applies for such information if:

  (i) the applicant is aged over 16 (to access non-identifying information) or 18 (to access identifying information), and
  (ii) the applicant appears to have been conceived using the donor's gametes, or embryos created using the donor's gametes

(k) the importance of supplying up-to-date contact information so that they can be informed if and when disclosure of identifiable information will be made,
(l) the potential for identification through direct to consumer DNA testing matching services. Although the clinic and HFEA will continue to manage and potentially disclose the donor's information in line with the HFE Act (and as described in 11.35 (i) and (j) and detailed below under 'Informing donors about information available to donor-conceived people'), there is the potential at any time for donors, donor-conceived people and their close genetic relatives to become identifiable, or for their identity to be inferred, through direct to consumer DNA testing and matching services. This risk of identification exists regardless of whether or not the donor or donor-conceived person is themselves a registered user who has provided genetic information for matching on these sites, because such services identify matches between close genetic relatives,
(m) the importance of the information provided at 11.32 and 11.33 to people born as a result of their donation,
(n) the possibility that a donor-conceived person who is disabled as a result of an inherited condition that the donor knew about, or ought reasonably to have known about, but failed to disclose, may be able to sue the donor for damages,
(o) their right to consent to storage of their donation for up to 55 years. They can specify any period of storage up to 55 years and do not need to renew their consent,
(p) the procedure for donors to withdraw consent for the use and storage of their gametes, or embryos created with their gametes, and
(q) the fact that if the donor is an egg donor who is not a patient, she is free to withdraw from the donation process after preparation for egg recovery has begun without incurring a financial or other penalty.

11.37 Men who wish to donate embryos originally created for the treatment of their partner and themselves, and those people considering treatment with such embryos, should be:

(a) informed of the uncertain legal status of men donating embryos created originally for the treatment of their partner and themselves, when the embryos are used in the treatment of a single woman
(b) referred to information on the HFEA's website on this issue, and
(c) advised to seek independent legal advice before consenting to donate their embryos or being treated with the embryos.

11.38 Centres must consider whether there may be additional information requirements for trans donors and provide relevant information tailored to their specific needs and circumstances. Where the donor is transitioning, the purpose for which they are intending to donate their gametes will determine what kind of information centres should provide and the consent requirements. For example, a trans donor who is consenting to donate their gametes for use in someone else's treatment, may require different information from a trans patient who is being screened as a donor for the use of their gametes in a surrogacy arrangement.

See also

Guidance note 4 – Information to be provided prior to consent

Guidance note 5 – Consent to treatment, storage, donation and disclosure of information

Guidance note 12 – Egg sharing arrangements

Guidance note 20 – Donor assisted conception

Giving donors information about children born as a result of their donation

Interpretation of mandatory requirements 11B

If donors of gametes and embryos ask, centres must provide the following information about any children born as a result of their donation:

(a) number
(b) sex, and
(c) year of birth.

If the centre is unable to provide this information, it should direct donors to the Authority.

11.39 The centre should inform donors and potential donors that they may ask at any time how many children have been born as a result of their donation.

11.40 The centre should inform donors seeking information about children born as a result of their donation that they may find counselling, or similar support services, helpful in considering the implications of receiving such information.

11.41 The centre should inform anonymous donors seeking information about children resulting from their donation that they have the right to re-register as identifiable, if they wish.

Informing donors about information available to donor-conceived people

11.42 The centre should inform donors that anyone born as a result of their donation will have access to the following non-identifying information provided by them, from the age of 16:

(a) physical description (height, weight, and eye, hair and skin colours)
(b) year and country of birth
(c) ethnic group
(d) whether the donor had any genetic children when they registered, and the number and sex of those children
(e) other details the donor may have chosen to supply (eg, occupation, religion, gender history and interests)
(f) the ethnic group(s) of the donor's parents
(g) whether the donor was adopted or donor conceived (if they are aware of this)
(h) marital status (at the time of donation)
(i) details of any screening tests and medical history
(j) skills
(k) reason for donating
(l) a goodwill message, and
(m) a description of themselves as a person (pen portrait).

11.43 The centre should also inform donors who register or re-register after 31 March 2005 that anyone born as a result of their donation will have access to the following identifying information, from the age of 18:

(a) full names (and any previous names)
(b) date of birth, and town or district where born, and

(c) last known postal address (or address at time of registration).

11.44 The centre should inform and make clear to donors that at any time, outside of the managed system of information provision described in the section above, direct to consumer DNA testing and matching services potentially enable anyone born as a result of their donation (or a close genetic relative) to identify the donor. Neither the donor nor the donor-conceived person themselves necessarily need to be signed up to such a service for a genetic link, and possibly even their identity, to be inferred. If a donor or donor-conceived person's close genetic family members have opted into genetic matching services, but not the donor or donor-conceived

person themselves, then it is still possible (in combination with information from other sources) that other wider genetic relationships may be inferred, which could include the donor or a donor-conceived person. If a donor has joined a DNA testing service themselves and opted into matching, this will increase the likelihood of them being directly identifiable to genetic relatives that they are matched with. The centre should make clear that the use of direct to consumer DNA testing and matching services has greatly increased over the last few years, which may increase the likelihood of such matches or inferences being made.

11.45 Centres are not required to proactively contact people who have donated gametes in the past to inform them of the potential impact of direct to consumer DNA testing and matching services. Centres are also not required to proactively contact donors whose gametes are already in storage and who have already consented to their use in treatment.

11.46 The centre should inform identifiable donors that it will make a reasonable attempt to contact and forewarn them before disclosing identifiable details to anyone born as a result of their donation. The centre should encourage donors to provide up-to-date contact details to facilitate this.

11.47 The centre should advise trans donors that information disclosed by the HFEA to anyone born as a result of their donation may reveal the donor's gender history (eg, where a trans woman donated sperm and registered with the clinic and the HFEA in her acquired female gender. On disclosure of her identifying information, it will be apparent to the person born as a result of her donation that she is a trans woman having donated sperm).

11.48 The centre should inform donors who are, or will be, transitioning that following their donation, they have the option to notify the clinic or HFEA that they have transitioned and may, if they wish, provide details of their acquired identity so that the HFEA Register can be updated. This will allow anyone conceived as a result of their donation at age 18 to find out about the donor's current identity.

11.49 The centre should inform donors that the HFEA is legally obliged to disclose the information set out at 11.41 and 11.42 to anyone conceived as a result of their donation.

See also

Guidance note 4 – Information to be provided prior to consent

Guidance note 5 – Consent to treatment, storage, donation and disclosure of information

Guidance note 11 – Donor recruitment, assessment and screening

Guidance note 20 – Donor assisted conception

Guidance note 30 – Confidentiality and privacy

Provision of counselling to those considering donation

Interpretation of mandatory requirements 11C

All prospective donors must be given a suitable opportunity to receive proper counselling.

Where embryos are to be donated, the recruiting centre must offer counselling to each person whose gametes were used to create the embryos.

11.50 If the possibility of donating gametes or embryos for the treatment of others, or for research or training, arises during the course of treatment, the centre should allow potential donors enough time to consider the implications and to receive counselling before giving consent.

Interpretation of mandatory requirements 11D

The law requires the centre to obtain written informed consent from a person before it uses:

(a) their gametes for the treatment of others or for non-medical fertility services, or

(b) embryos created with their gametes for the treatment of others.

Those giving consent can specify conditions for the use of their gametes and embryos.

The use of donor gametes or embryos to create more families than a donor has consented to is a breach of Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended)

11.51 Where someone intends to donate gametes or embryos for the treatment of others, the centre should ensure it obtains written consent to do so from that person. Such consent should include the number of families that may have children using the donated gametes or embryos.

11.52 Centres should aim to make best use of donated sperm within the maximum number of families the donor has consented to (up to the 10-family limit).

11.53 If the donor has consented to using the sperm for more than one family, the recruiting centre should not allow patients to reserve more sperm than is reasonable for one family allocation.

11.54 Where the centre uses sperm from donors who have been recruited at another centre, the centre should take reasonable steps to assure itself that patients have not reserved more sperm than is reasonable for one family allocation.

11.55 The centre is not required to obtain the consent of the donor's partner or spouse. However, if the donor is married, in a civil partnership or in a long-term relationship, the centre should encourage them to seek their partner's support for the donation of their gametes.

See also

Guidance note 5 – Consent to treatment, storage, donation and disclosure of information

Monitoring and complying with the 10-family limit

11.56 Licensed centres in the UK may not use the gametes or embryos of a donor to create more than 10 families (or any lower figure specified by the donor); this is referred to as the 10-family limit. Centres should establish documented procedures to ensure that if the number of families created through treatment at UK licensed clinics using gametes (or embryos created using donated gametes) from a particular donor has reached 10 (or any lower figure specified by the donor), that those gametes or embryos are not used or distributed for use in further treatment if that treatment will result in more than 10 families being created using that donor's gametes (or embryos created with their gametes).

11.57 For the purpose of this guidance, a 'family' is defined as the patient to be treated and their partner (if they have one) and any existing legal child or children of either partner. Any donor-conceived child born from future treatment at any UK licensed centre will form part of the same family provided the child is a genetic sibling or half sibling of any existing donor-conceived child, and shares at least one legal parent with the existing donor-conceived child.

11.58 Where a woman has treatment resulting in the birth of a donor-conceived child and her same sex partner subsequently has treatment using the same donor, any child born will form part of the existing family and not a new family.

11.59 If a couple with a donor-conceived child separates and one or both former partners subsequently return for treatment either alone or with a new partner and uses gametes from the same donor, any child that is born will form part of the existing family, not a new family. This is provided that the child born from the treatment shares at least one legal parent with the existing donor-conceived child.

11.60 A donor-conceived child born in the UK to a patient who has previously had a donor-conceived child following treatment abroad using gametes from the same donor will form part of the existing family even if that donor's gametes have already resulted in the creation of 10 families in the UK. This is because the child will be a full or half genetic sibling for the existing donor-conceived child.

11.61 The first centre to use a particular donor's gametes in treatment is defined as the primary centre, and any subsequent centre which uses the same donor's gametes in treatment is defined as the secondary centre. Before authorising a secondary centre to use gametes (or embryos created using gametes) from a particular donor, the primary centre should ensure that no more than 10 families (or any lower figure specified by the donor) at any time:

(a) have had live births as a result of treatment using that donor's gametes
(b) have embryos created using that donor's gametes and placed in storage so they are available for subsequent transfer, or
(c) are being treated using that donor's gametes (or embryos created using gametes).

11.62 If a centre uses gametes (or embryos created using gametes) from a particular donor who was recruited by another centre, it should notify that primary centre each time a new patient has:

(a) a live birth as a result of treatment using that donor's gametes, or
(b) embryos created using that donor's gametes and placed in storage so they are available for subsequent transfer.

Where a centre uses the sperm of a donor in pronuclear transfer and where the donor will consequently be genetically related to any child born, a) and b) must be complied with. In the case of egg donors who have donated their mitochondria only, or sperm donors who have donated for pronuclear transfer where they will not be genetically related to the child, clinics do not need to comply with the above.

11.63 The primary centre for a particular donor should notify any secondary centres having or using gametes (or embryos created using gametes) from that donor, within two working days, when it becomes aware that six families (The six-family alert applies where the donor has not specified a family limit lower than 10) have had:

(a) a live birth as a result of treatment using that donor's gametes, or
(b) embryos created using that donor's gametes and placed in storage so they are available for subsequent transfer.

After this, gametes (or embryos created using gametes) from that donor should not be used without authorisation from the primary centre, unless they are used to treat a family who already has a child using that donor. However, if recipients have already begun or had medical, surgical or obstetric treatment (such as ovarian stimulation or egg collection) when the notification is given, this should be allowed to continue.

11.64 When using gametes (or embryos created using gametes) from a particular donor authorised in this way by a primary centre, a secondary centre should notify the primary centre each time a woman starts or ends relevant treatment.

11.65 Relevant treatment situations are where the woman has:

(a) begun, but not completed, a treatment cycle (eg, ovarian stimulation)
(b) received treatment (insemination or embryo transfer) and is awaiting confirmation of pregnancy
(c) a confirmed ongoing pregnancy
(d) embryos created that have not yet been transferred (eg, placed in storage), or
(e) received treatment but has not reported the outcome.

11.66 Primary centres should notify secondary centres, and vice versa, when embryos created using a donor's gametes are removed from storage and allowed to perish, donated to research or used for training.

See also

Guidance note 17 – Storage of gametes and embryos

Benefits in kind

11.67 Centres may offer benefits in kind, in the form of reduced-price or free licensed services (for example, fertility treatment or storage) or quicker access to those services, in return for providing eggs or sperm for the treatment of others.

11.68 The centre should, as appropriate, treat gamete providers donating for benefits in kind in the same way as other potential gamete donors.

See also

Guidance note 12 – Egg sharing arrangements

Other legislation, professional guidelines and information

Legislation

Medical Devices Regulations 2002
Gender Recognition Act 2004

Equality Act 2010

Professional guidelines

UK guidelines for the medical and laboratory procurement and use of sperm, oocyte and embryo donors (2019)

Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) Donor Selection Criteria Report (2017) Version 2

British Infertility Counselling Association: Guidelines for good practice in infertility counselling (fourth edition, 2019)

Department of Health (Advisory Committee on the Safety of Blood, Tissues and Organs): Donor selection criteria for men who have had sex with men (2013)

Clinic Focus articles

Information on HTLV screening, issued in Clinic Focus (April 2021)

Clinic Focus Article: Zika virus - what it means for donors and fertility patients (February 2016)

Clinic Focus Article: Updated guidance on Ebola (March 2016)

Clinic Focus article: Zika update (June 2019)

Clinic Focus Article: Placing conditions on donation (October 2020)

Clinic Focus article: Best practice for handling donor information (March 2021)

Clinic Focus article: HTLV screening reminder (April 2021)

Clinic Focus article: Screening requirements for women who provide eggs or embryos with their eggs for their partners (August 2021)

Clinic Focus article: Screening requirements relating to SLC T52 (September 2022)

Clinic Focus article: CE marked devices in GB can be used after 30 June 2023 (February 2023)

Annex 7

12. Egg sharing arrangements

Version 2.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

12 General conditions

(1) The following shall be conditions of any licence granted under this Act—

…(e) that no money or other benefit shall be given or received in respect of any supply of gametes, embryos or human admixed embryos unless authorised by Directions…

Directions

0001 – Gamete and embryo donation

Note: Gamete donors may receive licensed services, such as treatment, storage, or access to licensed services, in return for supplying gametes or mitochondria for donation (including mitochondrial donation). Egg or mitochondrial donors who receive a benefit should be provided with that benefit in the course of the donation cycle unless there is a medical reason why they cannot be. An egg donation cycle is defined as the period from the first consultation to the end of the donor's recuperation.

HFEA guidance

Selection of egg and sperm providers

12.1 Where relevant, the possibility of donating gametes for fertility treatment, mitochondrial donation or research should be raised before a potential donor's treatment begins. Patients should not be put under pressure or unduly influenced to donate gametes or embryos.

12.2 The centre should, as appropriate, treat gamete providers receiving benefits in kind in the same way as other potential gamete donors.

12.3 The centre should ensure that:

(a) care is taken when selecting egg and sperm providers donating for benefits in kind
(b) egg and sperm providers are fully assessed and medically suitable, and
(c) the benefit offered is the most suitable for the egg or sperm provider and recipient(s) (where relevant).

See also

Guidance note 8 – Welfare of the child

Guidance note 11 – Donor recruitment, assessment and screening

Benefits

12.4 Centres may offer benefits in kind, in the form of reduced-price or free licensed services (for example, fertility treatment or storage) or quicker access to those services, in return for providing eggs or sperm for fertility treatment or mitochondrial donation.

12.5 If benefits in the form of licensed services are offered to an egg provider (including a mitochondrial donor), they should be given in connection with the cycle in which eggs are supplied for a recipient's treatment unless providing treatment to the egg provider at this stage could be harmful, or there is a clinical reason(s) to defer treatment to the egg provider.

In the circumstance where deferring treatment to the egg provider is appropriate, egg or embryo freezing should be offered where possible.

12.6 In an egg sharing arrangement, centres should ensure that, where the minimum number of eggs required for the arrangement are collected, eggs are distributed equally between the egg provider and the recipient(s). Where an odd number of eggs is collected, the benefits in kind agreements should clearly set out who will receive the additional egg.

See also

Guidance note 11 – Donor recruitment, assessment and screening

Information

12.7 The centre should provide women receiving eggs or sperm with the same information as other people seeking treatment with donated gametes. Also, before treatment begins, the centre should give the gamete provider and the recipient the following written information setting out:

(a) the criteria for selecting people providing and receiving gametes in exchange for benefits in kind
(b) how the centre proposes to distribute the gametes between the provider and the recipient(s) (where relevant)
(c) the screening that the gamete provider in a benefit in kind arrangement will undergo
(d) the terms of the agreement to be made
(e) the law relating to consent, in particular the rights of a person providing gametes to vary or withdraw consent, and the implications of doing so
(f) available alternative treatment options.

See also

Guidance note 4 – Information to be provided prior to consent

Guidance note 5 – Consent to treatment, storage, donation and disclosure of information

Guidance note 11 – Donor recruitment, assessment and screening

Consent

12.8 The person obtaining consent should ensure that the gamete provider's consent is recorded so that different conditions can be placed on:

(a) the use or storage of the gametes, and the use and storage of embryos created for the gamete provider's own treatment, and
(b) the use of eggs or sperm, and the use and storage of embryos created for the treatment of the recipient(s).

These conditions should be able to be varied independently of each other.

12.9 The person obtaining consent should tell the gamete provider and recipient(s) that the gamete provider may withdraw or vary their consent up to when the gametes or embryo(s) are:
(a) transferred to a woman
(b) used in a research project (defined as being under the control of the researchers and being cultured for use in research)
(c) used for training, or
(d) allowed to perish.

If the gamete provider is providing gametes or embryos solely for use in mitochondrial donation treatment, the donor cannot withdraw or vary their consent once the patient's nuclear DNA has been inserted into their egg or embryo.

The possible consequences of this should:
(a) be made clear to the gamete provider and the recipient(s) before the treatment begins, and
(b) be set out in the written patient information included with the benefits in kind agreement.

12.10 The gamete provider should be given enough time to consider the implications of donating, before the donation is used (see guidance note 4.1-4.4). Our expectation is that the discussion of implications should be delivered by a qualified counsellor.

12.11 If either the gamete provider or the recipient in a benefits in kind arrangement withdraws their consent to treatment after preparation has begun, the centre should bear any financial loss it sustains as a result. Gamete providers may withdraw or vary their consent up to when the gametes or embryo(s) are transferred to a woman. This should be discussed in implications counselling with all parties being made clear of the consequences before treatment begins and set out in the written patient information included with the benefits in kind agreement.

Note: Each centre may interpret 'preparation' differently. A gamete provider should be told the centre's definition of 'preparation' in relation to a benefit in kind arrangement and this should be recorded in the written patient information included with the benefits in kind agreement.

See also

Guidance note 4 – Information to be provided prior to consent

Guidance note 5 – Consent to treatment, storage, donation and disclosure of information

HFEA consent forms

Counselling

Interpretation of mandatory requirements 12A

The centre must offer anyone intending to participate in a benefits in kind arrangement the opportunity for counselling.

12.12 The counselling of those intending to participate in a benefits in kind arrangement should accord with the guidance from the British Infertility Counselling Association (BICA).

12.13 The quality of information provision and counselling by the centre should ensure that the gamete provider and recipient are certain of the actions to be taken, implications, and the risk of consent withdrawals.

See also

Guidance note 3 – Counselling and patient support

Confidentiality

12.14 In addition to following standard procedures for protecting patient and donor confidentiality, the centre should ensure it keeps all notes, facilities and procedures for the gamete provider separate from those for the recipient(s) (where relevant). Care should be taken to ensure that confidentiality is not compromised, for example, if the gamete provider and recipient(s) are treated at the same centre at the same time.

See also

Guidance note 30 – Confidentiality and privacy

Benefits in kind agreements

12.15 The centre should draw up separate agreements with the gamete provider and with recipient(s). These agreements should be consistent with each other. The centre should abide by the terms of benefits in kind agreements it has made.

Agreement between a licensed centre and a gamete provider

12.16 When drawing up agreements between the centre and gamete providers, centres should seek legal advice.

12.17 The agreement between the centre and the gamete provider should set out all the terms of the arrangement. It should identify clearly the gamete provider and the centre, and be signed by both parties.

12.18 The agreement should include a statement confirming:

(a) that any patient who has consented to providing eggs or sperm for the treatment of others in licensed treatment under the HFE Act 1990 (as amended) will not be the legal parent of any resulting child/(ren)
(b) what information will be available to the gamete provider about the recipient and the outcome of her treatment, for example the number and sex of any resulting children, and
(c) what information will be available to the recipient about the gamete provider and the outcome of the treatment, for example the number and sex of any resulting children.

12.19 The agreement should include a full description of what the benefits in kind are expected to involve, including:

(a) the number of treatment cycles or length of storage covered by the agreement, and
(b) the expected waiting time for treatment.

12.20 The agreement should include a statement from the egg or sperm provider confirming that they have:

(a) had an opportunity to talk with a member of staff qualified to explain the procedures involved in providing gametes as part of a benefits in kind arrangement
(b) received verbal and written information about the treatment
(c) received all the appropriate information listed in the relevant parts of this Code of Practice
(d) been offered counselling
(e) discussed the implications of the treatment and donation, and
(f) been made aware of the screening that will be done before treatment begins.

See also

Guidance note 4 – Information to be provided prior to consent

Guidance note 11 – Donor recruitment, assessment and screening

12.21 The agreement should include a statement confirming:
(a) that the centre has obtained the patient's consent to the treatment
(b) that the centre has recorded appropriately the gamete provider's consent to the use of their gametes and to the creation, use and storage of embryos from the gametes
(c) that the agreement does not override the terms of paragraph 4A of Schedule 3 to the HFE Act 1990 (as amended). This states that the gamete provider may withdraw or vary their consent about any embryo created using their gametes at any time, until that embryo is:
  (i) transferred to a woman
  (ii) used in a research project
  (iii) used in training, or
  (iv) allowed to perish
  (v) in the case of mitochondrial donation, up until the nuclear DNA of the patient is inserted into the donor egg or the nuclear DNA taken from the patient's embryo is inserted into the donor embryo.
(d) the consequences of any variation or withdrawal of consent, and the liability of the parties involved to pay any resulting extra charges.

12.22 The agreement should include a statement setting out:
(a) what charges (if any) the gamete provider is expected to pay to the treatment centre,
(b) gamete providers may withdraw or vary their consent up to when the gametes or embryo(s) are transferred to a woman. This should be discussed in implications counselling with all parties being made clear of the consequences before treatment begins and set out in the written patient information included with the agreement, and
(c) if the gamete provider's treatment or storage of their gametes is provided at a discount, the circumstances under which they would be liable for the full cost of this treatment or storage, and the amount they would have to pay.

Note: If too few eggs are collected for use in a benefits in kind agreement, the woman should be given the option of using or storing all the eggs for her own treatment, at the agreed discount.

12.23 The agreement should include full details of the proposed arrangements for distributing the eggs or sperm between the provider and recipient(s), including:
(a) the minimum number of eggs required for a benefits in kind arrangement
(b) the number of recipients among whom the eggs or sperm will be shared (which for eggs should be no more than two, excluding the egg provider), and
(c) who will receive the additional egg if an odd number is collected.

Agreement between a licensed centre and a recipient

12.24 When drawing up agreements between the centre and recipient, centres should seek legal advice.

12.25 The agreement between the centre and the recipient should set out all the terms of the arrangement. It should identify clearly the recipient and the centre, and be signed by both parties.

12.26 The agreement should include a statement confirming:
(a) that anyone who has consented to providing eggs or sperm for the treatment of others in licensed treatment under the HFE Act 1990 (as amended) will not be the legal parent of any resulting child/(ren)

(b) the information that will be available to the egg or sperm provider about the recipient and the outcome of her treatment, for example the number and sex of any resulting children, and
(c) the information that will be available to the recipient about the egg or sperm provider and the outcome of the treatment, for example the number and sex of any resulting children, and the information that will be available to any children of the recipient about the egg or sperm provider, including:
(i) information recorded on the HFEA Register that the children are entitled to receive, and
(ii) the circumstances under which they may receive such information.

12.27 The agreement should set out what the treatment is expected to involve, including:
(a) the number of treatment cycles
(b) the expected waiting time for treatment, and
(c) that a proportion of the eggs collected from the egg provider will be used for the provider's own treatment.

12.28 The agreement should include a statement from the recipient confirming that she has:
(a) had an opportunity to discuss with an experienced member of the centre's staff the procedures involved in receiving eggs or sperm as part of a benefits in kind arrangement
(b) received verbal and written information about her treatment
(c) received all the appropriate information listed in the relevant parts of this Code of Practice (written information should be attached to the agreement)
(d) been offered counselling
(e) discussed the implications of the treatment and using donated gametes, and
(f) been informed about the screening that the egg or sperm provider has undergone and the limitations of that screening in avoiding transmissible conditions.

See also

Guidance note 4 – Information to be provided prior to consent

Guidance note 11 – Donor recruitment, assessment and screening

Guidance note 20 – Donor assisted conception

12.29 The agreement should include a statement confirming that the agreement does not override the terms of paragraph 4A of Schedule 3 to the HFE Act 1990 (as amended). This states that the egg or sperm provider may withdraw or vary their consent about any embryo created using their eggs or sperm at any time until that embryo is:
(a) transferred to a woman
(b) used in a research project
(c) used in training, or
(d) allowed to perish.

In the case of mitochondrial donation, up until the nuclear DNA of the patient is inserted into the donor egg or the nuclear DNA taken from the patient's embryo is inserted into the donor embryo.

12.30 The agreement should include a statement describing:
(a) what charges the egg recipient is expected to pay to the centre, and
(b) what treatment these charges will cover.

12.31 The agreement should set out the proposed arrangements for distributing the eggs between the provider and recipient(s), including:
(a) the minimum number of eggs required for the benefits in kind arrangement
(b) the number of recipients among whom the eggs or sperm will be shared (which for eggs should be no more than two, excluding the egg provider), and
(c) who will receive the additional egg if an odd number is collected.

Benefits in kind for research

12.32 As outlined in the previous sections, the centre should draw up agreements between the centre and the gamete provider, and the centre and the recipient (in this case, the research group), including all relevant information.

12.33 If gametes are being donated to research through a benefits in kind agreement, the centre must ensure that the eggs are divided between the donor and the recipient (the research project) by someone not directly involved in the research project.

12.34 If a centre offers benefits in kind in exchange for donating gametes to fertility treatment, mitochondrial donation and to research, equal benefits in kind should be available. This ensures there is no advantage in donating to one recipient rather than the other.

See also

Guidance note 22 – Research and training

Other legislation, professional guidelines and information

Professional guidelines

British Infertility Counselling Association: Guidelines for good practice in infertility counselling (fourth edition, 2019)

Clinic Focus articles

Clinic Focus article: Guidance on egg giving (March 2016)

Annex 8

15. Procuring, processing and transporting gametes and embryos

Version 4.0

The United Kingdom (UK) left the European Union (EU) on 31 January 2020, and the Implementation Period (IP) ended at 11pm on 31 December 2020. The Human Fertilisation and Embryology Act 1990 (HF&E Act) continues to apply UK wide, with some amendments resulting in certain provisions applying to centres in Northern Ireland (NI) only and other amendments applying to centres in Great Britain (England, Wales and Scotland) only.

Where there are distinct Licence Conditions or guidance for centres NI, the NI guidance has been highlighted below, within a light grey box.

Except in those cases where different requirements are highlighted, requirements and guidance in the Code apply to clinics in both NI and GB.

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Requirements for holding a licence for gametes and embryo preparation processes

11 In respect of gametes and embryos preparation processes, licence conditions shall require compliance with -

(a) the requirements of Article 20(2) and (3) (tissue and cell processing) and Article 21(2) to (4) of the first Directive, and

(b) the requirements laid down in the provisions of the third Directive listed in the right-hand column, the subject-matter of which are described in the left-hand column in respect of those provisions.

Relevant provisions of the third directive	
Reception of gametes and embryos at the tissue establishment	Annex II, Part A
Processing of gametes and embryos (validation, documentation and evaluation of critical procedures)	Annex II, Part B
Storage and release of gametes and embryos (criteria to be complied with, including standard operating procedures	Annex II, Part C
Distribution and recall of gametes and embryos (criteria to be complied with, including procedures to be adopted)	Annex II, Part D

Final labelling of gametes and embryo containers for distribution (information to be shown on container label or in accompanying documentation)	Annex II, Part E
External labelling of the shipping container (information to be shown on label on shipping container)	Annex II, Part F

Note: Directive 2006/86/EC (the third directive) implements directive 2004/23/EC as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.

Directions

0001 – Gamete and embryo donation

0009 (GB) – Keeping gametes and embryos in the course of carriage between premises (Great Britain)

0009 (NI) – Keeping gametes and embryos in the course of carriage between premises (Northern Ireland)

HFEA guidance

Documented procedures: general

Mandatory requirements

Licence conditions

T70 There must be a documented system in place that ensures the identification of all gametes and embryos from procurement to use or disposal.

There must be a documented system in place for ratifying that gametes and/or embryos meet appropriate specifications of safety and quality for use and for their transportation/distribution.

15.1 The centre should, where appropriate, have documented procedures that cover:

(a) superovulation regimes
(b) egg retrieval
(c) sedation
(d) resuscitation
(e) sperm aspiration
(f) gamete and embryo transfer
(g) insemination
(h) follow-up after treatment, including management of complications and establishing if any patients have experienced OHSS, and
(i) prevention and management of ovarian hyper-stimulation syndrome including maintaining clinical relationships with local hospitals who may treat the licensed centre's patients for OHSS and putting in place agreements around related appropriate information and data sharing.

See also

Specific documented procedures are referenced in the following sections of this guidance note:

- Home procurement
- Reception at the centre
- Processing and disposal of gametes and embryos
- Packaging, distribution and recall of gametes and embryos
- Quality and safety of gametes and embryos

Guidance note 31 – Record keeping and document control

Patient selection and procurement

Mandatory requirements

Licence conditions

T49 The clinician responsible for the patient must document the justification for the use of their gametes or embryos created with their gametes in treatment, based on the patient's medical history and therapeutic indications.

Interpretation of mandatory requirements 15A

Procurement of gametes is a licensable activity which must be undertaken at licensed premises or in accordance with a third party agreement.

15.2 In addition to meeting the requirements in licence conditions, the centre should, at the time of procurement, label each package containing gametes and embryos in a way that is not susceptible to unauthorised or undetectable alteration. If the size of the packaging permits, the identity of the patient, patient's partner or donor should also be noted.

15.3 The centre should not obtain gametes for treatment from anyone under the age of 18 unless:

(a) those gametes are intended for the patient's own treatment or that of their partner
(b) the centre can satisfy itself that the patient is capable of giving effective consent to the use of the gametes for that purpose, and
(c) the patient has given effective consent to the use of their gametes for that purpose.

Home insemination

Interpretation of mandatory requirements 15B

The centre may supply cryopreserved sperm only to a person covered by a licence. Sperm

supplied for home insemination must therefore be thawed or thawing. The use of a dry shipper or any other container that would preserve the sperm in a frozen or preserved state when it leaves the treatment centre is prohibited.

15.4 Sperm should be supplied for insemination at home (or another unlicensed site) only in exceptional circumstances. When this occurs, the treatment centre should:

(a) record this fact and explain the relevant exceptional circumstances in the medical records,
(b) complete the relevant DI (Donor Insemination) treatment form in the usual way, except that the date of supply or posting should be entered as the date of insemination and a note made that the sperm was supplied for home insemination, and

(c) make sure all other requirements have been met in the same way as if insemination had taken place at the treatment centre, including the provision of information, offer of counselling and obtaining all relevant consents.

15.5 Provided that the woman has attended the treatment centre for assessment, sperm for insemination at home (or another unlicensed site) may be either handed to her in person or sent to her by courier.

See also

HFEA donor Insemination treatment forms

Home procurement

Mandatory requirements

Licence conditions

T68 Where the sperm is procured at home, the centre must record this in the gamete provider's records.

15.6 A centre should normally store or use only sperm that has been obtained directly from the provider, another licensed clinic or a centre with which the licensed centre has a transport arrangement, or that has been imported in line with HFEA Directions.

15.7 The centre may use sperm produced by a man at home (or another unlicensed site). The centre should follow protocols to ensure, as far as possible, that:

(a) the identity of the sperm provider is confirmed
(b) the sperm provider confirms he produced the sperm
(c) the date and time of the sperm production is confirmed (and is no more than two hours before the centre received the sperm)
(d) the sperm has not been interfered with, and
(e) the sperm receptacle is clearly labelled with the sperm provider's full name and unique identifier.

The centre's documented procedures should ensure that this information is recorded in the patient's medical records.

15.8 If embryos have been created using partner sperm produced at home (or another unlicensed site) and donation is being considered, the centre should consider the fact that the sperm was not produced at a licensed treatment centre and tell prospective recipients.

15.9 The requirements for receipt from another centre also apply to sperm procured at home or another unlicensed site (see 'Reception at the centre' below).

See also

Guidance note 16 – Imports and exports

Reception at the centre

Mandatory requirements

Licence conditions

T109 The centre must put in place, maintain and implement a procedure for the receipt of gametes and/or embryos from another centre or third party premises to ensure that:

a. the centre is provided with copies of all relevant consent forms signed by patients and donors when their gametes or embryos were first placed in storage and any renewal consent forms signed by patients and donors

b. the consignment of gametes and/or embryos is verified against SOPs and specifications. These must include information relating to the transport conditions, packaging, labelling, patient/donor documentation, and any other associated documentation and samples. These must also include the technical requirements and other criteria considered by the establishment to be essential for the maintenance of acceptable quality, and

c. the gametes and embryos received are quarantined until they, along with associated documentation, have been inspected or otherwise verified as conforming to requirements. The review of relevant patient/donor and procurement information and thus acceptance of the donation needs to be carried out by specified/authorised persons.

T110 The following data must be registered at the centre:

a. consent including the purpose(s) for which the gametes and/or embryos may be used and any specific instructions for disposal if the gametes or embryos are not used for the consented purpose

b. patient/donor identification and characteristics: age, sex and presence of risk

c. all required records relating to the procurement and the taking of the patient/donor history

d. gametes and embryos obtained and relevant characteristics

e. the results of laboratory tests and of other tests, and

f. a properly documented review of the complete patient/donor evaluation against the selection criteria by an authorised and trained person.

15.10 In addition to the requirements in licence conditions, the documented procedures against which each consignment of gametes and embryos is verified should include requirements for:

(a) patient, patient's partner and donor verification
(b) packaging and transport
(c) labelling of containers for procured gametes, and
(d) labelling of shipping containers and any associated documents.

15.11 The documented procedure for the receipt of gametes or embryos from another centre should also ensure that records are kept to demonstrate that before gametes or embryos are released, all appropriate specifications have been met.

15.12 The centre's documented procedures should ensure that the relevant legal requirements are met for registering patients, patients' partners and donors.

Processing and disposal of gametes and embryos

Mandatory requirements

Licence conditions

T72 The critical processing procedures must be validated and must not render the gametes or embryos clinically ineffective or harmful to the recipient. This validation may be based on studies performed by the establishment itself, or on data from published studies or from well-established processing procedures, by retrospective evaluation of the clinical results of tissues provided by the establishment.

T73 Before implementing any significant change in processing, the modified process must be validated and documented.

15.13 The centre should take account of the special status of the human embryo when the development of an embryo is to be brought to an end. Terminating the development of embryos and disposing of the remaining material should be approached with appropriate sensitivity, having regard to the interests of the gamete providers and anyone for whose treatment the embryos were being kept.

See also

Guidance note 10 – Embryo testing and sex selection

Packaging, distribution and recall of gametes and embryos

Mandatory requirements

Licence conditions

T105 All gametes and embryos must be packaged and transported in a manner that minimises the risk of contamination and preserves the required characteristics and biological functions of the gametes or embryos. The packaging must also prevent contamination of those responsible for packaging and transportation.

T106 The packaged gametes/embryos must be shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos.

T107 The transport conditions, including temperature and time limit, must be specified and the labelling of every shipping container must include as a minimum:

a. a label marked “TISSUES AND CELLS” and “HANDLE WITH CARE”

b. the identification of the establishment from which the package is being transported (address and telephone number) and a contact person in the event of problems

c. the identification of the tissue establishment of destination (address and telephone number) and the person to be contacted to take delivery of the package

d. the date and time of the start of transportation

e. the type of gametes/embryos plus their identification code

f. specifications concerning conditions of transport relevant to the quality and safety of the gametes or embryos

g. specifications concerning storage conditions such as “DO NOT FREEZE”

h. in the case of all gametes and embryos, the following indication: “DO NOT IRRADIATE”, and

i. when a product is known to be positive for a relevant infectious disease marker, the

following indication: “BIOLOGICAL HAZARD”.

If any of the information under the points above cannot be included on the primary container label, it must be provided on a separate sheet accompanying the primary container. The sheet must be packaged with the primary container in a manner that ensures that they remain together.

T108 The container/package must be secure and ensure that the gametes or embryos are maintained in the specified conditions. All containers and packages need to be validated as fit for purpose.

Interpretation of mandatory requirements 15C

When a third party transports gametes or embryos, they must be subject to a third party agreement, and a documented agreement must be in place to ensure that the required conditions are fulfilled.

The centre originating the distribution must have a recall procedure that defines the responsibilities and actions required when a distribution is recalled. Such a recall should be investigated using the procedure for investigating adverse incidents. There must be a procedure for handling returned gametes and embryos that includes their reacceptance into the inventory, if applicable.

15.14 If a container used to ship packaged gametes or embryos has not been validated by the manufacturer or supplier for specified transport conditions, these conditions should be monitored during transport, or validated by the centre or third party responsible for transport.

15.15 The centre’s documented procedures should ensure that the following are recorded:

(a) packaging and labelling procured gametes for distribution
(b) transporting gametes and embryos
(c) labelling shipping containers, and
(d) recalling gametes and embryos.

See also

Guidance note 24 – Third party agreements

Guidance note 27 – Adverse incidents

Quality and safety of gametes and embryos

Mandatory requirements

Licence conditions

T50 Prior to the processing of patient gametes or embryos, intended for use in treatment or storage, the centre must:

a. carry out the following biological tests to assess the risk of cross contamination:

- HIV 1 and 2: Anti-HIV – 1, 2
- Hepatitis B: HBsAg and Anti-HBc
- Hepatitis C: Anti-HCV-Ab.

b. devise a system of storage which clearly separates:

- quarantined/unscreened gametes and embryos,
- gametes and embryos which have tested negative, and
- gametes and embryos which have tested positive.

c. perform HTLV- 1 antibody testing for patients living in or originating from high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas, and

d. in certain circumstances, carry out additional testing depending on the patient's travel and exposure history and the characteristics of the tissue or cells donated (eg, Rh D, Malaria, CMV, T.cruzi)

Positive results will not necessarily prevent the use of the partners' gametes.

NOTE: Centres storing ovarian or testicular tissue for use in transplantation must refer to the Human Tissue Authority's guidelines as the requirements for screening patients prior to the storing of their tissue for use in transplantation are different than those listed above.

T51 The centre must ensure that the laboratory tests required by licence condition T50 meet the following requirements, namely:

a. the test must be carried out by a laboratory which is accredited to conduct that test by UKAS, the national accreditation body for the UK, or another body accrediting to an equivalent standard, using CE marked, CE and UK(NI) marked, or UKCA marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge, and

b. blood samples must be obtained within a timeframe specified by the Authority.

NOTE: CE marked medical devices (including testing kits) will continue to be accepted on the UK market until 30 June 2023. Medical devices placed on the GB market after 30 June 2023 must be UKCA marked rather than CE marked, as set out in the Medical Devices Regulations 2002 (as amended). This requirement does not prevent centres from continuing (after 30 June 2023) to use CE marked medical devices which were on the market prior to 1 July 2023. The UK Government has guaranteed unfettered access for NI businesses to the rest of the UK internal market. This means that any conformity mark held by a NI business which validates a medical device for sale on the NI market is valid for the whole of the UK. Accordingly, NI businesses can continue to place CE marked and CE and UK(NI) marked devices on the GB market after 30 June 2023.

NOTE: The Government has announced that the deadline for manufacturers placing CE marked devices on the GB market will be extended beyond 30 June 2023.

This means that, despite the wording of the notes under Standard Licence Conditions T30, T51, T53, R59 and R67 centres can continue to use CE marked devices placed on the GB market after 30 June 2023. See February 2023 Clinic Focus.

T51 for centres in Northern Ireland

T51 The centre must ensure that the laboratory tests required by licence condition T50 meet the following requirements, namely:

a. the test must be carried out by a laboratory accredited to conduct that test by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard, using CE marked or CE and UK(NI) marked, testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge, and
b. blood samples must be obtained within a timeframe specified by the Authority.

NOTE: The UKCA mark is not available for devices placed on the NI market. Medical devices (including testing kits) used in Northern Ireland should be CE marked if certified by a notified body in the European Union. Medical devices certified for the market in Northern Ireland by a UK notified body should be both CE and UK(NI) marked as set out in the Medical Devices Regulations 2002 (as amended).

Interpretation of mandatory requirements 15D

The law requires centres to obtain blood samples for HIV 1 and HIV 2, hepatitis B and hepatitis C screening from patients and their partners within three months before they first provide their gametes for use in treatment. Where the same person provides gametes for further treatment of their partner, the centre must obtain new blood samples within two years of the previous sampling. Patients who have screening tests at one licensed clinic and then move to another do not have to have repeat screening tests if within these timescales. However, individual clinics must decide whether the appropriate screening has taken place in the required timeframe. These screening requirements apply to individuals who provide gametes, or embryos created with their gametes, that will be processed or stored.

Where treatment involves the use of gametes, or embryos created with gametes, from two people who are not in an intimate physical relationship:

(a) the person providing the gametes to the woman being treated must be screened according to licence condition T52 on donor screening

(b) the centre, in discussion with the patient, should consider the merit of additional donor screening in line with guidance by professional bodies.

15.16 The centre should establish and use documented procedures to ensure that:

(a) procedures involving the manipulation of gametes or embryos (for example, sperm preparation, separation of eggs from cumulus cells, and fertilisation of eggs) are performed in a controlled environment with appropriate air quality
(b) the risk of bacterial or other contamination is minimised
(c) appropriate measures are in place for handling contaminated samples
(d) gametes or embryos are handled in a way that protects those properties that are required for their ultimate clinical use
(e) where permitted, the mixture of gametes or embryos that have been subject to different laboratory procedures before transfer (eg, IVF and ICSI) is recorded and the reasons for their mixture are clearly set out, and
(f) all blood products with which gametes or embryos may come into contact, except those of the woman receiving treatment, are pre-tested for HIV, hepatitis B and hepatitis C.

15.17 If it is impractical to carry out a procedure involving the manipulation of gametes or embryos in a Grade C environment, it should be done in an environment of at least Grade D air quality. If the environmental air quality drops below Grade D during a procedure involving the manipulation of gametes or embryos, those gametes or embryos should be used in treatment only if the centre can assure itself that this poses no extra risk to the woman to be treated or to any resulting child.

15.18 Air quality monitoring should be used as a routine measure of quality assurance (for example, through particle counts or the use of settle plates, recording any cultures observed). The process of validating air quality should include:

(a) documenting culture conditions, and
(b) mapping temperature and using control charts to predict the effects of any change in procedures.

15.19 Where possible, cryopreserved gametes should be accompanied by documents that indicate their expected post-thaw quality.

15.20 The centre should not use for treatment gametes or embryos exposed to a material risk of contamination or damage that may harm recipients or resulting children. If in any doubt about these risks, the centre should seek expert advice.

Single European Code (SEC) for centres in Northern Ireland

15.21 The EU Commission Directive 2004/23/EC sets out standards of quality and safety for donation, procurement, testing, processing, preservation and distribution of all human tissue and cells intended for human application. It also sets out that, to facilitate traceability, it is necessary for centres in NI to establish a unique identifier applied to tissues and cells (including reproductive cells) distributed in the EU (by way of a Single European Code). The SEC must provide information on the main characteristics and properties of the tissues and cells.

15.22 The SEC is applied to the movement of donor gametes and embryos between licensed centres in NI (or tissue establishments) within and outside the EU. Movement of 'partner' embryos and gametes are exempt from the requirements.

15.23 A further exemption relates to where gametes and embryos are imported from a tissue establishment and not distributed thereafter (that is for use in that clinic). The SEC need not be applied in such cases.

15.24 The SEC is the unique identifier for tissues and cells distributed in the EU. It is made up of the following (six) features.

Donation identification sequence			Product identification sequence		
ISO country code	**Tissue establishment code**	**Unique donation number**	**Product code**	**Split number**	**Expiry date**
2 alpha characters	6 alpha-numeric characters	13 alpha-numeric characters	1+7 alpha-numeric characters	3 alpha-numeric characters	8 numeric characters Yyyy/mm/dd
XI	**000123**	**00000000XX456**	**E0000059**	**001**	**20181231**
United Kingdom in respect to Northern Ireland	HFEA licensed centre number	Clinic's donor registration 'number' and a donation event-specific identifier, which together function as a unique donation number or code	1 of 5 for reproductive cells (EUTC system) -Embryos (56) -Sperm (59) -Oocytes (57) -Ovarian tissue (58) -Testicular tissue (60)	If sperm, for example, are distributed to more than one TE	Date of expiry of consent, for example, 31 December 2018
SEC XI00012300000000XX456 E000005900120181231					

15.25 There are three coding platforms permitted by the EU (and HFEA), one of which must be accessed to identify a product code.

1. The EU coding platform: https://webgate.ec.europa.eu/eucoding
2. ICCBBA ISBT128: https://www.iccbba.org (International Council for Commonality in Blood Banking Automation)
3. Eurocode international blood labelling system (IBLS): http://www.eurocode.org/.

15.26 Each coding platform provides tools to create a SEC. The EU coding platform contains detailed information on all tissue establishments in Europe in the tissue establishment compendium. If your clinic distributes embryos or gametes to a licensed clinic or tissue establishment, or similarly receives them, then you must access the EU coding platform to access the compendium.

15.27 The HFEA has a responsibility for ensuring the details of all NI HFEA licensed clinics on the compendium are current. We will do so further to changes we make to the Register of licensed clinics as part of our usual licensing activity.

15.28 We will check compliance at inspection by sampling donor gamete and embryo movements into, and out of, the clinic to ensure the SEC has been applied appropriately.

15.29 Clinics identifying an error or change in relation to its details held on the EU tissue establishment compendium must notify their HFEA inspector as soon as practicable. Once the SEC is allocated the donation identification sequence must not be altered unless there is an encoding error. If this happens, a new code should be correctly issued and a record should be kept of the error and amended code.

15.30 Clinics in NI receiving gametes or embryos without an SEC from a licensed clinic or tissue establishment in NI or the EU must note this as is a serious adverse incident and report it to the HFEA using the current incident reporting channel.

15.31 A licensed centre in NI must notify the HFEA when:

(a) information about the centre which is contained in the EU tissue establishment compendium requires update or correction

(b) the EU tissue and cell product compendium requires an update, or

(c) a situation is identified of significant non-compliance with requirements relating to the Single European Code concerning embryos and gametes received from other EU tissue establishments.

15.32 A situation of significant non-compliance in 15.31(c) is one which poses a significant direct (critical) or indirect (major) risk of affecting safety and causing harm to a patient, donor, embryo, gamete or any child born as a result of treatment, or a significant shortcoming from the statutory requirements.

Other legislation, professional guidelines and information

Legislation

Commission Directive 2006/17/EC of 8 February 2006

Commission Directive 2012/39/EU of 26 November 2012

The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019

The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020

Professional guidelines

British Fertility Society Policy and Practice Committee: Prevention of Ovarian Hyperstimulation Syndrome (2014)

Medicines and Healthcare products Regulatory Agency: Good manufacturing practice and good distribution practice (2014)

Clinic Focus articles

Information on HTLV screening, issued in Clinic Focus (April 2021)

General information

Royal College of Obstetricians and Gynaecologists: Patient information leaflet on Ovarian hyperstimulation syndrome

Annex 9

17. Storage of gametes and embryos

Version 3.0

The United Kingdom (UK) left the European Union (EU) on 31 January 2020, and the Implementation Period (IP) ended at 11pm on 31 December 2020. The Human Fertilisation and Embryology Act 1990 (HF&E Act) continues to apply UK wide, with some amendments resulting in certain provisions applying to centres in Northern Ireland (NI) only and other amendments applying to centres in Great Britain (England, Wales and Scotland) only.

Where there are distinct Licence Conditions or guidance for centres NI, the NI guidance has been highlighted below, within a light grey box.

Except in those cases where different requirements are highlighted, requirements and guidance in the Code apply to clinics in both NI and GB.

On 1 July 2022 new laws governing the storage of gametes and embryos came into effect. This version of the Code of Practice was updated in October 2023 to reflect the new storage law and includes guidance on transitional provisions which apply during and immediately after the Transitional Period (1 July 2022 to 30 June 2024). Information on the Transitional Provisions is clearly marked in blue boxes.

The rules are different for patients (storing for their own treatment or treatment with their partner), donors and those donating gametes or embryos for training or research. Care should be taken to apply the legislation correctly.

The Code of Practice should be read alongside the **HFEA Clinic Practical Guide on legal changes to storage limits and guidance** which was published in May 2022, and the **Clinic FAQs on new storage legislation**.

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

1 Meaning of "embryo", "gamete" and associated expressions

(4) In this Act (except in section 4A) -

(a) references to eggs are to live human eggs, including cells of the female germ line at any stage of maturity, but (except in subsection (1)(b)) not including eggs that are in the process of fertilisation or are undergoing any other process capable of resulting in an embryo,

(b) references to sperm are to live human sperm, including cells of the male germ line at any stage of maturity, and

(c) references to gametes are to be read accordingly.

3 Prohibitions in connection with embryos

(1) No person shall bring about the creation of an embryo except in pursuance of a licence.

(1A) No person shall keep or use an embryo except -

(a) in pursuance of a licence, or

(b) in the case of-

(i) the keeping, without storage, of an embryo intended for human application, or

(ii) the processing, without storage, of such an embryo

in pursuance of a third party agreement.

(3) A licence cannot authorise -

…(c) keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use

4 Prohibitions in connection with gametes

(1) No person shall -

(a) store any gametes…

except in pursuance of a licence.

(2) A licence cannot authorise storing or using gametes in any circumstances in which regulations prohibit their storage or use.

14 Conditions of storage licences

(1) The following shall be conditions of every licence authorising the storage of gametes, embryos or human admixed embryos

(a) that gametes of a person shall be placed in storage only if -

(i) received from that person,

(ii) acquired in circumstances in which by virtue of paragraph 9 or 10 of Schedule 3 that person's consent to the storage is not required, or

(iii) acquired from a person to whom a licence or third party agreement applies,

(aa) that an embryo taken from a woman shall be placed in storage only if -

(i) received from that woman, or

(ii) acquired from a person to whom a licence or third party agreement applies,

(ab) that an embryo the creation of which has been brought about in vitro otherwise than in pursuance of that licence shall be placed in storage only if acquired from a person to whom a licence or third party agreement applies,

(ac) that a human admixed embryo the creation of which has been brought about in vitro otherwise than in pursuance of that licence shall be placed in storage only if acquired from a person to whom a licence under paragraph 2 or 3 of Schedule 2 applies,

(b) that gametes or embryos which are or have been stored shall not be supplied to a person otherwise than in the course of providing treatment services unless that person is a person to whom a licence applies,

(ba) that human admixed embryos shall not be supplied to a person unless that person is a person to whom a licence applies,

(c) that the requirements of subsection (3) (maximum storage periods) are met,

(ca) that any gametes, embryos or human admixed embryos that have been kept in storage pursuant to the licence must, once they may no longer lawfully be so kept, be removed from storage and disposed of, and

(d) that such information as the Authority may specify in directions as to the persons whose consent is required under Schedule 3 to this Act, the terms of their consent and the

circumstances of the storage and as to such other matters as the Authority may specify in directions shall be included in the records maintained in pursuance of the licence.

(2) No information shall be removed from any records maintained in pursuance of such a licence before the expiry of such period as may be specified in directions for records of the class in question.

(3) The requirements referred to in subsection (1)(c) are as follows—

(a) gametes must not be kept in storage for longer than such period not exceeding 55 years beginning with the day on which they are first placed in storage as the licence may specify;

(b) an embryo must not be kept in storage for treatment purposes for longer than such period not exceeding 55 years beginning with the day on which it is first so kept as the licence may specify;

(c) an embryo that is kept in storage for the research or training purpose but not for treatment purposes must not be so kept for longer than such period not exceeding 10 years beginning with the day on which consent was given under Schedule 3 to the storage of the embryo for that purpose as the licence may specify;

(d) a human admixed embryo must not be kept in storage for longer than such period not exceeding 10 years beginning with the day on which it is first placed in storage as the licence may specify.

(4) Where under Schedule 3 consent is given to the storage of an embryo for the training or research purpose by different persons on different days, the reference in subsection (3)(c) to the day on which consent was given is to be taken as a reference to the last of those days.

(5) For the purposes of this section—

(a) "treatment purposes" are purposes referred to in paragraph 2(1)(a) or (b) of Schedule 3;

(b) the "training purpose" is the purpose referred to in paragraph 2(1)(ba) of that Schedule;

(c) the "research purpose" is the purpose referred to in paragraph 2(1)(c) of that Schedule.]

14A Conditions of licences: human application

(1) This section applies to –

(a) every licence under paragraph 1 or 1A of Schedule 2,

(b) every licence under paragraph 2 of that schedule, so far as authorising storage of gametes or embryos intended for human application, and

(c) every licence under paragraph 3 of that schedule, so far as authorising activities in connection with the derivation from embryos of stem cells that are intended for human application.

(2) A licence to which this section applies may not authorise the storage, procurement, testing, processing or distribution of gametes or embryos unless it contains the conditions required by Schedule 3A.

(3) In relation to any gametes or embryos imported into Northern Ireland from an EEA state, compliance with the requirements of the laws or other measures adopted in the relevant state or territory for the purpose of implementing the first, second and third Directives shall be taken to be compliance with the conditions required by Schedule 3A.

(4) Subsection (3) shall not apply to any licence conditions imposed by the Authority which amount to more stringent protective measures for the purposes of Article 4(2) of the first directive.

41 Offences

(1) A person who –

...(b) does anything which, by virtue of section 3(3) of this Act, cannot be authorised by a licence, is guilty of an offence and liable on conviction on indictment to imprisonment for a term not exceeding ten years or a fine or both.

(2) A person who –

(a) contravenes section 3(1) or (1A) of this Act, otherwise than by doing something which, by virtue of section 3(3) of this Act, cannot be authorised by a licence,…

(b) keeps any gametes in contravention of section 4(1)(a) of this Act,…

is guilty of an offence.

Schedule 3

Consent to use or storage of gametes, embryos or human admixed embryos etc

Storage of gametes and embryos

8 (1) A person's gametes must not be kept in storage unless there is an effective consent by that person to their storage and they are stored in accordance with the consent.

(2) An embryo the creation of which was brought about in vitro must not be kept in storage unless there is an effective consent, by each relevant person in relation to the embryo, to the storage of the embryo and the embryo is stored in accordance with those consents.

Cases where consent not required for storage

9 (1) The gametes of a person ("C") may be kept in storage without C's consent if the following conditions are met.

(2) Condition A is that the gametes are lawfully taken from or provided by C before C attains the age of 18 years.

(3) Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that C is expected to undergo medical treatment and that in the opinion of the registered medical practitioner –

(a) the treatment is likely to cause a significant impairment of C's fertility, and

(b) the storage of the gametes is in C's best interests.

(4) Condition C is that, at the time when the gametes are first stored, either –

(a) C has not attained the age of 16 years and is not competent to deal with the issue of consent to the storage of the gametes, or

(b) C has attained that age but, although not lacking capacity to consent to the storage of the gametes, is not competent to deal with the issue of consent to their storage.

(5) Condition D is that C has not, since becoming competent to deal with the issue of consent to the storage of the gametes –

(a) given consent under this Schedule to the storage of the gametes, or

(b) given written notice to the person keeping the gametes that C does not wish them to continue to be stored.

(6) In relation to Scotland, sub-paragraphs (1) to (5) are to be read with the following modifications - (a) for sub-paragraph (4), substitute –

"(4) Condition C is that, at the time when the gametes are first stored, C does not have capacity (within the meaning of section 2(4) of the Age of Legal Capacity (Scotland) Act 1991) to consent to the storage of the gametes.", and

(b) in sub-paragraph (5), for "becoming competent to deal with the issue of consent to the storage of the gametes" substitute "acquiring such capacity".

10 (1) The gametes of a person ("P") may be kept in storage without P's consent if the following conditions are met.

(2) Condition A is that the gametes are lawfully taken from or provided by P after P has attained the age of 16 years.

(3) Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that P is expected to undergo medical treatment and that in the opinion of the registered medical practitioner –

(a) the treatment is likely to cause a significant impairment of P's fertility,

(b) P lacks capacity to consent to the storage of the gametes,

(c) P is likely at some time to have that capacity, and

(d) the storage of the gametes is in P's best interests.

(4) Condition C is that, at the time when the gametes are first stored, P lacks capacity to consent to their storage.

(5) Condition D is that P has not subsequently, at a time when P has capacity to give a consent under this Schedule –

(a) given consent to the storage of the gametes, or

(b) given written notice to the person keeping the gametes that P does not wish them to continue to be stored.

(6) In relation to Scotland -

(a) references in sub-paragraphs (3) and (4) to P lacking capacity to consent are to be read as references to P being incapable, within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000, of giving such consent,

(b) the references in sub-paragraphs (3) and (5) to P having capacity are to be read as references to P not being so incapable, and

(c) that Act applies to the storage of gametes under this paragraph to the extent specified in section 84A of that Act.

11 A person's gametes must not be kept in storage by virtue of paragraph 9 or 10 after the person's death.

Licence conditions

T50 Prior to the processing of patient gametes or embryos, intended for use in treatment or storage, the centre must:

a. carry out the following biological tests to assess the risk of cross contamination:
- HIV 1 and 2: Anti-HIV – 1, 2
- Hepatitis B: HBsAg and Anti-HBc
- Hepatitis C: Anti-HCV-

b. devise a system of storage which clearly separates:
- quarantined/unscreened gametes and embryos,
- gametes and embryos which have tested negative, and
- gametes and embryos which have tested positive.

c. perform HTLV- 1 antibody testing for patients living in or originating from high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas

d. in certain circumstances, carry out additional testing depending on the patient's travel and exposure history and the characteristics of the tissue or cells donated (eg, Rh D, Malaria, CMV, T.cruzi)

Positive results will not necessarily prevent the use of the partners' gametes.

NOTE: Centres storing ovarian or testicular tissue for use in transplantation must refer to the Human Tissue Authority's guidelines as the requirements for screening patients prior to the storing of their tissue for use in transplantation are different than those listed above.

T51 for centres in Great Britain

T51 The centre must ensure that the laboratory tests required by licence condition T50 meet the following requirements, namely:

a. the test must be carried out by a laboratory which is accredited to conduct that test by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard, using CE marked, CE and UK(NI) marked, or UKCA marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge, and

b. blood samples must be obtained within a timeframe specified by the Authority

NOTE: CE marked medical devices (including testing kits) will continue to be accepted on the UK market until 30 June 2023. Medical devices placed on the GB market after 30 June 2023 must be UKCA marked rather than CE marked, as set out in the Medical Devices Regulations 2002 (as amended). This requirement does not prevent centres from continuing (after 30 June 2023) to use CE marked medical devices which were on the market prior to 1 July 2023. The UK Government has guaranteed unfettered access for NI businesses to the rest of the UK internal market. This means that any conformity mark held by a NI business which validates a medical device for sale on the NI market is valid for the whole of the UK. Accordingly, NI businesses can continue to place CE marked and CE and UK(NI) marked devices

on the GB market after 30 June 2023.

NOTE: The Government has announced that the deadline for manufacturers placing CE marked devices on the GB market will be extended beyond 30 June 2023.

This means that, despite the wording of the notes under Standard Licence Conditions T30, T51, T53, R59 and R67 centres can continue to use CE marked devices placed on the GB market after 30 June 2023. See February 2023 Clinic Focus.

T51 for centres in Northern Ireland

T51 The centre must ensure that the laboratory tests required by licence condition T50 meet the following requirements, namely:

a. the test must be carried out by a laboratory accredited to conduct that test by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard, using CE marked or CE and UK(NI) marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge, and
b. blood samples must be obtained within a timeframe specified by the Authority.

NOTE: CE marked medical devices (including testing kits) will continue to be accepted on the UK market until 30 June 2023. Medical devices placed on the GB market after 30 June 2023 must be UKCA marked rather than CE marked, as set out in the Medical Devices Regulations 2002 (as amended). This requirement does not prevent centres from continuing (after 30 June 2023) to use CE marked medical devices which were on the market prior to 1 July 2023. The UK Government has guaranteed unfettered access for NI businesses to the rest of the UK internal market. This means that any conformity mark held by a NI business which validates a medical device for GB version Page 9 of 24 sale on the NI market is valid for the whole of the UK. Accordingly, NI businesses can continue to place CE marked and CE and UK(NI) marked devices on the GB market after 30 June 2023.

T75 Centres must ensure that all storage processes are carried out under controlled conditions.

T76 Gametes of a person must be placed in storage only if –
a. received from that person,
b. acquired in circumstances in which by virtue of paragraph 9 and 10 of Schedule 3 to the Human Fertilisation and Embryology Act 1990 (as amended) that person's consent to the storage is not required, or
c. acquired from a person to whom a licence or third party agreement applies.

T77 Embryos taken from a woman must be placed in storage only if –
a. received from that woman, or
b. acquired from a person to whom a licence or third party agreement applies.

T78 Embryos which have been created in vitro otherwise than in pursuance of this licence must be placed in storage only if acquired from a person to whom a licence or third party agreement applies.

T79 Gametes and embryos that have been kept in storage pursuant to this licence must be removed from storage and disposed of once they may no longer lawfully be so kept.

T80. Gametes must not be kept in storage for longer than such period not exceeding 55 years beginning with the day on which they are first placed in storage.

T81. a. Embryos must not be kept in storage for treatment purposes[1] for longer than such period not

[1] Treatment purposes" are the purposes referred to in paragraph 2(1)(a) or (b) of Schedule 3 of the Human Fertilisation and Embryology Act 1990. This includes:
"A consent to the use of any embryo must specify one or more of the following purposes—
(a) use in providing treatment services to the person giving consent, or that person and another specified person together, (b) use in providing treatment services to persons not including the person giving consent".

exceeding 55 years beginning with the day on which they are first so kept.

b. Embryos kept in storage for training purposes[2] but not for treatment purposes, must not be so kept for longer than such period not exceeding 10 years beginning with the day on which consent to the storage of the embryo for that purpose was given under Schedule 3.

T83 Gametes or embryos which are or have been stored must not be supplied to a person otherwise than in the course of providing treatment services, unless that person is a person to whom a licence applies.

T85 A documented risk assessment must be undertaken to determine the fate of all stored gametes and embryos following the introduction of any new donor/patient selection or testing criterion or any significantly modified processing step that enhances safety or quality.

Directions

0007 - Consent

HFEA guidance

Statutory definitions relevant to this Guidance note

Interpretation of mandatory requirements 17A

Consent Period	the period of 10 years beginning with the Relevant Day and each successive period of 10 years
Relevant Day	in most cases, this is the day on which the gametes are first placed in storage in the UK. Where the gametes are stored on behalf of a person before they have attained the age of 18 who either lack competence or capacity to deal with the issue of consent to storage, the Relevant Day is the day on which they give consent after becoming competent and having capacity to give such consent.
Renewal Period	the period which begins 12 months before the end of the Consent Period and ends 6 months after the end of the Consent Period
Transitional Period	the period beginning on 1 July 2022 and ending with 30 June 2024.

[2] "Training purpose" is the purpose referred to in paragraph 2(1)(ba) of Schedule 3. This includes:

"A consent to the use of any embryo must specify one or more of the following purposes—

(ba) use for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques.

Maximum storage periods and renewal requirements*

Interpretation of mandatory requirements 17B

	Gamete	Embryo	Human Admixed Embryo
Donated (for treatment of others)	Max: 55 years No renewal required	55 years No renewal required	n/a – Human admixed embryos can only be used for research
For own/with partner treatment	Max: 55 years 10-year renewals required	55 years 10-year renewals required	n/a – Human admixed embryos can only be used for research
Training and Research	55 years	10 years**	10 years – for research only**

*The table does not apply in special cases (e.g. where gametes were stored under the 2009/2020 Regulations and are still in storage).

** 10 years commences when consent is given to use those embryos for T&R. No statutory limit applies to embryos that were stored for T&R prior to 01.07.22.

Patients consenting to storage for their own treatment

Interpretation of mandatory requirements 17C

The law requires the centre to obtain written, **effective consent** from a person before storing their gametes or embryos created with their gametes. Gametes or embryos must not be kept in storage unless they are stored in accordance with the consent given. Lawful storage of embryos requires the effective consent of both gamete providers.

Patients can store gametes and embryos for their own treatment for a maximum of **55 years**. However, patients can only consent to the storage of gametes and embryos for use in their own treatment for up to 10 years at a time. They will need to renew their consent every 10 years.

The maximum storage period is calculated from the **Relevant Day**. At any point during storage a patient may decide to **withdraw their consent** to storage. Patients wishing to withdraw their consent to storage should do so on the appropriate HFEA withdrawal of consent form.

If a patient wishes to consent to storage but is unable to sign consent forms because of **illness, injury or physical disability**, they can direct another person to sign on their behalf in their presence and the presence of at least one witness.

In cases of **shared motherhood**, the partner providing the eggs is considered a patient for the purpose of consenting to storage and treatment. Similarly, intended parents who provide their own gametes for use in **surrogacy** should be considered patients for the purpose of consenting to storage and treatment. In both cases, centres should follow the requirements relating to patients (rather than donors) when considering storage periods for gametes or embryos stored for their treatment (though it should be noted that additional screening tests may need to be carried out, as in donation, before gametes are used in treatment).

Centres must ensure that patients are given r**elevant information (see paragraphs 17.4 to 17.7) and offered counselling about the implications of being provided with fertility treatment services (implications counselling)** before giving and renewing their consent to storage.

17.1 Centres should encourage patients to carefully consider decisions around storage of gametes and embryos, and the implications for them and their families.

17.2 Implications counselling should be offered in sufficient time for the patient or donor to be able to access it before they give their consent and the offer of counselling should be documented.

17.3 Centres should not restrict storage consent to tie in with payment or **funding arrangements**: a patient's legal right to consent to store for up to 55 years (with 10-year renewals) is not dependent on whether they have funding for that length of storage. Contractual agreements covering payment or funding should be separate to consent, and patients should be given enough information to understand the terms and conditions of the agreement and the steps the centre will take if these terms and conditions are broken while there is still valid consent in place.

Information to be provided to patients consenting to storage for treatment the first time

17.4 The centre should give people seeking treatment information about the availability of facilities for freezing gametes and embryos, and about the implications of storing and then using stored gametes or embryos before they consent to storage of their gametes and embryos.

17.5 If there is an intention to store gametes or embryos, or where this possibility arises during treatment, in addition to relevant information about treatment and donation, centres should give those providing the gametes or embryos **specific information tailored to their needs and circumstances**. Where relevant, this should include information appropriate for children and young people. Information to be provided should include:

(a) the likelihood of a live birth resulting from previously cryopreserved embryos or gametes, and the possible deterioration or loss of viability of gametes or embryos as a result of the processes which are required to store and use frozen gametes and embryos and the potential risk of cross-contamination between samples.
(b) screening tests to be done, the cost of these, the reason for them and the implications of the tests for the gamete providers.
(c) storage periods for gametes and embryos which permit patients to store for a maximum of 55 years, with periodic renewal of consent required at least every 10 years.
(d) the fact that patients may at any point during storage of their gametes (or embryos created with their gametes) vary or withdraw their consent to storage.
(e) the consent renewal process. Centres should explain that they will contact the patient at least 12 months before the end of the 10-year Consent Period to seek their renewed consent to store for up to 10 more years. Centres should explain what will happen if, at the end of the Renewal Period, the patient has not provided written renewed consent: that their consent will be deemed to have been withdrawn, and their gametes or embryos removed from storage and disposed of.
(f) information about the requirement that both gamete providers provide renewed consent in order for storage of embryos to continue, and the process the centre will follow if gamete providers do not agree on renewing consent to storage.
(g) information about the lawful storage of embryos created from donated gametes. In cases where donor gametes have been used to create embryos then storage cannot exceed the period to which the donor gamete provider(s) consented to storage.
(h) all relevant information for patients to make informed decisions about whether and how they want their gametes or embryos stored and/or used after their death (see paragraphs 17.22 to 17.32 for further details), including the need to consent to posthumous use of gametes or embryos by a named partner, the possibility of registering a deceased partner as the parent of a child resulting from treatment, and the conditions for doing so.
(i) if use in the event of death would involve a surrogate, information about additional consent forms and further screening tests that would need to be completed before the patient dies to allow treatment to take place.
(j) all relevant information for patients to make informed decisions about whether and how they want their gametes or embryos stored and/or used in the event of their incapacity, including the need to consent to use of gametes or embryos by a named partner in the event of their incapacity (see paragraphs 17.22 to 17.35 for further details).
(k) the patient's options for consenting to alternative uses of their gametes or embryos in the future, including for use in someone else's treatment, training, or research, and further information about each of these options.
(l) the independence of the consent process from any contractual agreement regarding payment for storage. Centres should explain that patients are able to consent to the storage of their gametes or embryos for any period of up to 55 years, irrespective of whether they currently have payment or funding arrangements in place, providing that they renew their consent at least every 10 years.
(m) information to enable patients to understand the terms and conditions of any contractual agreements between the centre and the patient and the steps the centre will take if these terms and conditions are broken. Centres should provide information about the circumstances in which the patient's gametes or embryos could be removed from storage and disposed of before their consent expires. For example, that the centre may only continue to store the patient's gametes or embryos for the period specified in their consent if the patient, or their funding provider, continues to pay the storage fees.

Keeping contact details up to date

17.6 Centres should explain to patients the importance of ensuring that they keep the centre up to date with their latest contact information so the centre can get in touch with them about renewing their consent to storage at the appropriate times. If centres send renewal notices to patients at their last known address and patients do not respond and renew consent during the Renewal Period, then by law consent is taken as withdrawn. Centres will then be required to remove the gametes or embryos from storage and dispose of them.

17.7 Centres should also explain to patients the importance of notifying the centre of any changes in their circumstances which may affect their consent to storage (for example if they have separated from their partner or have a new partner) so that if relevant they can document their decisions of what

should happen if they die or lack capacity. Centres should ensure that any previous consent forms are checked, and the patient is asked to complete any relevant consent forms to ensure their stored samples can be used in accordance with their wishes; for example, the patient might need to complete a new treatment form.

17.8 Centres should ensure they have processes in place so that they have up to date contact details of their patients and could consider whether patients wish to provide contact details for next of kin etc. Any information collected should be compliant with data protection requirements.

Patients renewing consent to storage for own treatment

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Schedule 3 - Consents to use or Storage of Gametes, Embryos or Human Admixed Embryos etc
Consent

1(3) In this Schedule—
(a) "effective consent" means a consent under this Schedule which has not been withdrawn,
(b) references to renewal of consent are to renewal of consent to the storage of any gametes or embryo under paragraph 11A or 11C.

Renewal of consent to storage of gametes
11A (1) This paragraph applies where—
(a) the gametes of a person ("P") are in storage,
(b) P's consent to the storage of the gametes is required under paragraph 8(1),
(c) there is effective consent from P to the storage of the gametes, and
(d) the gametes are being kept for use for the purposes of providing treatment services to—
(i) P, or
(ii) P and another person together.

(2) The person keeping the gametes in storage ("K") must, in each consent period, request P to renew consent to storage of the gametes within the renewal period.
For the meaning of "consent period" and "renewal period", see paragraph 11B.

(3) A request under sub-paragraph (2) must be given in writing before the start of the renewal period.

(4) The duty in sub-paragraph (2) ceases to apply if K is notified that P has died.

(5) The duty in sub-paragraph (2) does not apply in relation to any consent period if—
(a) K has at any time been informed in writing that P has been certified as lacking capacity to renew consent to storage of the gametes, and
(b) K has not subsequently been informed in writing, before the start of the renewal period which relates to that consent period, that P has been certified as having capacity to renew consent to storage of the gametes.

(6) P renews consent by informing K in writing that P consents to the storage of the gametes.

(7) If P's consent is not renewed under sub-paragraph (6) before the end of the consent period, K must, as soon as possible after the end of that period, give a notice to P stating that if P does not renew consent before the end of the renewal period, the gametes will be removed from storage and disposed of.

(8) P's consent to the storage of the gametes is to be taken as having been withdrawn at the end of a renewal period that relates to a consent period if—

(a) K has complied with the requirements of sub-paragraphs (2) and (7) in relation to that consent period, and

(b) P's consent is not renewed under sub-paragraph (6) before the end of the renewal period.

But this is subject to sub-paragraphs (9) and (10).

(9) If, in a case referred to in sub-paragraph (8)(a) and (b), P dies before the end of the renewal period—

(a) P's consent is not to be taken as withdrawn under sub-paragraph (8), but

(b) if at the end of the period of 10 years beginning with the day on which P died there is still effective consent from P to the storage, P's consent is to be taken as withdrawn at that time.

(10) If, in a case referred to in sub-paragraph (8)(a) and (b), before the end of the renewal period P is certified as lacking capacity to renew consent—

(a) P's consent is not to be taken as withdrawn under sub-paragraph (8), but

(b) if at the end of the period of 10 years beginning with the day on which P was so certified there is still effective consent from P to the storage, P's consent is to be taken as withdrawn at that time.

(11) But P's consent is not to be taken as withdrawn under sub-paragraph (10)(b) if, before the time it would be taken to be withdrawn under that sub-paragraph—

(a) P is certified as having capacity to renew consent to storage of the gametes, and

(b) P renews consent to storage of the gametes by informing K in writing that P consents to their storage.

(12) In a case where P renews consent under sub-paragraph (11)(b), this paragraph applies subsequently as if references to a consent period were to—

(a) the period of 10 years beginning with the day on which P so renewed consent, and

(b) each successive period of 10 years.

11B (1) For the purposes of paragraph 11A, each of the following is a "consent period"—

(a) the period of 10 years beginning with the relevant day, and

(b) each successive period of 10 years.

(2) In sub-paragraph (1)(a) "relevant day" means—

(a) the day on which the gametes are first placed in storage, or

(b) in a case where sub-paragraph (3) or (5) applies, the day on which P gives consent to the storage of the gametes.

(3) This sub-paragraph applies where the gametes are taken from or provided by P before P attains the age of 18 years and, at the time the gametes are first stored—

(a) P has not attained the age of 16 years and is not competent to deal with the issue of consent to storage of the gametes, or

(b) P has attained that age but, although not lacking capacity to consent to the storage of the gametes, is not competent to deal with the issue of consent to their storage.

(4) In relation to Scotland, sub-paragraph (3) is to be read as if, for paragraphs (a) and (b), there were substituted "P does not have capacity (within the meaning of **section 2(4)** of the Age of Legal Capacity (Scotland) Act 1991) to consent to storage of the gametes".

(5) This sub-paragraph applies where the gametes are taken from or provided by P after P attains the age of 16 years and, at the time the gametes are first stored, P lacks capacity to consent to their storage.

(6) In paragraph 11A "the renewal period", in relation to a consent period, means the period which—

(a) begins 12 months before the end of the consent period, and

(b) ends 6 months after the end of the consent period.

(7) In paragraph 11A "certified" means certified in writing by a registered medical practitioner.

(8) In paragraph 11A and this paragraph, in relation to Scotland, references to a person lacking or having capacity to consent or renew consent are to be read as references to the person being or not being incapable (within the meaning of **section 1(6)** of the Adults with Incapacity (Scotland) Act 2000) of consenting or renewing consent.

Renewal of consent to storage of embryos

11C (1) This paragraph applies where—

(a) an embryo, the creation of which was brought about *in vitro*, is in storage,

(b) the embryo is being kept for use for the purposes of providing treatment services to—

(i) a person ("P") whose gametes or human cells were used to bring about the creation of the embryo, or

(ii) P and another person together,

(c) P's consent to the storage of the embryo is required under paragraph 8(2), and

(d) there is effective consent from P to the storage of the embryo.

(2) The person keeping the embryo in storage ("K") must, in each consent period, request P to renew consent to storage of the embryo within the renewal period.

For the meaning of "consent period" and "renewal period", see paragraph 11D.

(3) A request under sub-paragraph (2) must be given in writing before the start of the renewal period.

(4) The duty in sub-paragraph (2) ceases to apply if—

(a) K is notified that P has died, or

(b) K is notified under paragraph 4A(1)(c) of the withdrawal of a person's consent to storage of the embryo.

(5) The duty in sub-paragraph (2) does not apply in relation to any consent period if—

(a) K has at any time been informed in writing that P has been certified as lacking capacity to renew consent to storage of the embryo, and

(b) K has not subsequently been informed in writing, before the start of the renewal period which relates to that consent period, that P has been certified as having capacity to renew consent to storage of the embryo.

(6) P renews consent by informing K in writing that P consents to the storage of the embryo.

(7) If P's consent is not renewed under sub-paragraph (6) before the end of the consent period, K must, as soon as possible after the end of that period, give a notice to P stating that if P does not renew consent before the end of the renewal period, the embryo will be removed from storage and disposed of.

(8) P's consent to the storage of the embryo is to be taken as having been withdrawn at the end of a renewal period that relates to a consent period if—

(a) K has complied with the requirements of sub-paragraphs (2) and (7) in relation to that consent period, and

(b) P's consent is not renewed under sub-paragraph (6) before the end of the renewal period.

But this is subject to sub-paragraphs (9) and (10).

(9) If, in a case referred to in sub-paragraph (8)(a) and (b), P dies before the end of the renewal period—

(a) P's consent is not to be taken as withdrawn under sub-paragraph (8), but

(b) if at the end of the period of 10 years beginning with the day on which P died there is still effective consent from P to the storage, P's consent is to be taken as withdrawn at that time.

(10) If, in a case referred to in sub-paragraph (8)(a) and (b), before the end of the renewal period P is certified as lacking capacity to renew consent—

(a) P's consent is not to be taken as withdrawn under sub-paragraph (8), but

(b) if at the end of the period of 10 years beginning with the day on which P was so certified there is still effective consent from P to the storage, P's consent is to be taken as withdrawn at that time.

(11) But P's consent is not to be taken as withdrawn under sub-paragraph (10)(b) if, before the time it would be taken to be withdrawn under that sub-paragraph—

(a) P is certified as having capacity to renew consent to storage of the embryo, and

(b) P renews consent to storage of the embryo by informing K in writing that P consents to its storage.

(12) In a case where P has renewed consent under sub-paragraph (11)(b), this paragraph applies subsequently as if references to the consent period were to—

(a) the period of 10 years beginning with the day on which P so renewed consent, and

(b) each successive period of 10 years.

(13) Where P's consent is taken as withdrawn under this paragraph, K must, as soon as possible, take all reasonable steps to give notice of the withdrawal to each person whose gametes or human cells were used to bring about its creation.

(14) Storage of the embryo remains lawful until—

(a) the end of the period of 6 months beginning with the day on which P's consent is taken as withdrawn under this paragraph, or

(b) if, before the end of that period, K receives a notice from each person notified under sub-paragraph (13) stating that the person consents to the disposal of the embryo, the time at which the last of those notices was received.

11D (1) For the purposes of paragraph 11C, each of the following is a "consent period"—

(a) the period of 10 years beginning with the day on which the embryo is first placed in storage, and

(b) each successive period of 10 years.

(2) In paragraph 11C "the renewal period", in relation to a consent period, means the period which—

(a) begins 12 months before the end of the consent period, and

(b) ends 6 months after the end of the consent period.

(3) In paragraph 11C "certified" means certified in writing by a registered medical practitioner.

(4) In paragraph 11C, in relation to Scotland, references to a person lacking or having capacity to renew consent are to be read as references to the person being or not being incapable (within the meaning of **section 1(6)** of the Adults with Incapacity (Scotland) Act 2000) of renewing consent.

Health and Care Act 2022

Schedule 17, Part 2

Time for first renewal of consent

15 (1) This paragraph applies in relation to the storage of gametes under a pre-commencement gamete storage licence where the statutory storage period applicable immediately before the commencement day was provided for by—

(a) regulation 4, 4A, 7 or 8 of the 2009 Regulations, or

(b) regulation 4 of the 2020 Regulations.

(2) For the purposes of paragraph 11A of Schedule 3 to the 1990 Act (as inserted by paragraph 7 of this Schedule), paragraph 11B(1)(a) of that Schedule has effect as if the reference to the period of 10 years beginning with the relevant day were a reference to the period which—

a) begins with the relevant day, and

b) ends at the end of the statutory storage period referred to in sub-paragraph (1).

16 (1) This paragraph applies in relation to the storage of an embryo under a pre-commencement embryo storage licence where the statutory storage period applicable immediately before the commencement day was provided for by—

(a) regulation 3, 3A, 5 or 6 of the 2009 Regulations, or
(b) regulation 3 of the 2020 Regulations.

(2) For the purposes of paragraph 11C of Schedule 3 to the 1990 Act (as inserted by paragraph 7 of this Schedule), paragraph 11D(1)(a) of that Schedule has effect as if the reference to the period of 10 years beginning with the day on which the embryo was first placed in storage were a reference to the period which—

a) begins with the day on which the embryo was first so placed, and
b) ends at the end of the statutory storage period referred to in sub-paragraph (1).

Interpretation of Mandatory Requirements 17E

In this guidance 'renewing consent' only refers to the legal process of renewing consent to storage beyond the end of a Consent Period.

Centres must contact patients in writing to ask whether they wish to renew their consent to storage before the start of the Renewal Period. This is in effect at least 12 months prior to the end of the patient's Consent Period.

General Directions 0007, 0012 and 0015 require centres to maintain a record of evidence that the centre has complied with statutory requirements to issue notices to patients regarding renewing their consent to storage. Patients who want to renew their consent to storage beyond their current Consent Period must be asked to complete the appropriate HFEA renewal forms. The form must be correctly completed, signed, and dated.

Centres must offer patients relevant information about renewing their consent and offer counselling.

If the patient has not renewed their consent to storage by the end of the Consent Period, centres must send to the patient another HFEA statutory notice, which explains that if they do not renew their consent to storage within 6 months of the end of their Consent Period (and by the end of the Renewal Period), their consent is taken as withdrawn and their gametes or embryos will be removed from storage and disposed of.

The consent renewal process

17.9 Centres should use the 18-month Renewal Period to find out whether patients wish to renew their consent to storage for a further period of up to 10 years. It is important that centres correctly calculate when a patient's Consent Period ends and when their Renewal Period begins so that they contact patients about renewal of consent at the appropriate time. For patients renewing consent to storage for the first time after the law changed on 1 July 2022, the end of the relevant Consent Period will be the end of the statutory storage period which was applicable before the amendments to the Act on 1 July 2022. For additional guidance on how to calculate this in cases of storage under the 1991/1996 Regulations or 2009 Regulations and to consider the effect of the application (if relevant) of the 2020 Regulations, please see the Clinic Guide (6.8.2) and the Clinic FAQs (1.2).

17.10 Centres can contact patients by post and/or email. Centres should record that the patient has been given proper information and offered implications counselling in the patient's medical records. Counselling should be offered in sufficient time for the patient or donor to be able to access counselling before they renew their consent to storage. Centres should inform patients that if they fail

to renew their consent by the end of the Renewal Period, their consent will be taken as having been withdrawn, and their gametes or embryos removed from storage and disposed of.

17.11 Patients who want to renew their consent to storage must be asked to complete the appropriate HFEA renewal of consent forms. Centres must keep a copy of the patient's completed renewal of consent form. For more guidance on information that centres are required to retain relating to renewal of consent see General Direction 0015.

17.12 Centres should have bring-forward systems for patients to renew their consent to storage within the Renewal Period.

Interpretation of Mandatory Requirements 17F

Where patients do not renew their consent to storage there are different rules for the steps centres should take with respect to gametes and embryos. If patients have not renewed consent to storage of their gametes according to the renewal of consent process set out above (see 17E and paragraphs 17.9 to 17.12) by the end of the Renewal Period then the centre is legally required to remove gametes from storage and dispose of them. Centres must not continue storing gametes beyond the end of the Renewal Period if consent to storage has not been renewed by the patient.

For embryos, if either patient has not renewed consent to storage according to the renewal of consent process set out above then the centre is legally required to write to each gamete provider and give notice of the fact that consent is taken to have been withdrawn. In these circumstances, centres are permitted to continue storing the embryos for a further 6 months before disposing of them. However, the embryos can no longer be used in treatment, and consent cannot be renewed.

Both gamete providers must have renewed their consent in order for centres to be able to continue storing embryos.

When gametes or embryos have been in storage for 55 years they must be removed from storage and disposed of (unless the patient consents at this stage to storage for a different purpose, for example, for research or training purposes).

Patients who do not wish to renew their consent to storage

17.13 Patients who do not wish to renew their consent should be provided with information on their options which could include the donation of the gametes or embryos for research, training or for the treatment of others. If contact with the patient is not possible, the centre should record the steps it has taken in the patient's medical records.

Storage of gametes and embryos for someone else's treatment

Interpretation of mandatory requirements 17G

These rules apply to people donating gametes or embryos for someone else's treatment (not including their partner's treatment).

People donating gametes or embryos for someone other than their partner's treatment, can consent to storage for up to 55 years. They can specify any period of storage up to 55 years and **do not need to renew their consent.**

Embryos created using **donor gametes,** including embryos created with **donor gametes and a patient's own gametes,** cannot be stored for any longer than the period to which the donor has consented to storage.
In the case of embryos created with **donor gametes and a patient's own gametes:**

- The donor will not need to be contacted to renew their consent to storage.
- The patient will need to be contacted every 10 years to ask if they wish to renew their consent in line with the process described above (see 17E and paragraphs 17.9 to 17.12).

Centres must ensure that donors are given **relevant information (see paragraphs 17.14 to 17.21) and offered implications counselling** before giving their consent to storage.

Information to be provided to people donating gametes or embryos for someone else's treatment

17.14 Prior to obtaining consent, centres should discuss with donors how long they wish to consent to store their gametes or embryos for. There are different considerations pertaining to donating gametes, embryos created from donor gametes, and embryos created from patient's own gametes, and the implications for them and any donor conceived people born from donated gametes or embryos that may have been in storage for several years. For example, the possibility that longer-term storage could lead to large age gaps between donor conceived siblings. Longer-term storage might also have implications for donor-conceived people trying to get in contact with the donor once they reach 18 years old and can access identifiable information about the donor from the HFEA, which may be many years after the donor donated their gametes. For more information see Guidance Note 3 on Counselling and Guidance Note 11 on Donor recruitment, assessment and screening.

17.15 The centre should tell donors that by consenting to donate their gametes or embryos, they are also agreeing to them being used and stored if they were to die or lack capacity. If they do not want their gametes or embryos to be used in the event of their death or lack of capacity, donors should specifically state this as a restriction on the relevant HFEA consent form.

17.16 Donors should be made aware that centres can only act on donation restrictions relating to death or incapacity if they are made aware of the donor's death or lack of capacity.

17.17 Gamete donors should be informed that storage periods for embryos created with their gametes will also be determined by the consent given by the other person whose gametes were used to create the embryos (such as a patient or another gamete donor). Therefore, embryos created with the donor's gametes may be stored for a shorter period of time than consented to by a gamete donor. However, storage periods cannot be longer than the period to which the donor consented and cannot exceed the 55-year maximum.

17.18 Gamete donors should be informed that that they can make changes to, or withdraw, their consent to the use and storage of their gametes at any point until the time that their gametes have been transferred to a woman, used in training or research, or disposed of.

17.19 The centre should also explain to gamete donors the importance of informing the centre of any change in their contact details.

17.20 Embryo donors should be informed that they can make changes to, or withdraw, their consent to the use and storage of embryos at any point before embryos transferred to a woman, used in training or research, or disposed of. They should be informed that once embryos are allocated, the patient using the embryos in treatment can consent to a different period of storage. However, this period can never be longer than the period to which the donor consented.

17.21 Donors should be informed that centres are not required to, and might not, store donated gametes or embryos for the full period to which the donor consented.

Consent to the storage and use of gametes or embryos in the event of death or incapacity

17.22 A patient's gametes and embryos can only be stored and used posthumously or in the event of their incapacity if the patient has provided **written consent** to their storage and use in these circumstances.

17.23 Centres should inform patients and their partners that if they would like their partner to use their gametes or embryos in the event of their death or incapacity they must provide consent to this, and their **partner must be named** on the relevant consent form(s).

17.24 Centres should inform patients and their partners that if treatment would involve a **surrogate**, then additional consent forms and further screening tests must be completed before the gamete provider dies, to allow treatment to take place. Centres should give patients information about surrogacy arrangements and make an offer of implications counselling.

When a patient dies or lacks capacity

17.25 Centres should have **processes** in place to consider what actions they will take if they are notified that a patient with gametes or embryos in storage has died or lacks capacity. For example, they should review the specific circumstances of the patient and consider how they will communicate with a partner named on a consent form to ensure they are aware that the gametes or embryos can remain in storage for up to 10 years from the date the patient died or lost capacity, depending on what the patient consented to. Centres should provide further information and offer implications counselling to the partner named by the patient so that they can consider their options for using the gametes or embryos. Centres should consider how to maintain contact with the partner named by the patient and ensure that they are given sufficient notice of the expiry of the period of lawful storage after the patient's death or loss of capacity.

17.26 If a centre is notified that a patient has died the centre should obtain a copy of the **patient's death certificate**. If the centre cannot obtain a copy of the patient's death certificate, they should satisfy themselves that there is reliable documentary evidence to confirm death, recording the reasons why they consider it to be so, and the reason for which a death certificate was not obtained. If a centre is notified that a patient lacks capacity this must be certified in writing by a registered medical practitioner.

17.27 Where a gamete provider had consented to their gametes or embryos being used in the event of their death or incapacity, the law permits their gametes or embryos to be stored for their named partner's use for **up to 10 years from the date of death or the date on which the patient is certified as lacking capacity**. The date of death should be recorded as the date registered on the patient's death certificate. The date the patient is certified as lacking capacity should be provided by a registered medical practitioner.

17.28 The gametes or embryos can be stored for up to 10 years after the date on which the patient dies or loses capacity irrespective of how many years are left until the end of their current Consent Period (unless, in the case of embryos, the other gamete provider withdraws or fails to renew their consent –

see 17L and paragraph 17.66). For example, if a patient consented to the storage of their gametes for 10 years and to the storage and use of their gametes for 10 years after their death, if they died 8 years into the Consent Period, their material could remain in storage for a further 10 (rather than 2) years from the date of death.

17.29 Lawful storage of embryos in the event of the patient's death or incapacity cannot continue without the consent of the other, living gamete provider. This means that even if a gamete provider who has died or lacks capacity had consented to the storage of their embryos in those circumstances, **the consent of the other gamete provider is needed for storage to continue**. If the living gamete provider withdraws their consent to storage at any point during the period of lawful storage following the patient's death or lack of capacity, embryos must be removed from storage and disposed of.

17.30 Centres must **remove all unused gametes or embryos from storage and dispose** of them at the end of the period to which the patient consented to posthumous use, which can be no more than 10 years after the patient's death. It is unlawful to store a patient's gametes or embryos beyond 10 years after the date on which the patient died. Centres must remove all unused gametes or embryos from storage and dispose of them at the end of the period to which the patient consented to use in the event of their incapacity, unless the patient regains capacity before the end of this period. If the patient regains capacity in this period, centre should/must contact the patient and ask them to renew their consent to storage for up to 10 years from the date that they regain capacity.

17.31 The maximum period of storage for which a patient can consent in the event that they lose capacity is 10 years. If the patient does not regain capacity before the end of the period to which they have given consent to storage in the event of lost capacity, then the gametes or embryos must be removed from storage after that time (see paragraphs 17.33 to 17.35 for guidance on what to do if a patient regains capacity).

17.32 Centres should **contact the patient's named partner** 12 months before the end of the period of lawful storage following the patient's death or loss of capacity, to inform them that at the end of this period any of the patient's unused gametes or embryos will be removed from storage and disposed of (unless the patient who lacks capacity regains capacity before this point – see paragraphs 17.33 to 17.35).

If a patient regains capacity

17.33 If a centre is notified that a patient who had previously lacked capacity has regained capacity this must be certified in writing by a registered medical practitioner.

17.34 The centre should, as soon as possible after this, contact the patient about renewing their consent.

17.35 If the patient wishes to renew consent to storage, any subsequent Consent Period should be calculated using the date on which the patient renewed their consent after regaining capacity. However, the total storage period for gametes or embryos must not exceed 55 years. The only circumstances in which storage can exceed 55 years is if a patient's embryos have been stored for treatment purposes for 55 years, and the patient subsequently consents to storage for a different purpose, for example, for training purposes.

Storage of gametes and embryos for research and training

Mandatory requirements

14 Conditions of storage licences

(3) The requirements referred to in subsection (1)(c) are as follows—

(a) gametes must not be kept in storage for longer than such period not exceeding 55 years beginning with the day on which they are first placed in storage as the licence may specify….

Interpretation of mandatory requirements 17H

The law allows patients to consent to the use and storage of their gametes and embryos for training and research purposes. Patients can consent to storage for any period up to the maximum period as set out in the law. For material stored for training and research purposes, these periods are as follows:

- For gametes: 55 years, calculated from the date on which the gametes were first placed in storage for any purpose, under section 14(3)(a) of the HFEA Act 1990 (as amended).
- For embryos: 10 years, calculated from the date on which the gamete providers gave consent to storage of the embryo(s) for either training or research purposes, under section 14(3)(c) of the HFEA Act 1990 (as amended).

According to section 14(4) of the 1990 Act (as amended) where gamete providers give their consent to use and storage of embryos created with their gametes for training or research purposes on different days the storage period begins on the later date.

Keeping gametes or embryos in storage for longer than the maximum period is unlawful.

Before giving their consent to use and storage for research or training purposes, patients must be given relevant information and an offer of counselling (see also mandatory requirements outlined in guidance note 22 – research and training)

17.36 Patients who are considering providing gametes or embryos for these purposes should be given information and implications counselling that is specific to that purpose. In addition to the information in this guidance note, clinics should provide patients with the information set out in guidance note 22.

17.37 Patients may be asked during the renewal process to consider consenting to the use of their gametes or embryos in training or research. Patients who wish to do so must give consent to storage for use in training or research before the end of the Renewal Period (six months after the end of the consent period). Clinics should ensure that patients are aware of this and, for patients who are considering this option, that they are provided with relevant information and an offer of implications counselling in sufficient time before the end of the Renewal Period to allow them to make an informed decision. If consent is not obtained by the end of the Renewal Period, the centres will not be able to continue to store the gametes or embryos lawfully and they must be removed from storage and disposed of.

Information to be provided to people seeking to consent to the storage of their gametes or embryos for research of training purposes

17.38 The centre should provide patients who are considering providing their gametes or embryos for use in training or research with relevant information about storage, including:

(a) That gametes and embryos provided for use in training or research may be stored and that it is not possible to consent to use in training or research without consenting to storage.
(b) If they are providing **gametes** for use in training or research, the maximum storage period that applies to gametes and how this storage period is calculated.
(c) If they are providing **embryo(s)** for use in training or research, the maximum storage period that applies to embryos stored for use in training or research and how this storage period is calculated.
(d) That patients may choose to consent to a shorter period of storage than the maximum storage period.
(e) For patients who have used donor gametes to create embryos, that embryos must be used and stored in accordance with the consent provided by the donor, who may have consented to a shorter period of storage for research or training purposes (or not at all).
(f) That gametes or embryos provided for use in training or research may be used or disposed of before the end of the storage period to which the patient consented. For example, if a patient provides their gametes for use in training and consents to 55 years of storage, their gametes might not remain in storage for that length of time.

Clinics should also provide information as set out in Guidance Note 22 and offer implications counselling.

Transitional Provisions

Mandatory requirements

Health and Care Act 2022

Schedule 17, Part 2 – Transitional Provisions

Interpretation

8 (1) In this Part of this Schedule—

"the commencement day" means 1 July 2022;

"the transitional period" means the period beginning with the commencement day and ending with 30 June 2024…

(3) In this Part of this Schedule—

"pre-commencement", in relation to a storage licence, or a storage licence of any description,

(4) In this Part of this Schedule—

"statutory storage period" has the same meaning as in the 1990 Act immediately before the commencement day;

Application of Part 1 to material already in storage

9 (1) The amendments in paragraphs 2 to 6 of this Schedule have effect in relation to pre-commencement storage licences under which gametes, embryos or human admixed embryos are kept in storage on or after the commencement day (as well as having effect in relation to post-commencement storage licences).

This is subject to sub-paragraphs (2) and (3).

(2) In the case of a pre-commencement embryo storage licence, the condition imposed by section 14(3)(c) of the 1990 Act (as substituted by paragraph 2 of this Schedule) does not apply in relation to an embryo which, on the commencement day, is kept in storage for the training or research purpose but not for treatment purposes.

(3) In the case of any pre-commencement storage licence, the condition imposed by section 14(1)(ca) of the 1990 Act (as substituted by paragraph 5 of this Schedule) applies only in relation to times on or after the commencement day.

10 The amendments made by paragraph 7 of this Schedule have effect in relation to the storage of gametes and embryos under a pre-commencement gamete or embryo storage licence, where the gametes or embryos are kept in storage on or after the commencement day (as well as having effect in relation to the storage of gametes and embryos under a post-commencement gamete or embryo storage licence).

Date of first storage

11 (1) This paragraph applies if the person storing gametes or an embyro under a pre-commencement gamete or embryo storage licence—

(a) has, before the end of the transitional period, taken all reasonable steps to establish the date on which the gametes were or embryo was first placed in storage, but

(b) is unable to establish that date.

(2) The person may give a notice to each person whose consent to the storage is required under Schedule 3 to the 1990 Act specifying a date on which the gametes are or embryo is to be regarded as having been first placed in storage.

(3) Where notice is given under sub-paragraph (2), the gametes are or embryo is to be regarded, for all purposes of the 1990 Act and this Part of this Schedule, as having been first placed in storage on the date specified in the notice.

Storage periods specified in pre-commencement storage licences

12 (1) For the purposes of section 14(3)(a) of the 1990 Act (as substituted by paragraph 2 of this Schedule), a pre-commencement gamete storage licence under which, on and after the commencement day, gametes are kept in storage is to be regarded as specifying the period of 55 years beginning with the day on which the gametes were first placed in storage.

(2) For the purposes of section 14(3)(b) of the 1990 Act (as substituted by paragraph 2 of this Schedule), a pre-commencement embryo storage licence under which, on and after the commencement day, an embryo is kept in storage for treatment purposes is to be regarded as specifying for those purposes the period of 55 years beginning with the day on which the embryo was first so kept.

Storage after expiry of pre-commencement consent

13 (1) If a pre-commencement consent to the storage of gametes or an embryo expires at any time in the transitional period, the storage of the gametes or embryo for the remainder of that period is not unlawful merely because of that fact.

(2) In sub-paragraph (1)—

(a) "pre-commencement consent" means consent given under Schedule 3 to the 1990 Act before the commencement day;

(b) the reference to expiry of consent does not include withdrawal.

Storage with no effective consent prior to commencement

14 (1) This paragraph applies in relation to the storage of gametes or an embryo under a pre-commencement gamete or embryo storage licence where, immediately before the commencement day, there is no effective consent to the storage by a relevant person.

(2) The person keeping the gametes or embryo in storage must request the relevant person to give consent to the storage under Schedule 3 to the 1990 Act.

(3) A request under sub-paragraph (2) must be given before 1 July 2023 in writing.

(4) The storage of the gametes or embryo at any time before the end of the transitional period is not unlawful merely because there is no effective consent to the storage by the relevant person.

(5) In this paragraph—

"effective consent" means consent under Schedule 3 to the 1990 Act which has not been withdrawn;

"relevant person" means a person whose consent is required under Schedule 3 to the 1990 Act to storage of the gametes or embryo.

Renewals falling due in the transitional period

17 (1) This paragraph applies in relation to the storage of gametes under a pre-commencement gamete storage licence in a case where—

(a) paragraph 11A of Schedule 3 to the 1990 Act applies in relation to the storage, and

(b) for the purposes of that paragraph, the first consent period (see paragraph 11B(1)(a) of that Schedule) ends in the transitional period.

(2) Where this paragraph applies, paragraph 11A of Schedule 3 to the 1990 Act has effect in relation to that first consent period as if—

(a) for sub-paragraphs (2) and (3) there were substituted—

"(2) The person keeping the gametes in storage ("K") must request P to renew consent to storage of the gametes before 1 July 2024.

(3) A request under sub-paragraph (2) must—

(a) be given in writing before 1 July 2023;

(b) state that if P does not renew consent before 1 July 2024, the gametes will be removed from storage and disposed of.";

(b) in sub-paragraph (5)(b), for "the start of the renewal period which relates to that consent period" there were substituted "1 July 2023";

(c) sub-paragraph (7) were omitted;

(d) for sub-paragraph (8) there were substituted—

"(8) P's consent to the storage of the gametes is to be taken as having been withdrawn at the beginning of 1 July 2024 if—

(a) K has complied with sub-paragraph (2), and

(b) P's consent is not renewed under sub-paragraph (6) before 1 July 2024.

But this is subject to sub-paragraphs (9) and (10).";

(e) in sub-paragraphs (9) and (10), references to the end of the renewal period were to 1 July 2024.

18 (1) This paragraph applies in relation to the storage of an embryo under a pre-commencement embryo storage licence in a case where—

(a) paragraph 11C of Schedule 3 to the 1990 Act applies in relation to the storage, and

(b) for the purposes of that paragraph, the first consent period (see paragraph 11D(1)(a) of that Schedule) ends in the transitional period.

(2) Where this paragraph applies, paragraph 11C of Schedule 3 to the 1990 Act has effect in relation to that first consent period as if—

(a) for sub-paragraphs (2) and (3) there were substituted—

"(2) The person keeping the embryo in storage ("K") must request P to renew consent to storage of the embryo before 1 July 2024.

(3) A request under sub-paragraph (2) must—

(a) be given in writing before 1 July 2023;

(b) state that if P does not renew consent before 1 July 2024, the embryo will be removed from storage and disposed of.";

(b) in sub-paragraph (5)(b), for "the start of the renewal period which relates to that consent period" there were substituted "1 July 2023";

(c) sub-paragraph (7) were omitted;

(d) for sub-paragraph (8) there were substituted—

"(8) P's consent to the storage of the embryo is to be taken as having been withdrawn at the beginning of 1 July 2024 if—

(a) K has complied with sub-paragraph (2), and

(b) P's consent is not renewed under sub-paragraph (6) before 1 July 2024.

But this is subject to sub-paragraphs (9) and (10).";

(e) in sub-paragraphs (9) and (10), references to the end of the renewal period were to 1 July 2024.

Patients with gametes or embryos already in storage on 1 July 2022 where there was no effective consent to storage or where consent ends during the Transitional Period

17.39 30 June 2023 was the deadline for centres to contact patients who had gametes or embryos in storage on or before 30 June 2022 with either **no effective consent to storage** or where **consent expires during the transitional period.** Such patients should have been advised that if they do not renew their consent to storage by 30 June 2024 then their gametes or embryos must be removed from storage and disposed of.

17.40 If consent to storage of gametes is not renewed by 30 June 2024 gametes must be removed from storage and disposed of on 1 July 2024. If consent to the storage of embryos is not renewed by 30

June 2024, centres are required to take all reasonable steps to give notice of the withdrawal of consent to each person whose gametes were used to bring about the creation of the embryo. In these circumstances the continued storage of the embryos will remain lawful until 31 December 2024 unless, before that date, written notification of withdrawal of consent to storage of the embryo from each person notified is received.

Even during the Transitional Period, any gametes or embryos in storage without effective consent to storage cannot be used in treatment until effective consent to storage is in place.

17.41 If gametes or embryos were already subject to an extension of storage under the 2009 Regulations and this ends in the transitional period, i.e., the effective consent ends with an MPS expiring in the transitional period, or when the consent expires prior to the MPS, then centres must request renewal of consent by 30 June 2023.

Patients with gametes or embryos in storage where consent ends after the end of the Transitional Period

17.42 Centres should follow the guidance on calculating the end of patients' Consent Period and ask patients to renew their consent to storage in line with the process set out above (17E and paragraphs 17.11 to 17.12).

Contacting donors who donated before 1 July 2022 about varying their consent

17.43 Donors with gametes or embryos already in storage on 1 July 2022 can vary their consent to storage.

17.44 Centres should review the circumstances of donors before contacting them to ask if they wish to consider varying their consent to storage as this could present risks relating to confidentiality. It may be appropriate to contact a donor to ask if they wish to consent to further storage if:

(a) The gametes or embryos have been allocated to a patient who still wishes to use the gametes or embryos for their treatment but the storage period is shortly due to end.
(b) The gametes or embryos have not yet been used to create 10 families and storing them for longer could help potential recipients, especially, for example, if the material is from a donor from an ethnic background from which it is hard to recruit donors.

17.45 Where centres decide to contact donors, they should take all necessary steps to avoid breaching the donor's confidentiality and before seeking the donor's consent, centres must provide relevant information about the change in the law and implications of varying their consent. Centres should consider whether they should also offer implications counselling.

17.46 Centres contacting donors should consider the following:
(a) Donors may not be expecting any further contact from the centre and therefore receiving unexpected correspondence or communication may cause them emotional distress or harm.
(b) The donor's circumstances may have changed, and their family or current partner may not be aware of their donation. Correspondence or communication from the centre could potentially breach the donor's confidentiality (breach of section 33A 1990 Act). The donor's partner or relative could also access any correspondence.
(c) Contact details may no longer be correct and correspondence going to a last known address may be opened by the new residents.
(d) Risks could be mitigated by for example, using the donor's preferred method of contact or considering whether it is appropriate to contact donors who have not maintained contact with the centre since donating. Once contact has been made centres should follow the required steps to obtain renewal of consent as set out at section x.

(e)

Donor gametes or embryos already in storage where consent to storage ended on or before 30 June 2022

17.47 In cases where donated gametes or embryos were in storage on or before 1 July 2022 without effective consent to continued storage, storage of those gametes or embryos up to the end of the Transitional Period will not be unlawful. However, any gametes or embryos in storage without effective consent cannot be used in treatment until effective consent to storage is in place. Clinics should have contacted the gamete provider by 30 June 2023 to request that they consent to storage. If the gamete provider has not given consent to storage by 30 June 2024, the gametes or embryos must be removed from storage and disposed of on that date.

Donor gametes and embryos currently in storage where consent to storage was given on or before 30 June 2022 and remains effective after 1 July 2022

17.48 Donors who donated prior to 1 July 2022 may have given a consent to storage for 55 years (for use by prematurely infertile patients), but centres should not assume that this consent will remain effective following the changes to the Act on 1 July 2022. Guidance on considerations pertaining to whether this consent would remain effective can be found at section 7.3 of the Clinic Guide.

17.49 Gamete and embryo donors who donated on or before 1 July 2022, can vary (or withdraw) their consent. They can provide consent to storage for up to a maximum of 55 years from the date their donated gametes or embryos were first placed in storage if they wish to, without needing to renew consent. In these circumstances, centres should ensure that donors record their variation of consent using the relevant HFEA consent form before their consent to storage expires.

Gametes placed in storage for training or research purposes on or before 30 June 2022

17.50 Gametes that were placed in storage for training or research purposes on or before 30 June 2022 can be stored for a maximum of 55 years, calculated from the date that they were first placed in storage. Gamete providers do not need to renew their consent to storage.

Embryos placed in storage for training or research purposes on or before 30 June 2022

17.51 Before 1 July 2022, embryos that were placed in storage for training or research purposes were subject to a maximum storage period of 10 years, calculated from date of first storage applied to these embryos. After 1 July 2022, the same maximum storage period will continue to apply to embryos that were placed in storage for training or research purposes on or before 30 June 2022. Accordingly, those embryos can be stored for a maximum of 10 years from the date of first storage or, where applicable, any shorter period of storage to which the gamete provider consented to.

Facilities and documented procedures

17.52 The centre should establish documented procedures to ensure that all storage and handling of gametes and embryos comply with licence conditions, regulations, and relevant patient and donor consent.

17.53 The centre should ensure that the storage facilities for gametes and embryos:

(a) are dedicated for the purpose, and adequate for the volume and types of activities
(b) are designed to avoid proximity to ionising radiation (radioactive material), any known potential source of infection, or chemical or atmospheric contamination, and
(c) have a storage-location system that minimises the amount of handling required to retrieve gametes and embryos.

17.54 The centre should also have emergency procedures to deal with damage to storage vessels, failure of storage conditions or both. A contingency plan should be in place to be used in the event of:

(a) a suspension of parts or all of a centre's services or
(b) centre closure.

17.55 The centre's documented procedures should also ensure that:

(a) gametes and embryos are stored under controlled conditions that are validated and monitored
(b) gametes and embryos are packaged for storage in a way that:

  (i) prevents any adverse effects on the material
  (ii) minimises the risk of contamination

(c) records are kept indicating every occasion when gametes and embryos are handled during storage and release, and by whom
(d) records are kept indicating that gametes and embryos meet requirements for safety and quality before release, and
(e) risk assessments (approved by the person responsible) are done to determine the fate of all stored material whenever any of the following is introduced:

  (i) a new donor selection criterion
  (ii) a new criterion for testing donors, patients' partners or patients
  (iii) a new processing step to enhance safety, quality or both
  (iv) a new procedure for appropriate disposal of gametes and embryos.

Safety of equipment used to store cryopreserved gametes and embryos

17.56 Centres should store gametes and embryos in a designated area. Access to this area should be limited to staff authorised under the terms of the centre's licence. Cryopreservation dewars should be fitted with local alarms and be linked to an auto-dial or similar facility, (eg, a link to a fire alarm board) to alert staff to non-conformities outside normal working hours.

17.57 The centre should have adequate staff and funding for an 'on-call' system for responding to alarms out of hours, and adequate spare storage capacity to enable transfer of samples if a dewar fails.

17.58 A centre storing gametes and/or embryos for patients whose future fertility may be impaired by a medical condition or procedure should divide individual patients' samples into separate storage vessels, in case of dewar failure.

See also

Guidance note 26 – Equipment and materials

Screening and storage of samples to prevent cross-contamination

Interpretation of mandatory requirements 17I

The law requires centres to obtain blood samples for HIV 1 and HIV 2, hepatitis B and

hepatitis C screening from patients and their partners within three months before they first provide their gametes for use in treatment. Where the same person provides gametes for further treatment of their partner, the centre must obtain new blood samples within two years of the previous sampling. Patients who have screening tests at one licensed clinic and then move to another do not have to have repeat screening tests if within these timescales. However, individual clinics must decide whether the appropriate screening has taken place in the required timeframe. These screening requirements apply to individuals who provide gametes, or embryos created with their gametes, that will be processed or stored.

Where treatment involves the use of gametes, or embryos created with gametes, from two people who are not in an intimate physical relationship:

(a) the person providing the gametes to the woman being treated must be screened according to licence condition T52 on donor screening

(b) the centre, in discussion with the patient, should consider the merit of additional donor screening in line with guidance by professional bodies.

17.59 The centre should ensure that no gametes or embryos are placed in storage unless the people who provided the gametes have been screened in accordance with current recommended professional guidelines.

17.60 Centres should:

(a) assess the risks of cross-contamination during the quarantine period
(b) put procedures in place to minimise these risks, and
(c) document the rationale for the chosen quarantine procedures.

See also

Guidance note 15 – Procuring, processing and transporting gametes and embryos

Guidance note 19 – Traceability

Guidance note 20 – Donor assisted conception

Storing ovarian and testicular tissue

Interpretation of mandatory requirements 17J

Ovarian and testicular tissue, as cells of the germ line, fall within the definition of gamete in the Human Fertilisation and Embryology Act 1990 (as amended) and so are subject to the same storage requirements as sperm and eggs.

HFEA-licensed clinics currently storing ovarian or testicular tissue can continue to do so without a licence from the Human Tissue Authority (HTA) until the tissue is to be used. If a patient's own tissue is to be transplanted (known as autologous transplant), it must be transferred at the time of use to an

HTA-licensed facility for processing and/or distribution to the transplant facility. Details of HTA-licensed facilities are on the HTA website.

An HTA licence is not needed to store ovarian or testicular tissue intended for fertility treatment (eg, in vitro maturation of gametes). HFEA centres licensed to store gametes can store, process and use

ovarian or testicular tissue to extract gametes for patients' own use in licensed fertility treatment, subject to the same conditions that apply to the use of sperm and eggs.

Storing gametes and embryos following mitochondrial donation

17.61 Only centres that are licensed to undertake mitochondrial donation can store gametes or embryos following maternal spindle transfer or pronuclear transfer.

Storing gametes and embryos that have been imported into the UK

17.62 The maximum storage periods for gametes and embryos are calculated from when these are first placed in storage at a UK centre.

17.63 If gametes or embryos are exported from the UK and imported back into the UK at a later date, the centre should exclude the period of time the samples were out of the UK when calculating the remaining storage period. When a centre receives gametes or embryos that have been imported back into the UK after being in storage abroad, the period of time they were stored outside of the UK should not be included when calculating their remaining maximum storage period or the time until renewal of consent is required. Gametes or embryos must not be stored for longer than the period of storage that patients have consented to.

17.64 If the receiving centre was not the first UK centre to store the gametes or embryos, they should contact the UK clinic (or clinics) that previously stored the gametes or embryos to confirm how long they were stored before the export(s) took place. Copies of records relating to storage dates and all previous transfers of gametes or embryos out of, and back into, the UK should be obtained and retained to ensure that the period of storage in the UK can be accurately calculated and evidenced.

See also

Guidance note 4 – Information to be provided prior to consent

Guidance note 5 – Consent to treatment, storage, donation and disclosure of information

HFEA consent forms

Treatment using cryopreserved eggs or embryos

17.65 The centre should ensure that the following sets of eggs or embryos are only transferred during the same treatment cycle in exceptional circumstances, with an upper limit of 2% of all cases:

(a) fresh eggs and eggs that have been cryopreserved, or
(b) embryos that have been created using cryopreserved eggs, and embryos created using fresh eggs, or
(c) cryopreserved embryos that have been created using cryopreserved eggs and cryopreserved embryos that have been created using fresh eggs.

The circumstances justifying such a transfer should be specified in the patient's notes.

Consent to storage and cases where consent is not required for storage

Interpretation of mandatory requirements 17K

The law requires the centre to obtain written, informed consent from a person before storing their gametes or embryos created with their gametes, and gametes or embryos must not be kept in storage unless they are stored in accordance with the consent given. There must be effective consent to storage and storage in accordance with that consent at all times, without any gaps in consent.

In very limited circumstances, the law allows gametes to be stored without consent. Those circumstances are set out in paragraphs 9 and 10 of Schedule 3 of the HFE Act 1990 (as amended). A person's gametes must not be kept in storage under either paragraph 9 or 10 after their death. Gametes stored by virtue of either of these paragraphs may only be used if the person from whom they were collected gives written, effective consent to their use.

For guidance about steps to take when consent is not required, see guidance note 5 – Consent to treatment, storage, donation, and disclosure of information.

See also

Guidance note 5 – Consent to treatment, storage, donation and disclosure of information

HFEA consent forms

Disputes involving the withdrawal of consent to storage

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Schedule 3

Consent to use or storage of gametes, embryos or human admixed embryos etc 4A

(1) This paragraph applies where -

(a) a permitted embryo, the creation of which was brought about in vitro, is in storage,
(b) it was created for use in providing treatment services,
(c) before it is used in providing treatment services, one of the persons whose gametes were used to bring about its creation ("P") gives the person keeping the embryo notice withdrawing P's consent to the storage of the embryo, and
(d) the embryo was not to be used in providing treatment services to P alone.

(2) The person keeping the embryo must as soon as possible take all reasonable steps to notify each interested person in relation to the embryo of P's withdrawal of consent.

(3) For the purposes of sub-paragraph (2), a person is an interested person in relation to an embryo if the embryo was to be used in providing treatment services to that person.

(4) Storage of the embryo remains lawful until-

(a) the end of the period of 12 months beginning with the day on which the notice mentioned in sub-paragraph (1) was received from P, or

(b) if, before the end of that period, the person keeping the embryo receives a notice from each person notified of P's withdrawal under sub-paragraph (2) stating that the person consents to the destruction of the embryo, the time at which the last of those notices is received.

(5) The reference in sub-paragraph (1)(a) to a permitted embryo is to be read in accordance with section 3ZA.

Renewal of consent to storage of embryos

11C (14) Storage of the embryo remains lawful until—

(a) the end of the period of 6 months beginning with the day on which P's consent is taken as withdrawn under this paragraph, or

(b) if, before the end of that period, K receives a notice from each person notified under sub-paragraph (13) stating that the person consents to the disposal of the embryo, the time at which the last of those notices was received.

Interpretation of mandatory requirements 17 L

If one of the gamete providers withdraws consent to the continued storage of embryos intended for treatment (created from their gametes), the law requires the centre to take all reasonable steps to notify each interested person, including the intended recipient(s).

When (only) one gamete provider has **withdrawn their consent** to storage of embryos, ongoing storage for up to 12-months from the date on which consent was withdrawn is lawful, unless or until the point at which each interested person has also withdrawn their consent. After the 12-month 'cooling off' period the centre must remove the embryos from storage and dispose of them. However, if the period to which effective consent to storage was previously given expires before the 12 months, embryos must be removed from storage and disposed of by that date. For guidance about the withdrawal of consent see guidance note 5 – Consent to treatment, storage, donation, and disclosure of information.

When (only) one gamete provider has **failed to renew their consent** to storage of embryos before the end of the Renewal Period and their consent is **taken as having been withdrawn**, ongoing storage for a further 6-month period from the end of the Renewal Period is lawful unless, before the end of that period, the centre receives a notice from each gamete provider confirming their consent to the disposal of the embryo (further guidance can be found at 17F). After this 6-month period the centre must remove the embryos from storage and dispose of them.

17.66 If an Order from a Court is obtained requiring that the centre continue to store gametes or embryos, the centre should comply with that Order. If centres receive credible information or formal notice that legal proceedings are about to be commenced by a patient, notwithstanding that continued storage may be unlawful, it is reasonable for the centre to continue storing the gametes or embryos for a short period to enable an application to be made to a Court and thereafter, in accordance with any order made by the Court in the course of those proceedings. Where this happens, centres must notify their inspector as soon as they become aware of any threatened or actual legal proceedings. This approach is justified to enable an application to be made to a Court and for the Court to determine if storage should be maintained pending a final determination. If legal proceedings are not commenced promptly centres will be expected to remove the gametes or embryos from storage and dispose of them.

See also

Guidance note 5 – Consent to treatment, storage, donation and disclosure of information

HFEA consent forms

Storage review

17.67 The centre should establish documented procedures to ensure that:

a. reviews of stored gametes and embryos are done at least once every two years to:

   (i) reconcile the centre's records with material in storage

   (ii) review the purpose and duration of storage

   (iii) ensure that any actions relating to storage will be flagged by the bring-forward system at the appropriate time. For example, when any statutory notices need to be sent to patients as part of the renewal of consent process, and

   (iv) identify any action needed

b. if the number of families created using gametes (or embryos created using donated gametes) from a particular donor has reached 10, those gametes or embryos are not used or distributed for use in further treatment.

See also

Guidance note 11 – Donor recruitment, assessment and screening

Guidance note 20 – Donor assisted conception

17.68 The centre should operate a bring-forward system in order to ensure sufficient advance notice of the end of the Consent Period, or any shorter period as specified by a person who provided the gametes, for gametes or embryos in storage. The centre should ensure the bring-forward system links to processes regarding storage periods.

Bring-forward systems

17.69 Centres should have a **bring-forward system** in place which creates alerts when a patient's Renewal Period is approaching. The alert should be set long enough in advance for centres to contact the patient in writing before the start of the Renewal Period asking whether they wish to renew their consent.

17.70 The bring-forward system should also alert centres in advance of the expiry of any shorter period to which a patient consented and before reaching the maximum permitted storage period.

17.71 Centres should contact patients using all contact details available to them, including at least one written form of contact.

17.72 Centres should also ensure their bring-forward systems alert them prior to the end of the maximum storage period.

End of storage

Interpretation of mandatory requirements 17M

No centre may keep embryos or store gametes after the expiry of the maximum storage period, or after the end of any shorter period specified by the gamete provider(s). Storing embryos or gametes in the absence of consent is a criminal offence, punishable by a prison sentence, fine or both.

17.73 At the end of storage, patients should be provided with information about the options available to them and be given enough notice to enable them to consider those options and to access appropriate advice. Options could include the donation of the gametes or embryos for research, training or, where continued storage for treatment is possible, for the treatment of others.

17.74 If contact with the patient is not possible, the centre should record the steps it has taken in the patient's medical records.

Other legislation, professional guidelines and information

Professional guidelines

Association of Biomedical Andrologists, Association of Clinical Embryologists, British Andrology Society, British Fertility Society and Royal College of Obstetricians and Gynaecologists: UK guidelines for the medical and laboratory screening of sperm, oocyte and embryo donors (2019)

Department of Health: Guidance on the microbiological safety of human organs (2011)

The Human Tissue Authority: The regulator for human tissue and organs

Clinic Focus articles

Clinic Focus article: Storage period for imported gametes (July 2019)

Chair's letters

Chair's Letter CH(03)03: Withdrawal of consent to storage (May 2003)

Chair's letter CH(22)03: Important changes to storage rules following changes to the HFE Act 1990

General Directions

Directions | HFEA

Other information

HFEA Portal - New storage laws

Annex 10

19. Traceability

Version 3.0

The United Kingdom (UK) left the European Union (EU) on 31 January 2020, and the Implementation Period (IP) ended at 11pm on 31 December 2020. The Human Fertilisation and Embryology Act 1990 (HF&E Act) continues to apply UK wide, with some amendments resulting in certain provisions applying to centres in Northern Ireland (NI) only and other amendments applying to centres in Great Britain (England, Wales and Scotland) only.

Where there are distinct Licence Conditions or guidance for centres in NI, the NI guidance has been highlighted below, within a light grey box.

Except in those cases where different requirements are highlighted, requirements and guidance in the Code apply to clinics in both NI and GB.

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

2 Other terms

(1) "traceability" means the ability -

(a) to identify and locate gametes and embryos during any step from procurement to use for human application or disposal,

(b) identify the donor and recipient of particular gametes or embryos,

(c) to identify any person who has carried out any activity in relation to particular gametes or embryos, and

(d) to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

12 General Conditions

(3) It shall be a condition of every licence to which this subsection applies that -

(a) such information as is necessary to facilitate the traceability of gametes and embryos, and

(b) any information relating to the quality or safety of gametes or embryos, shall be recorded and provided to the Authority upon request.

Schedule 3A

Traceability system

1 Licence conditions shall require that all persons to whom a licence applies adopt such systems as the Authority considers appropriate to secure compliance with the requirements of Article 8 of the first Directive (traceability) and Article 9 of the third Directive (traceability).

Licence conditions

T99 The centre must establish, implement and comply with documented procedures to ensure that:

a. all gametes and embryos, and
b. all relevant data relating to anything coming into contact with those gametes or embryos

are traceable from procurement of gametes to patient treatment or disposal and vice versa.

T100 for centres in Great Britain

T100 The documented procedures referred to in licence condition T99 include the following information:

a. the unique and accurate identification of each patient/donor
b. the unique and accurate identification of each set of gametes and embryos
c. date of procurement
d. place of procurement
e. type of treatment
f. description and origin of any and all products associated with the procurement, processing, use and storage of gametes and embryos, and
g. description of all processing steps applied to the procurement, use and storage of gametes and embryos.

T100 for centres in Northern Ireland

T100 The documented procedures referred to in licence condition T99 include the following information:

a. the unique and accurate identification of each patient/donor
b. the unique and accurate identification of each set of gametes and embryos, including the Single European Code applied to each set of gametes and embryos when required by General Direction 0013 (NI)
c. date of procurement
d. place of procurement
e. type of treatment
f. description and origin of any and all products associated with the procurement, processing, use and storage of gametes and embryos, and
g. description of all processing steps applied to the procurement, use and storage of gametes and embryos.

T101 for centres Great Britain

T101 The centre must ensure that all containers (dishes, vials, ampoules, tubes etc) used in the course of procurement, processing, use and storage of gametes and embryos are labelled with the patient's/donor's full name and a further identifier. If at some stages (eg, labelling patient/donor sperm) it is not possible to label the dishes or tubes with the patient/donor name then it must be ensured that the patient/donor code used is uniquely identifying.

T101 for centres Northern Ireland

T101 The centre must ensure that all containers (dishes, vials, ampoules, tubes etc) used in the course of procurement, processing, use and storage of gametes and embryos are labelled with the patient's/donor's full name and a further identifier. If at some stages (eg, labelling patient/donor sperm) it is not possible to label the dishes or tubes with the patient/donor name then it must be ensured that the patient/donor code used is uniquely identifying.

Containers holding gametes and embryos or the paperwork attaching to any containers must be labelled with a Single European Code in those circumstances specified in General Direction 0013 (NI).

T102	The centre must record such information as is necessary to facilitate the traceability of gametes and embryos and any information relating to the quality or safety of gametes and embryos. This information must be provided to the Authority upon request.
T103	The centre must keep data necessary to ensure traceability for a minimum of 30 years (and for such longer period as may be specified in Directions) in an appropriate readable storage medium.
T104	Records not covered by licence condition T103 and test results that impact on the safety and quality of the embryos and gametes, must be kept so as to ensure access to the data for at least 10 years after the expiry date, clinical use or disposal.

HFEA guidance

Traceability requirements

19.1 Procedures for ensuring traceability of gametes and embryos should be documented. Centres should ensure that:

(a) they uniquely and accurately identify:

(i) the patient
(ii) the patient's partner, donor or both, as applicable
(iii) gametes and embryos, and
(iv) any containers used for the receipt and distribution of gametes and embryos.

(b) quarantined, non-quarantined and rejected material is clearly distinguishable at all processing stages.
(c) they keep records of the equipment and materials used to receive, process, store and discard gametes and embryos
(d) they keep registers of received, processed, stored, distributed and discarded gametes or embryos. Registers should enable a centre to investigate adequately if a problem is identified after the gametes have been used. Registers should also enable the centre to identify:

(i) a patient, patient's partner or donor
(ii) processing steps applied to gametes or embryos (or both) and, if applicable, third parties involved in processing
(iii) individual procurement of gametes and embryos
(iv) the institution from which gametes and embryos have come
(v) distributed gametes or embryos, and
(vi) the institutions to which gametes or embryos have been sent (whether for a patient's use or for research).

19.2 For the system of identification, centres should use an identifying code that contains at least the following information:

(a) for donors:

(i) their identity, and
(ii) the centre's identity.

(b) for gametes and embryos:

i) a unique code
ii) split number (if applicable), and
iii) end of statutory storage period.

19.3 The centre's traceability procedures should cover any materials or equipment that could affect the quality or safety of gametes and embryos, for example:

(a) culture media
(b) serial numbers or batch numbers of equipment and materials coming into contact with gametes and embryos, and
(c) records of the monitoring and maintenance of the required conditions in incubators and storage tanks.

See also

Guidance note 26 – Equipment and materials

19.4 For gametes that have been stored at the centre (eg, for oncology or pre-vasectomy patients) and then supplied to another centre (eg, to be stored or used in treatment), the centre will not be expected to hold traceability data for subsequent processes involving those gametes outside the centre. However, the storing centre's record keeping procedures should show a link to the centre to which the gametes are supplied, so that the complete process from procurement to use or disposal can be traced if needed.

Single European Code (SEC) for centres in Northern Ireland

19.5 For details on the SEC requirements for centres in NI, please see guidance note 15.

Annex 11

22. Research and training

Version 4.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

3 Prohibitions in connection with embryos

(2) No person shall place in a woman -

(a) an embryo other than a permitted embryo (as defined by section 3ZA), or

(b) any gametes other than permitted eggs or permitted sperm (as so defined).

(3) A licence cannot authorise -

(a) keeping or using an embryo after the appearance of the primitive streak,

(b) placing an embryo in any animal, or

(c) keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use.

(4) For the purposes of subsection (3)(a) above, the primitive streak is to be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with the day on which the process of creating the embryo began, not counting any time during which the embryo is stored.

4A Prohibitions in connection with genetic material not of human origin

(1) No person shall place in a woman -

(a) a human admixed embryo,

(b) any other embryo that is not a human embryo, or

(c) any gametes other than human gametes.

14 Conditions of licences for treatment

(12) No embryo appropriated for the purpose mentioned in paragraph 1(1)ca of Schedule 2 (training in embryological techniques) shall be kept or used for the provision of treatment services.

15 Conditions of research licences

(1) The following shall be conditions of every licence under paragraph 3 of Schedule 2 to this Act.

(2) The records maintained in pursuance of the licence shall include such information as the Authority may specify in directions about such matters as the Authority may so specify.

(3) No information shall be removed from any records maintained in pursuance of the licence before the expiry of such period as may be specified in directions for records of the class in question.

(4) No embryo appropriated for the purposes of any project of research shall be kept or used otherwise than for the purposes of such a project.

12 General conditions

(1) The following shall be conditions of every licence granted under this Act -

(a) except to the extent that the activities authorised by the licence fall within paragraph (aa), that those activities shall be carried on only on the premises to which the licence relates and under the supervision of the person responsible,

41 Offences

(1) A person who -

(a) contravenes section 3(2), 3A or 4A(1) of this Act, or

(b) does anything which, by virtue of section 3(3) of this Act, cannot be authorised by a licence,

is guilty of an offence and liable on conviction on indictment to imprisonment for a term not exceeding ten years or a fine or both.

(2) A person who -

(a) contravenes section 3(1) or (1A) of this Act, otherwise than by doing something, which by virtue of section 3(3) of this Act, cannot be authorised by a licence

Schedule 2

is guilty of an offence.

Licences for treatment

1 (1) A licence under this paragraph may authorise any of the following in the course of providing treatment services –

(ca) using embryos for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques,

Licences for research

3 (1) A licence under this paragraph may authorise any of the following -

(a) bringing about the creation of embryos in vitro, and

(b) keeping or using embryos,

for the purposes of a project of research specified in the licence.

(2) A licence under this paragraph may authorise mixing sperm with the egg of a hamster, or other animal specified in Directions, for the purpose of developing more effective techniques for determining the fertility or normality of sperm, but only where anything which forms is destroyed when the research is complete and, in any event, no later than the two cell stage.

(3) A licence under this paragraph may authorise any of the following -

(a) bringing about the creation of human admixed embryos in vitro, and

(b) keeping or using human admixed embryos,

for the purposes of a project of research specified in the licence.

(4) A licence under sub-paragraph (3) may not authorise the activity which may be authorised by a licence under sub-paragraph (2).

(5) No licence under this paragraph is to be granted unless the Authority is satisfied that any proposed use of embryos or human admixed embryos is necessary for the purposes of the research.

(6) Subject to the provisions of this Act, a licence under this paragraph may be granted subject to such conditions as may be specified in the licence.

(7) A licence under this paragraph may authorise the performance of any of the activities referred to in sub-paragraph (1), (2) or (3) in such manner as may be so specified.

(8) A licence under this paragraph may be granted for such period not exceeding three years as may be specified in the licence.

(9) This paragraph has effect subject to paragraph 3A.

Purposes for which activities may be licensed under paragraph 3

3A (1) A licence under paragraph 3 cannot authorise any activity unless the activity appears to the Authority -

(a) to be necessary or desirable for any of the purposes specified in sub-paragraph (2) ("the principal purposes"),

(b) to be necessary or desirable for the purpose of providing knowledge that, in the view of the Authority, may be capable of being applied for the purposes specified in sub-paragraph (2)(a) or (b), or

(c) to be necessary or desirable for such other purposes as may be specified in regulations.

(2) The principal purposes are -

(a) increasing knowledge about serious disease or other serious medical conditions,

(b) developing treatments for serious disease or other serious medical conditions,

(c) increasing knowledge about the causes of any congenital disease or congenital medical condition that does not fall within paragraph (a),

(d) promoting advances in the treatment of infertility,

(e) increasing knowledge about the causes of miscarriage,

(f) developing more effective techniques of contraception,

(g) developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation, or

(h) increasing knowledge about the development of embryos.

General

4 (1) A licence under this Schedule can only authorise activities to be carried on -

(a) on premises specified in the licence or, in the case of activities to which section 3(1A)(b) or (1B) or 4(1A) applies, on relevant third party premises, and

(b) under the supervision of an individual designated in the licence.

(1A) A licence which authorises activities falling within paragraph 1 or 1A above may not also authorise activities falling within paragraph 3 above.

(2) A licence cannot -

(a) authorise activities falling within both paragraph 1 [Licenses for treatment] and paragraph 3 above,

(b) apply to more than one project of research,

(c) authorise activities to be carried on under the supervision of more than one individual, or

(d) apply to premises of the person who holds the licence in different places.

Schedule 3

Consent

2 (1) A consent to the use of any embryo must specify one or more of the following purposes -

…

(ba) use for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques, or

(c) use for the purposes of any project of research,

and may specify conditions subject to which the embryo may be so used.

Variation and withdrawal of consent

4 (1) The terms of any consent under this Schedule may from time to time be varied, and the consent may be withdrawn, by notice given by the person who gave the consent to the person keeping the gametes, human cells, embryo or human admixed embryo to which the consent is relevant.

(1A) Sub-paragraph (1B) applies to a case where an egg is used in the process set out in regulation 4 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 (and "egg A" and "egg B" have the same meanings in this paragraph as in that regulation).

(1B) The terms of the consent to that use of egg A or egg B cannot be varied, and such consent cannot be withdrawn, once all the nuclear DNA of egg B which is not polar body nuclear DNA is inserted into egg A.

(2) Subject to sub-paragraphs (3) to (3B), the terms of any consent to the use of any embryo cannot be varied, and such consent cannot be withdrawn, once the embryo has been used -

(aa) in training persons in embryo biopsy, embryo storage or other embryological techniques, or

(b) for the purposes of any project of research.

(3) Where the terms of any consent to the use of an embryo ("embryo A") include consent to the use of an embryo or human admixed embryo whose creation may be brought about in vitro using embryo A, that consent to the use of that subsequent embryo or human admixed embryo cannot be varied or withdrawn once embryo A has been used for one or more of the purposes mentioned in sub-paragraph (2)(a) or (b).

(3A) Sub-paragraph (3B) applies to a case where an embryo is used in the process set out in regulation 7 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 (and "embryo A" and "embryo B" have the same meanings in sub-paragraph (3B) as in that regulation).

(3B) The terms of the consent to that use of embryo A or embryo B cannot be varied, and such consent cannot be withdrawn, once all the nuclear DNA of embryo B which is not polar body nuclear DNA is inserted into embryo A…

In vitro fertilisation and subsequent use of embryos

6 (1) A person's gametes or human cells must not be used to bring about the creation of any embryo in vitro unless there is an effective consent by that person to any embryo, the creation of which may be brought about with the use of those gametes or human cells, being used for one or more of the purposes mentioned in paragraph 2(1) … (c) above.

(2) An embryo the creation of which was brought about in vitro must not be received by any person unless there is an effective consent by each relevant person in relation to the embryo to the use for one or more of the purposes mentioned in paragraph 2(1) … (ba) and (c) above of the embryo.

(3) An embryo the creation of which was brought about in vitro must not be used for any purpose unless there is an effective consent by each relevant person in relation to the embryo to the use for that purpose of the embryo and the embryo is used in accordance with those consents.

Embryos obtained by lavage etc.

7 (1) An embryo taken from a woman must not be used for any purpose unless there is an effective consent by her to the use of the embryo for that purpose and it is used in accordance with the consent.

(2) An embryo taken from a woman must not be received by any person for use for any purpose unless there is an effective consent by her to the use of the embryo for that purpose.

(4) An embryo taken from a woman must not be used to bring about the creation of any embryo in vitro or any human admixed embryo in vitro.

Regulations

The Human Fertilisation and Embryology (Special Exemptions) Regulations 2009

Licence conditions

R18 The provisions of Schedule 3 to the Human Fertilisation and Embryology Act 1990 (as amended) must be complied with (relating to consent to the use of embryos and human admixed embryos and for the storage of gametes, embryos and human admixed embryos for use in research).

R19 Prior to giving consent, persons providing gametes or human cells must be provided with the necessary information including:

a. the nature of the research project

b. that the decision whether to donate will not affect their treatment in any way

c. that they can vary or withdraw the terms of their consent until the point the embryos or human admixed embryos are used in the project of research

d. whether the embryos or human admixed embryos will be reversibly or irreversibly anonymised, and the implications of this

e. whether any information will be fed back to the them, and

f. how the research is funded, including any benefit which will accrue to the researchers and/or their departments.

g. that they may consent to the storage of their gametes for research purposes for up 55 years, calculated from the day on which they are first placed in storage

h. that they may consent to the storage and use of their embryos for research purposes for up to 10 years beginning with the day on which consent to research was given, and

i. that they may consent to storage of any admixed embryos created using their gametes for up to 10 years beginning with the day on which they are first placed in storage.

R20 Prior to giving consent persons providing gametes or human cells for use in research that involves the derivation of embryonic stem cells/lines, must be provided with the following additional information:

a. that once an embryo or human admixed embryo has been used in the project of research they will have no control over any future use of the embryonic cells or any stem cells derived

b. that any stem cells/lines created may continue indefinitely and be used in many different research projects and/or clinical therapy

c. that stem cells derived in this research project will be deposited in the UK Stem Cell Bank and the implications of this including that they may be available to other research groups nationally or internationally

d. that the stem cells/lines may be used for commercial purposes, but that they will not benefit financially from this, and

e. that any stem cells/lines derived or discoveries made using them, could be patented, but that they will not benefit financially from this.

R21 The information referred to in licence conditions R19 and R20 must be given by trained personnel in a manner and using terms that are easily understood by the persons providing gametes or human cells.

R22 The centre must ensure that a designated individual, who is not directly involved in the patient's treatment is available to discuss with the patient the project of research and the possibility of donating material to the project.

R23 No embryo/human admixed embryo obtained for the purposes of any research project may be kept or used for any purpose other than the purposes of that research project.

R24 No money or other benefit must be given or received in respect to any supply of gametes, embryos or human admixed embryos unless authorised by Directions.

R26 Each embryo or human admixed embryo must be uniquely labelled in accordance with any directions and/or guidance issued by the Authority.

R27 The centre must establish, implement and comply with documented procedures to ensure that clinical and research roles are separated.

R28 The centre must establish, implement and comply with documented procedures to ensure that embryos or human admixed embryos do not develop after 14 days or the primitive streak has appeared (if earlier).

R29 If embryos or human admixed embryos have been created using human cells that have been stored before 1 October 2009 then the centre must take steps to ensure that the embryos or human admixed embryos cannot subsequently be attributed to the person whose cells were so used.

R31 Gametes of a person must only be placed in storage (for use in licensed research) only if

a. received from that person

b. acquired in circumstances in which by virtue of paragraphs 9 and 10 of Schedule 3 to the Human Fertilisation and Embryology Act 1990 (as amended) that person's consent to the storage is not required, or

c. acquired from a person to whom a licence or third party agreement applies.

R32 Embryos taken from a woman must be placed in storage only if –

a. received from that woman, or

b. acquired from a person to whom a licence or third party agreement applies.

R33 Embryos which have been created in vitro otherwise than in pursuance of this licence must be placed in storage only if acquired from a person to whom a licence or third party agreement applies.

R34 Human admixed embryos which have been created in vitro otherwise than in pursuance of this licence must be placed in storage only if acquired from a person to whom a licence under paragraph 2 or 3 of Schedule 2 to the Human Fertilisation and Embryology Act 1990 (as amended) applies.

R35 Gametes must not be kept in storage for longer than such period not exceeding 55 years beginning with the day on which they are first placed in storage. The statutory storage period in respect of gametes is such period not exceeding ten years as the licence may specify.

R36 a. Embryos kept in storage for research purposes1 must not be so kept for longer than such period not exceeding 10 years beginning with the day on which consent was given under Schedule 3 to the storage of embryos for that purpose.

b. Where consent is given to the storage of embryos for research purposes by different persons on different days, the reference to the day on which consent was given is to be taken as a reference to the last of those days. The statutory storage period in respect of embryos is such period not exceeding ten years as the licence may specify.

R37 Human admixed embryos must not be kept in storage for longer than such period not exceeding 10 years beginning with the day on which they are first placed in storage. The statutory storage period in respect of human admixed embryos is such period not exceeding ten years as the licence may specify.

R38 Regulations may provide that licence conditions R35, R36 and R37 must have effect as if for ten years there were substituted -

a. such shorter period, or

b. in such circumstances as may be specified in the relevant Regulations, such longer period, as may be specified in the relevant Regulations.

R39 No gametes, embryos or human admixed embryos shall be kept in storage for longer than the statutory storage period and, if stored at the end of the period, must be allowed to perish.removed from storage and disposed of.

T92 Embryos kept in storage for training[3] or research but not for treatment purposes must not be so kept for longer than such period not exceeding 10 years beginning with the day on which consent to the storage of the embryo for that purpose was given under Schedule 3.

a. Where consent under Schedule 3 is given to the storage of an embryo for training or research purposes by different persons on different days, the day on which consent was given is to be taken as a reference to the last of those days.

b. No embryo appropriated for the purpose of training staff in embryological techniques must be kept or used for the provision of treatment services.

T93 Embryos may only be used, for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques and in those activities that are expressly authorised by the Authority.

T94 Embryos may only be used, for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques, where both gamete providers have consented to the use of embryos, created using their gametes, for the purpose of training.

T95 The centre must have procedures in place to ensure that there is no actual or perceived conflict of interest between the use of embryos in training and the use of embryos in the provision of treatment services.

This would normally consist of:

a. having a designated individual, who is not directly involved in the patient's treatment, to discuss with the patient the training activity and the possibility of donating material for it; and

b. making sure that the person obtaining consent for the use of the embryos in training is not involved in the training project.

Where limited staffing makes this difficult to achieve, the centre must develop its own robust procedures for ensuring that the conflict of interest requirement is met.

T97 Prior to giving consent, each gamete provider must be provided with the necessary information including:

a. the nature of the training for which embryos will be used

b. that the decision whether to donate will not affect their treatment in any way

[3] "Training purpose" is the purpose referred to in paragraph 2(1) (ba) of Schedule 3 of the Human Fertilisation and Embryology Act 1990 and includes use for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques

c. that they can vary or withdraw the terms of their consent until the point the embryos are used in training, and

d. that if they give consent to storage of embryos for training purposes, their embryos may be stored for up to 10 years, calculated from the date consent to storage for training purposes was given, and

e. whether any information will be fed back to them.

T98 The information referred to in licence condition T97 must be given by trained personnel in a manner and using terms that are easily understood by the persons providing gametes.

Directions

0002 – Recording and providing information to the HFEA under a research licence

0008 – Information to be submitted to the HFEA as part of the licensing process

HFEA guidance

General

Interpretation of mandatory requirements 22A

The law prohibits:

(a) embryos being placed in any animal

(b) embryos that are not human being placed in a woman

(c) gametes that are not human being placed in a woman

(d) mixing human gametes with animal gametes, except for when carrying out the 'hamster test' in line with a licence

(e) embryos being kept or used after 14 days from when the process of creating the embryo began, or after the primitive streak has appeared (if earlier than 14 days)

(f) embryos intended for a research project being used for any purposes other than those of that research project

(g) an embryo created or obtained for research being placed in a woman

(h) keeping the results of the 'hamster test' after any research is complete or, in any event, after the two cell stage

(i) a research licence being used for any project other than the one specified in that licence

(j) research activities being carried out on premises other than those specified in the licence

(k) research activities being carried out under the supervision of anyone other than the specific person designated in the licence

(l) a treatment licence authorising the activities of a research project, and

(m) a research licence applying to more than one research project.

The HFE (Special Exemptions) Regulations 2009 allow gametes to be stored without a licence for research on gametes, for developing pharmaceutical or contraceptive products, or for teaching, provided that the gametes are not used for treatment purposes or for other prohibited purposes set out in the Regulations.

22.1 The person named as the person responsible on a research licence should not also be named as the person responsible on a treatment licence.

22.2 The centre should have documented procedures for:

(a) obtaining embryos to be used for research or training purposes, and
(b) obtaining written informed consent from donors for research and training purposes, and ensuring that embryos are used only in line with this consent.

22.3 If embryos or human admixed embryos will be used for research or training purposes, the research centre should record, before the project starts:

(a) the proposed duration of the culture period
(b) the procedure that will be used to ensure that embryos do not develop after 14 days or the primitive streak has appeared (if earlier), and
(c) the method that will be used to terminate development.

22.4 The centre should have documented procedures for ensuring that embryos and human admixed embryos are used within the maximum period of storage permitted by law or within any period of storage specified in the donor's consent (if shorter).

Eggs that have failed to fertilise

22.5 Eggs that have failed to fertilise need not be regarded in the same way as an embryo under the terms of the act if it can be established that the process of fertilisation has permanently halted. Fertilisation has failed if the egg is at least 48 hours old and there is no visible evidence of a pro-nucleus or of a second polar body. Manipulation of eggs that have failed to fertilise can only be carried out without a research licence (eg, in ICSI training) if the eggs are at least 48 hours old and there is no visible evidence of a pro-nucleus or of a second polar body.

See also

Guidance note 17 – Storage of gametes and embryos

Disclosure of interests

22.6 Staff involved in research should follow relevant guidelines produced by the respective professional bodies (eg, the General Medical Council, or the Nursing and Midwifery Council). The centre should ensure that:

(a) all financial interests and sums of money known or estimated to be paid for the research are disclosed to a research ethics committee, and
(b) all members of the research team, including nurses and non-medical staff, are informed about how the research is being financed and managed.

Information provided to donors

Interpretation of mandatory requirements 22B

The law requires that before a person consents to donating embryos, or gametes or cells to be used to create embryos, for research or training, they should be given:

(a) enough information to understand the nature, purpose and implications of their donation, and

(b) information about the procedure for varying or withdrawing any consent given, including the fact that they can do this only until the embryos are used in the research project.

An embryo is regarded as being used in research when any of the methods, techniques or processes associated with the particular licensed research project are applied to it. An embryo is regarded as being used in training when it is under the control of the trainers/trainees or is being cultured for use in training.

Specific additional information must be given to individuals before they consent to any donation of their embryos to research projects involving, or intending to involve, human embryonic stem cell lines.

22.7 The centre should ensure that donors are given information about how the research is funded, including any direct payments or benefits that researchers, their departments or both would receive, and any financial interests the centre has in the research project or in its sponsoring organisations.

22.8 For any research project, the centre should ensure that before donors give their consent to their gametes or embryos, or cells used to create embryos, being used in research, they are given oral information (supported by relevant written material) that confirms:

(a) the specific research project and its aims
(b) details of the research project, including likely outcomes and how any individual donation will impact on the overall project
(c) whether the embryos will be reversibly or irreversibly anonymised, and the implications of this
(d) whether donors will be given any information that is obtained during the research and is relevant to their health and welfare
(e) that donors are expected to have an opportunity to ask questions and discuss the research project
(f) that donating gametes or embryos to research in the course of treatment services will not affect the patient's treatment in any way
(g) that patients are under no obligation to donate gametes and embryos for research and that their decision whether to do so will have no repercussions for any treatment they may receive
(h) that only fresh or frozen gametes and embryos not required for treatment can be used for research
(i) that research is experimental, and so any gametes and embryos used and created for any research project must not be used in treatment
(j) that donors may specify conditions for the use of the gametes or embryos
(k) that after the research has been completed, all donated gametes and embryos will be allowed to perish, and
(l) that, for any individual who donates cells for creating embryos for research, consent to use these cells includes consent to do so after the individual's death, unless stated otherwise.

22.9 If donated gametes or embryos could be used in secondary research, the centre should inform those considering donation of this possibility and explain that:

(a) secondary research could include the fixing of gametes, embryos or embryo cell samples for future studies
(b) secondary research could also include genetic research (the implications of which the centre should describe)
(c) to protect confidentiality, gametes and embryos for secondary research may be anonymised but this may be reversible

(d) if gametes and embryos will be reversibly anonymised and genetic research proposed, those considering donation will be offered counselling about the implications and given the opportunity to reconsider the terms of their consent
(e) if gametes and embryos will be irreversibly anonymised, those considering donation will be fully informed of the implications, ie, that no information or results from the research, including clinically relevant information, could be fed back to them, and
(f) if embryos will be used for stem cell research, those considering donation will be given thorough and appropriate information about the nature of this kind of research and its implications, including that any stem cell lines created may continue indefinitely and be used in different research projects.

22.10 If genetic research will be done on identifiable samples, the centre should:

(a) first inform the donor about the project and what, if any, information may be fed back to them, and
(b) then obtain the explicit consent of those considering donation.

22.11 The centre should ensure that before donors consent to their gametes or embryos being used for training purposes, they are given oral information (supported by relevant written material) that confirms:

(a) the specific training
(b) details of the training, including likely outcomes and how any individual donation will impact on the overall training
(c) whether the gametes or embryos will be reversibly or irreversibly anonymised, and the implications of this
(d) whether any information, obtained during the training, that is relevant to the donor's health and welfare will be fed back to the donor
(e) that donors are expected to have an opportunity to ask questions and discuss the training
(f) that donating gametes or embryos to training in the course of treatment services will not affect the patient's treatment in any way
(g) that patients are under no obligation to donate gametes or embryos for training and that their decision whether to do so will have no repercussions for any treatment they may receive
(h) that only fresh or frozen gametes or embryos not required for treatment can be used for training
(i) that any embryos used in training must not be used in treatment
(j) that donors may specify conditions for the use of the embryos, and
(k) that after the training has been completed, all donated embryos will be allowed to perish.

22.12 If genetic research will be done on identifiable samples, the centre should:

(a) first inform the donor about the training and what, if any, information may be fed back to them, and
(b) then obtain the explicit consent of those considering donation.

Consent

Interpretation of mandatory requirements 22C

The law requires written, signed consent (subject to specific exemption for illness, injury or disability) from any individual before they donate embryos, or gametes or human cells used to create embryos in vitro, for the use in any research project. This consent can be varied or withdrawn at any time until the resulting embryo has been used for the purposes of the research project.

The law requires written, signed consent (subject to specific exemption for illness, injury or disability) from any individual before they donate embryos for training. This consent can be varied or withdrawn at any time until the embryo has been used for training people in embryo biopsy, embryo storage or other embryo techniques.

The HFE (Special Exemptions) Regulations 2009 allow gametes to be stored without a licence for research on gametes, for developing pharmaceutical or contraceptive products, or for teaching, provided that the gametes are not used for treatment purposes.

The law also requires the centre to obtain written informed consent from a person before procuring their gametes

22.13 The centre should obtain written informed consent from a person before using their gametes for research or training.

22.14 If donated material is used for research or training, the centre should ensure that clinical and research roles are separated. Individuals involved in advising patients when making clinical decisions about their licensed treatment should not be involved in research or training that patients are considering donating to.

22.15 If embryos or gametes, or cells used to create embryos, are used for licensed research, the centre should ensure that:

(a) a designated individual who is not directly involved in the donor's treatment (but could be part of the clinical team) is available to discuss with the donor the research project and the possibility of donating material
(b) the individual obtaining consent is suitably trained and qualified, has sufficient knowledge of the proposed research, understands the risks involved, complies with professional guidelines, and is not directly involved with the research, and
(c) the donor is given sufficient time to consider the implications of their donation before the donated material is used in any research project.

22.16 Consent should not be obtained under duress, especially if the donor is in a dependent relationship with someone involved in the research project.

22.17 The centre should not take gametes or cells from people under the age of 18 for research unless it can satisfy itself that the donor is capable of giving and actually gives effective consent to such research. The exception is in cases where cells may be taken from a person under the age of 18 for research if certain parental consent conditions have been met (as outlined below).

22.18 The centre should ensure that all the appropriate consents from all the gamete or embryo donors are in place before embryos are transferred between centres.

See also

Guidance note 3 – Counselling and patient support

Guidance note 5 – Consent to treatment, storage, donation, and disclosure of information

Guidance note 12 – Egg sharing arrangements

HFEA consent forms

Additional requirements for stem cell research

Mandatory requirements

Human Fertilisation and Embryology Act 1990 (as amended)

Licence conditions

12 General conditions

(2) Subsection (3) applies to-

… (c) every licence under paragraph 3 of that Schedule, so far as authorising activities in connection with the derivation from embryos of stem cells that are intended for human application.

(3) It shall be a condition of every licence to which this subsection applies that –

(a) such information as is necessary to facilitate the traceability of gametes and embryos, and

(b) any information relating to the quality or safety of gametes or embryos,

Shall be recorded and provided to the Authority upon request.

14A Conditions of licences: human application

(1) This section applies to -

(c) every licence under paragraph 3 of that Schedule [Schedule 2], so far as authorising activities in connection with the derivation from embryos of stem cells that are intended for human application.

(2) A licence to which this section applies may not authorise the storage, procurement, testing, processing or distribution of gametes or embryos unless it contains the conditions required by Schedule 3A.

(3) In relation to any gametes or embryos imported into Northern Ireland from an EEA state, compliance with the requirements of the laws or other measures adopted in the relevant state or territory for the purpose of implementing the first, second and third Directives shall be taken to be compliance with the conditions required by Schedule 3A.

(4) Subsection (3) shall not apply to any licence conditions imposed by the Authority which amount to more stringent protective measures for the purposes of Article 4(2) of the first Directive.

Licence conditions

R20 Prior to giving consent persons providing gametes or human cells for use in research that involves the derivation of embryonic stem cells/lines, must be provided with the following additional information:

a. that once an embryo or human admixed embryo has been used in the project of research they will have no control over any future use of the embryonic cells or any stem cells derived

b. that any stem cells/lines created may continue indefinitely and be used in many different research projects and/or clinical therapy

c. that stem cells derived in this research project will be deposited in the UK Stem Cell Bank and the implications of this including that they may be available to other research groups nationally or internationally

d. that the stem cells/lines may be used for commercial purposes, but that they will not benefit financially from this, and

e. that any stem cells/lines derived or discoveries made using them, could be patented, but that they will not benefit financially from this.

R30 Where this licence authorises the derivation of human embryonic stem cell lines:

a. a sample of all stem cell lines derived must be deposited in the UK Stem Cell Bank in accordance with any relevant Bank guidelines, and

b. the remainder of all stem cell lines (in so far as not used or destroyed as part of or in the course of the research project) must be deposited in the UK Stem Cell Bank or distributed in accordance with any relevant guidelines issued by the UK Stem Cell Bank.

R41 Centres deriving stem cells for intended human application must comply with the additional conditions set out in Annex A to this the Research Licence.

R68 The centre must record such information as is necessary to facilitate the traceability of stem cells derived from embryos that are intended for human application and any information relating to the quality or safety of gametes and embryos. This information must be provided to the Authority upon request.

Centres deriving stem cells for human application should adhere to the mandatory requirements and guidance, outlined in other guidance notes, regarding:

Traceability and coding system (guidance note 19 – Traceability)

Serious adverse events and serious adverse reactions (guidance note 27 – Adverse incidents)

Third party agreements and termination of licensed activities (guidance note 24 – Third party agreements)

Procurement of gametes and embryos (guidance note 15 – Procuring, processing and transporting gametes and embryos)

Selection criteria and laboratory tests required for donors of reproductive cells (guidance note 11 – Donor recruitment, assessment and screening)

Donation and procurement procedures and reception at the tissue establishment (guidance note 15 – Procuring, processing and transporting gametes and embryos)

22.19 The centre should have documented procedures for depositing samples of all embryonic stem cell lines developed or used in a research project in a stem cell bank.

22.20 Donors must give specific consent to their gametes, or embryos created with their gametes, being used in stem cell research.

See also

Guidance note 19 – Traceability

Use of human cells

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

15 Conditions of research licences

(5) If by virtue of paragraph 15F of Schedule 3 (existing cell lines) qualifying cells, as defined by paragraph 15F(2) of that Schedule, of a person ("P") are used to bring about the creation in vitro of an embryo or human admixed embryo without P's consent, steps shall be taken to ensure that the embryo or human admixed embryo cannot subsequently be attributed to P.

Schedule 3

In vitro fertilisation and subsequent use of embryos

6 (3A) If the Authority is satisfied that the parental consent conditions in paragraph 15A are met in relation to the proposed use under a licence of the human cells of a person who has not attained the age of 18 years ("C"), the Authority may in the licence authorise the application of sub-paragraph (3B) in relation to C.

(3B) Where the licence authorises the application of this sub-paragraph, the effective consent of a person having parental responsibility for C -

(a) to the use of C's human cells to bring about the creation of an embryo in vitro for use for the purposes of a project of research, or

(b) to the use for those purposes of an embryo in relation to which C is a relevant person by reason only of the use of C's human cells,

is to be treated for the purposes of sub-paragraphs (1) to (3) as the effective consent of C.

(3C) If C attains the age of 18 years or the condition in paragraph 15(3) ceases to be met in relation to C, paragraph 4 has effect in relation to C as if any effective consent previously given under sub-paragraphs (1) to (3) by a person having parental responsibility for C had been given by C but, subject to that, sub-paragraph (3B) ceases to apply in relation to C.

(3ZD)Sub-paragraphs (1) to (3) have effect subject to paragraphs 15B and 15F.

Storage of gametes and embryos

8 (2A) Where a licence authorises the application of paragraph 6(3B) in relation to a person who has not attained the age of 18 years ("C"), the effective consent of a person having parental responsibility for C to the storage of an embryo in relation to which C is a relevant person by reason only of the use of C's human cells is to be treated for the purposes of sub-paragraph (2) as the effective consent of C.

(2B) If C attains the age of 18 years or the condition in paragraph 15(3) ceases to be met in relation to C, paragraph 4 has effect in relation to C as if any effective consent previously given under sub-paragraph (2) by a person having parental responsibility for C had been given by C but, subject to that, sub-paragraph (2A) ceases to apply in relation to C.

(2C) For the purposes of sub-paragraphs (2) and (2A), each of the following is a relevant person in relation to an embryo the creation of which was brought about in vitro ("embryo A") -

(a) each person whose gametes or human cells were used to bring about the creation of embryo A,

(b) each person whose gametes or human cells were used to bring about the creation of any other embryo, the creation of which was brought about in vitro, which was used to bring about the creation of embryo A, and

(c) each person whose gametes or human cells were used to bring about the creation of any human admixed embryo, the creation of which was brought about in vitro, which was used to bring about the creation of embryo A.

Parental consent conditions

15 (1) In relation to a person who has not attained the age of 18 years ("C"), the parental consent conditions referred to in paragraphs 6(3A) and 12(4) are as follows.

(2) Condition A is that C suffers from, or is likely to develop, a serious disease, a serious physical or mental disability or any other serious medical condition.

(3) Condition B is that either -

(a) C is not competent to deal with the issue of consent to the use of C's human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of a project of research, or

(b) C has attained the age of 16 years but lacks capacity to consent to such use of C's human cells.

(4) Condition C is that any embryo or human admixed embryo to be created in vitro is to be used for the purposes of a project of research which is intended to increase knowledge about -

(a) the disease, disability or medical condition mentioned in sub-paragraph (2) or any similar disease, disability or medical condition, or

(b) the treatment of, or care of persons affected by, that disease, disability or medical condition or any similar disease, disability or medical condition.

(5) Condition D is that there are reasonable grounds for believing that research of comparable effectiveness cannot be carried out if the only human cells that can be used to bring about the creation in vitro of embryos or human admixed embryos for use for the purposes of the project are the human cells of persons who -

(a) have attained the age of 18 years and have capacity to consent to the use of their human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of the project, or

(b) have not attained that age but are competent to deal with the issue of consent to such use of their human cells.

(6) In relation to Scotland, sub-paragraphs (1) to (5) are to be read with the following modifications -

(a) for sub-paragraph (3) substitute -

"(3) Condition B is that C does not have capacity (within the meaning of section 2(4ZB) of the Age of Legal Capacity (Scotland) Act 1991) to consent to the use of C's human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of a project of research.",

(b) in sub-paragraph (5)(a), for "have capacity to consent" substitute "are not incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving consent", and

(c) in sub-paragraph (5)(b), for "are competent to deal with the issue of" substitute "have capacity (within the meaning of section 2(4ZB) of the Age of Legal Capacity (Scotland) Act 1991) to".

Adults lacking capacity: exemption relating to use of human cells etc.

16 (1) If, in relation to the proposed use under a licence of the human cells of a person who has attained the age of 18 years ("P"), the Authority is satisfied -

(a) that the conditions in paragraph 17 are met,

(b) that paragraphs (1) to (4) of paragraph 18 have been complied with, and

(c) that the condition in paragraph 18(5) is met,

the Authority may in the licence authorise the application of this paragraph in relation to P.

(2) Where a licence authorises the application of this paragraph, this Schedule does not require the consent of P -

(a) to the use (whether during P's life or after P's death) of P's human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of a project of research,

(b) to the storage or the use for those purposes (whether during P's life or after P's death) of an embryo or human admixed embryo in relation to which P is a relevant person by reason only of the use of P's human cells.

(3) This paragraph has effect subject to paragraph 19.

Consent to use of human cells etc. not required: adult lacking capacity

17 (1) The conditions referred to in paragraph 16(1)(a) are as follows.

(2) Condition A is that P suffers from, or is likely to develop, a serious disease, a serious physical or mental disability or any other serious medical condition.

(3) Condition B is that P lacks capacity to consent to the use of P's human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of a project of research.

(4) Condition C is that the person responsible under the licence has no reason to believe that P had refused such consent at a time when P had that capacity.

(5) Condition D is that it appears unlikely that P will at some time have that capacity.

(6) Condition E is that any embryo or human admixed embryo to be created in vitro is to be used for the purposes of a project of research which is intended to increase knowledge about -

(a) the disease, disability or medical condition mentioned in sub-paragraph (2) or any similar disease, disability or medical condition, or

(b) the treatment of, or care of persons affected by, that disease, disability or medical condition or any similar disease, disability or medical condition.

(7) Condition F is that there are reasonable grounds for believing that research of comparable effectiveness cannot be carried out if the only human cells that can be used to bring about the creation in vitro of embryos or human admixed embryos for use for the purposes of the project are the human cells of persons who -

(a) have attained the age of 18 years and have capacity to consent to the use of their human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of the project, or

(b) have not attained that age but are competent to deal with the issue of consent to such use of their human cells.

(8) In this paragraph and paragraph 18 references to the person responsible under the licence are to be read, in a case where an application for a licence is being made, as references to the person who is to be the person responsible.

(9) In relation to Scotland -

(a) references in sub-paragraphs (3) to (5) to P lacking, or having, capacity to consent are to be read respectively as references to P being, or not being, incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving such consent, and

(b) sub-paragraph (7) is to be read with the following modifications -

(i) in paragraph (a), for "have capacity to consent" substitute "are not incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving consent", and

(ii) in paragraph (b), for "are competent to deal with the issue of" substitute "have capacity (within the meaning of section 2(4ZB) of the Age of Legal Capacity (Scotland) Act 1991) to".

Consulting carers etc. in case of adult lacking capacity

18 (1) This paragraph applies in relation to a person who has attained the age of 18 years ("P") where the person responsible under the licence ("R") wishes to use P's human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of a project of research, in a case where P lacks capacity to consent to their use.

(2) R must take reasonable steps to identify a person who -

(a) otherwise than in a professional capacity or for remuneration, is engaged in caring for P or is interested in P's welfare, and

(b) is prepared to be consulted by R under this paragraph of this Schedule.

(3) If R is unable to identify such a person R must nominate a person who -

(a) is prepared to be consulted by R under this paragraph of this Schedule, but

(b) has no connection with the project.

(4) R must provide the person identified under sub-paragraph (2) or nominated under sub-paragraph (3) ("F") with information about the proposed use of human cells to bring about the creation in vitro of embryos or human admixed embryos for use for the purposes of the project and ask F what, in F's opinion, P's wishes and feelings about the use of P's human cells for that purpose would be likely to be if P had capacity in relation to the matter.

(5) The condition referred to in paragraph 16(1)(c) is that, on being consulted, F has not advised R that in F's opinion P's wishes and feelings would be likely to lead P to decline to consent to the use of P's human cells for that purpose.

(6) In relation to Scotland, the references in sub-paragraphs (1) and (4) to P lacking, or having, capacity to consent are to be read respectively as references to P being, or not being, incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving such consent.

Effect of acquiring capacity

19 (1) Paragraph 16 does not apply to the use of P's human cells to bring about the creation in vitro of an embryo or human admixed embryo if, at a time before the human cells are used for that purpose, P-

(a) has capacity to consent to their use, and

(b) gives written notice to the person keeping the human cells that P does not wish them to be used for that purpose.

(2) Paragraph 16 does not apply to the storage or use of an embryo or human admixed embryo whose creation in vitro was brought about with the use of P's human cells if, at a time before the embryo or human admixed embryo is used for the purposes of the project of research, P -

(a) has capacity to consent to the storage or use, and

(b) gives written notice to the person keeping the human cells that P does not wish them to be used for that purpose.

(3) In relation to Scotland, the references in sub-paragraphs (1)(a) and (2)(a) to P having capacity to consent are to be read as references to P not being incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving such consent.

Use of cells or cell lines

20 (1) Where a licence authorises the application of this paragraph in relation to qualifying cells, this Schedule does not require the consent of a person ("P") -

(a) to the use of qualifying cells of P to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of a project of research, or

(b) to the storage or the use for those purposes of an embryo or human admixed embryo in relation to which P is a relevant person by reason only of the use of qualifying cells of P.

(2) "Qualifying cells" are human cells which -

(a) were lawfully stored for research purposes immediately before the commencement date, or

(b) are derived from human cells which were lawfully stored for those purposes at that time.

(3) The "commencement date" is the date on which paragraph 9(2)(a) of Schedule 3 to the Human Fertilisation and Embryology Act 2008 (requirement for consent to use of human cells to create an embryo) comes into force.

Conditions for grant of exemption in paragraph 20

21 (1) A licence may not authorise the application of paragraph 20 unless the Authority is satisfied -

(a) that there are reasonable grounds for believing that scientific research will be adversely affected to a significant extent if the only human cells that can be used to bring about the creation in vitro of embryos or human admixed embryos for use for the purposes of the project of research are -

(i) human cells in respect of which there is an effective consent to their use to bring about the creation in vitro of embryos or human admixed embryos for use for those purposes, or

(ii) human cells which by virtue of paragraph 16 can be used without such consent, and

(b) that any of the following conditions is met in relation to each of the persons whose human cells are qualifying cells which are to be used for the purposes of the project of research.

(2) Condition A is that -

(a) it is not reasonably possible for the person responsible under the licence ("R") to identify the person falling within sub-paragraph (1)(b) ("P"), and

(b) where any information that relates to P (without identifying P or enabling P to be identified) is available to R, that information does not suggest that P would have objected to the use of P's human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of the project.

(3) Condition B is that -

(a) the person responsible under the licence ("R") has taken all reasonable steps to contact the person falling within subparagraph (1)(b) ("P") but has been unable to do so,

(b) R does not have any reason to believe P to have died, and

(c) the information relating to P that is available to R does not suggest that P would have objected to the use of P's human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of the project.

(4) Condition C is that -

(a) the person falling within sub-paragraph (1)(b) ("P") has died since P's human cells were first stored,

(b) the information relating to P that is available to the person responsible under the licence ("R") does not suggest that P would have objected to the use of P's human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of the project, and

(c) a person who stood in a qualifying relationship to P immediately before P died has given consent in writing to the use of P's human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of the project.

(5) The HTA consent provisions apply in relation to consent for the purposes of sub-paragraph (4)(c) as they apply in relation to consent for the purposes of section 3(6)(c) of the Human Tissue Act 2004; and for the purposes of this sub-paragraph the HTA consent provisions are to be treated as if they extended to Scotland.

(6) In sub-paragraph (5) "the HTA consent provisions" means subsections (4), (5), (6), (7) and (8)(a) and (b) of section 27 of the Human Tissue Act 2004.

(7) In this paragraph references to the person responsible under the licence are to be read, in a case where an application for a licence is being made, as references to the person who is to be the person responsible.

(8) Paragraphs 1 to 4 of this Schedule do not apply in relation to a consent given for the purposes of sub-paragraph (4)(c).

Interpretation

22 (1) In this Schedule references to human cells are to human cells which are not -

(a) cells of the female or male germ line, or

(b) cells of an embryo.

(4) Reference in this Schedule (however expressed) to the use of human cells to bring about the creation of an embryo or a human admixed embryo include the use of human cells to alter the embryo or, as the case may be, the human admixed embryo.

(5) References in this Schedule to parental responsibility are -

(a) in relation to England and Wales, to be read in accordance with the Children Act 1989,

(b) in relation to Northern Ireland, to be read in accordance with the Children (Northern Ireland) Order 1995, and

(c) in relation to Scotland, to be read as references to parental responsibilities and parental rights within the meaning of the Children (Scotland) Act 1995.

(6) References in this Schedule to capacity are, in relation to England and Wales, to be read in accordance with the Mental Capacity Act 2005.

(7) References in this Schedule to the age of 18 years are, in relation to Scotland, to be read as references to the age of 16 years.

Interpretation of mandatory requirements 22D

Human cells may be used to create embryos or human admixed embryos in vitro for use in research, or embryos may be used in research, without the consent of the person providing the cells in the following circumstances:

(a) If the person is under the age of 18

(i) The Authority must be satisfied that specified parental consent conditions have been met.

(ii) A parent of the person must have given effective consent on their behalf.

(iii) The parental conditions must remain satisfied.

(iv) The child must not have reached the age of 18, and must not have withdrawn or varied the consent, before the embryo is used for the research project.

(b) If the person is an adult

(i) The Authority must be satisfied that specified conditions relating to adults and consent have been met.

(ii) An appropriate person must have been consulted by the person responsible, and given suitable information and an opportunity to state what the adult's wishes and feelings would have been about the proposed use of their cells for that purpose.

(iii) The person consulted must not have stated that the adult would have been likely to refuse to consent.

(iv) Consent must not have been validly withdrawn by the person providing the cells before the use of the cells or any resulting embryo or human admixed embryo.

For both (a) and (b), the cells or embryos (or cells derived from these) must have been lawfully stored for research purposes before 1 October 2009, and certain conditions must have been met.

Human admixed embryos: general requirements

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

4A Prohibitions in connection with genetic material not of human origin

(1) No person shall place in a woman -

(a) a human admixed embryo,

(b) any other embryo that is not a human embryo, or

(c) any gametes other than human gametes.

(2) No person shall -

(a) mix human gametes with animal gametes,

(b) bring about the creation of a human admixed embryo, or

(c) keep or use a human admixed embryo,

except in pursuance of a licence.

(3) A licence cannot authorise the keeping or using of a human admixed embryo after the earliest of the following -

(a) the appearance of the primitive streak, or

(b) the end of the period of 14 days beginning with the day on which the process of creating the human admixed embryo began, but not counting any time during which the human admixed embryo is stored.

(4) A licence cannot authorise placing a human admixed embryo in an animal.

(5) A licence cannot authorise keeping or using a human admixed embryo in any circumstances in which regulations prohibit its keeping or use.

(6) For the purposes of this Act a human admixed embryo is -

(a) an embryo created by replacing the nucleus of an animal egg or of an animal cell, or two animal pronuclei, with -

(i) two human pronuclei,

(ii) one nucleus of a human gamete or of any other human cell, or

(iii) one human gamete or other human cell,

(b) any other embryo created by using -

(i) human gametes and animal gametes, or

(ii) one human pronucleus and one animal pronucleus,

(c) a human embryo that has been altered by the introduction of any sequence of nuclear or mitochondrial DNA of an animal into one or more cells of the embryo,

(d) a human embryo that has been altered by the introduction of one or more animal cells, or

(e) any embryo not falling within paragraphs (a) to (d) which contains both nuclear or mitochondrial DNA of a human and nuclear or mitochondrial DNA of an animal ("animal DNA") but in which the animal DNA is not predominant.

(7) In subsection (6) -

(a) references to animal cells are to cells of an animal or of an animal embryo, and

(b) references to human cells are to cells of a human or of a human embryo.

(8) For the purposes of this section an "animal" is an animal other than man.

(9) In this section "embryo" means a live embryo, including an egg that is in the process of fertilisation or is undergoing any other process capable of resulting in an embryo.

11 Licences for treatment, storage and research

(1) The Authority may grant the following and no other licences -

(b) licences under that Schedule authorising the storage of gametes, embryos or human admixed embryos

14 Conditions of storage licences

(1) The following shall be conditions of every licence authorising the storage of gametes, embryos or human admixed embryos -

(ac) that a human admixed embryo the creation of which has been brought about in vitro otherwise than in pursuance of that licence shall be placed in storage only if acquired from a person to whom a licence under paragraph 2 or 3 of Schedule 2 applies…

(ba) that human admixed embryos shall not be supplied to a person unless that person is a person to whom a licence applies,

(c) that no gametes, embryos or human admixed embryo shall be kept in storage for longer than the statutory storage period and, if stored at the end of the period, shall be allowed to perish,

(4A) The statutory storage period in respect of human admixed embryos is such period not exceeding ten years as the licence may specify.

Schedule 2

Licences for storage

2 (1A) A licence under this paragraph or paragraph 3 may authorise the storage of human admixed embryos (whether or not the licence also authorises the storage of gametes or embryos or both).

Licences for research

3 (3) A licence under this paragraph may authorise any of the following -

(a) bringing about the creation in vitro of things that are human admixed embryos by virtue of paragraph (a), (b), (c) or (d) of section 4A(5), and

(b) keeping or using things that are human admixed embryos by virtue of any of those paragraphs, for the purposes of a project of research specified in the licence.

(4) A licence under sub-paragraph (3) may not authorise the activity which may be authorised by a licence under sub-paragraph (2).

(5) No licence under this paragraph is to be granted unless the Authority is satisfied that any proposed use of embryos or human admixed embryos is necessary for the purposes of the research.

Purposes for which activities may be licensed under paragraph 3

3A (1) A licence under paragraph 3 cannot authorise any activity unless the activity appears to the Authority -

(a) to be necessary or desirable for any of the purposes specified in sub-paragraph (2) ("the principal purposes"),

(b) to be necessary or desirable for the purpose of providing knowledge that, in the view of the Authority, may be capable of being applied for the purposes specified in sub-paragraph (2)(a) or (b), or

(c) to be necessary or desirable for such other purposes as may be specified in regulations.

(2) The principal purposes are -

(a) increasing knowledge about serious disease or other serious medical conditions,

(b) developing treatments for serious disease or other serious medical conditions,

(c) increasing knowledge about the causes of any congenital disease or congenital medical condition that does not fall within paragraph (a),

(d) promoting advances in the treatment of infertility,

(e) increasing knowledge about the causes of miscarriage,

(f) developing more effective techniques of contraception,

(g) developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation, or

(h) increasing knowledge about the development of embryos.

Schedule 3

Terms of consent

2 (1A) A consent to the use of any human admixed embryo must specify use for the purposes of a project of research and may specify conditions subject to which the human admixed embryo may be so used.

(2) A consent to the storage of any gametes, any embryo or any human admixed embryo must -

(a) specify the maximum period of storage (if less than the period for which, by virtue of section 14(3), the gametes, embryo or human admixed embryo may be stored under the licence statutory storage period),

(b) except in a case falling within paragraph (c), state what is to be done with the gametes, embryo or human admixed embryo if the person who gave the consent dies or is unable, because the person lacks capacity to do so, to vary the terms of the consent or to withdraw it, and

(c) where the consent is given by virtue of paragraph 8(2A) or 13(2), state what is to be done with the embryo or human admixed embryo if the person to whom the consent relates dies,
and may (in any case) specify conditions subject to which the gametes, embryo or human admixed embryo may remain in storage.

(2A) A consent to the use of a person's human cells to bring about the creation in vitro of an embryo or human admixed embryo is to be taken unless otherwise stated to include consent to the use of the cells after the person's death.

(4) A consent under this Schedule may apply -

(a) to the use or storage of a particular embryo or human admixed embryo, or

(b) in the case of a person providing gametes or human cells, to the use or storage of -

(i) any embryo or human admixed embryo whose creation may be brought about using those gametes or those cells, and

(ii) any embryo or human admixed embryo whose creation may be brought about using such an embryo or human admixed embryo.

(5) In the case of a consent falling within sub-paragraph (4)(b), the terms of the consent may be varied, or the consent may be withdrawn, in accordance with this Schedule either generally or in relation to -

(a) a particular embryo or particular embryos, or

(b) a particular human admixed embryo or particular human admixed embryos.

Variation and withdrawal of consent

4 (1) The terms of any consent under this Schedule may from time to time be varied, and the consent may be withdrawn, by notice given by the person who gave the consent to the person keeping the gametes, human cells, embryo or human admixed embryo to which the consent is relevant.

(4) Subject to sub-paragraph (5), the terms of any consent to the use of any human admixed embryo cannot be varied, and such consent cannot be withdrawn, once the human admixed embryo has been used for the purposes of any project of research.

(5) Where the terms of any consent to the use of a human admixed embryo ("human admixed embryo A") include consent to the use of a human admixed embryo or embryo whose creation may be brought about in vitro using human admixed embryo A, that consent to the use of that subsequent human admixed embryo or embryo cannot be varied or withdrawn once human admixed embryo A has been used for the purposes of any project of research.

Creation, use and storage of human admixed embryos

12 (1) A person's gametes or human cells must not be used to bring about the creation of any human admixed embryo in vitro unless there is an effective consent by that person to any human admixed embryo, the creation of which may be brought about with the use of those gametes or human cells, being used for the purposes of any project of research.

(2) A human admixed embryo the creation of which was brought about in vitro must not be received by any person unless there is an effective consent by each relevant person in relation to the human admixed embryo to the use of the human admixed embryo for the purposes of any project of research.

(3) A human admixed embryo the creation of which was brought about in vitro must not be used for the purposes of a project of research unless -

(a) there is an effective consent by each relevant person in relation to the human admixed embryo to the use of the human admixed embryo for that purpose, and

(b) the human admixed embryo is used in accordance with those consents.

(4) If the Authority is satisfied that the parental consent conditions in paragraph 15 are met in relation to the proposed use under a licence of the human cells of a person who has not attained the age of 18 years ("C"), the Authority may in the licence authorise the application of sub-paragraph (5) in relation to C.

(5) Where the licence authorises the application of this subparagraph, the effective consent of a person having parental responsibility for C -

(a) to the use of C's human cells to bring about the creation of a human admixed embryo in vitro for use for the purposes of a project of research, or

(b) to the use for those purposes of a human admixed embryo in relation to which C is a relevant person by reason only of the use of C's human cells,

is to be treated for the purposes of sub-paragraphs (1) to (3) as the effective consent of C.

(6) If C attains the age of 18 years or the condition in paragraph 15(3) ceases to be met in relation to C, paragraph 4 has effect in relation to C as if any effective consent previously given under subparagraphs (1) to (3) by a person having parental responsibility for C had been given by C but, subject to that, sub-paragraph (5) ceases to apply in relation to C.

13 (1) A human admixed embryo the creation of which was brought about in vitro must not be kept in storage unless -

(a) there is an effective consent by each relevant person in relation to the human admixed embryo to the storage of the human admixed embryo, and

(b) the human admixed embryo is stored in accordance with those consents.

(2) Where a licence authorises the application of paragraph 12(5) in relation to a person who has not attained the age of 18 years ("C"), the effective consent of a person having parental responsibility for C to the storage of a human admixed embryo in relation to which C is a relevant person by reason only of the use of C's human cells is to be treated for the purposes of sub-paragraph (1) as the effective consent of C.

(3) If C attains the age of 18 years or the condition in paragraph 15(3) ceases to be met in relation to C, paragraph 4 has effect in relation to C as if any effective consent previously given under subparagraph (1) by a person having parental responsibility for C had been given by C but, subject to that, sub-paragraph (2) ceases to apply in relation to C.

14 For the purposes of paragraphs 12 and 13, each of the following is a relevant person in relation to a human admixed embryo the creation of which was brought about in vitro ("human admixed embryo A") -

(a) each person whose gametes or human cells were used to bring about the creation of human admixed embryo A,

(b) each person whose gametes or human cells were used to bring about the creation of any embryo, the creation of which was brought about in vitro, which was used to bring about the creation of human admixed embryo A, and

(c) each person whose gametes or human cells were used to bring about the creation of any other human admixed embryo, the creation of which was brought about in vitro, which was used to bring about the creation of human admixed embryo A.

Interpretation of mandatory requirements 22E

The law prohibits:

(a) human admixed embryos being placed in a woman, or

(b) human admixed embryos being kept or used after 14 days from when the process of creating the embryo began or after the primitive streak has appeared (if earlier than 14 days).

Human admixed embryos: information provided to donors

Interpretation of mandatory requirements 22F

The law requires that before a person consents to donating embryos, gametes or cells to create human admixed embryos for research purposes, they should be given:

(a) enough information to understand the nature, purpose and implications of their donation

(b) information about the procedure for varying or withdrawing any consent given, including the fact that they can do this only until the human admixed embryos are used in the research project.

Note: Human admixed embryos will be regarded as having been used for research as soon as they are under the control of the researchers and are being cultured for use in research.

22.21 The centre should inform any individual who donates cells for creating human admixed embryos for research that, unless they state otherwise, consent to use these cells includes consent to do so after the individual's death.

Human admixed embryos: consent and storage

Interpretation of mandatory requirements 22G

The law requires written, signed consent (subject to specific exemption for illness, injury or disability) from any individual before they donate gametes or human cells used to create human admixed embryos in vitro for use in any research project.

The consent must specify the maximum storage period (which must be less than the 10-year statutory maximum storage period for human admixed embryos).

This consent can be varied or withdrawn at any time until the embryo has been used for the purposes of the research project.

In certain situations, the law permits human cells to be used to create human admixed embryos without the consent of the person providing them.

See also

Guidance note 5 – Consent to treatment, storage, donation, and disclosure of information

Guidance note 17 – Storage of gametes and embryos

Other legislation, professional guidelines and information

Professional guidelines

Department of Health (Advisory Committee on the Safety of Blood, Tissues and Organs): Donation of starting material for cell-based advanced therapies (2014)

The Health Research Authority: Protects and promotes the interests of patients and the public in health and social care research

Medical Research Council (UK Stem Cell Bank steering committee)

UK Stem Cell Bank

UK Stem Cell Bank: Code of Practice – use of human stem cell lines (2010)

Annex 12

25. Premises, practices and facilities

Version 3.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

12 General conditions

(1) The following shall be conditions of every licence granted under this act –

(a) except to the extent that the activities authorised by the licence fall within paragraph (aa), that those activities shall be carried out on only on the premises to which the licence relates and under the supervision of the person responsible, (aa) that any activities to which section 3(1A)(b) or (1B) or 4(1A) applies shall be carried on only on the premises to which the licence relates or on relevant third party premises,…

16 Grant of licence

(1) The Authority may on application grant a licence to any person if the requirements of subsection (2) below are met.

(2) The requirements mentioned in subsection (1) above are—

…

(d) that the Authority is satisfied that the premises in respect of which the licence is to be granted and any premises which will be relevant third party premises are suitable for the activities…

(2) The Authority may revoke a licence otherwise than on application under subsection (1) if—

…

(d) it ceases to be satisfied that the premises specified in the licence are suitable for the licensed activity,

(e) it ceases to be satisfied that any premises which are relevant third party premises in relation to a licence are suitable for the activities entrusted to the third party by the person who holds the licence…

Schedule 2 – Activities for which licences may be granted

4 (1) a licence under this Schedule can only authorise activities to be carried out on –

(a) on premises specified in the licence or, in the case of activities to which section 3(1A)(b) or (1B) or

4 (1A) applies, on relevant third party premises…

(2) A licence cannot –

…

(d) apply to premises of the person who holds the licence in different places.

Licence conditions

T1 The activities authorised by the licence must be carried out only on the premises specified in this licence and under the supervision of the person responsible (PR). However, where authorised by a licence, procurement, testing, processing or distribution of gametes or embryos intended for human application can also be carried out on relevant third party premises, provided that such premises, and the activities undertaken there, are covered by the terms of a written third party agreement.

T2 Suitable practices must be used in the course of activities authorised by this licence and in other activities carried out in the course of providing treatment services that do not require a licence.

T17 A centre must have suitable facilities to carry out licensed activities, or other activities carried out for the purposes of providing treatment services that do not require a licence.

T20 In premises where the processing of gametes and embryos exposes them to the environment, the processing must take place in an environment of at least grade C air quality, with a background environment of at least grade D air quality as defined in the current European Guide to Good Manufacturing Practice (GMP) Annex 1. It must be demonstrated and documented that the chosen environment achieves the quality and safety required.

Note: Centres storing ovarian or testicular tissue for use in transplantation must refer to the Human Tissue Authority's guidelines as the requirements for processing tissue for use in transplantation are different than those listed above.

T21 If the centre has laboratories or contracts third party laboratories or practitioners to undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, these laboratories must be accredited to conduct the relevant test(s) by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. The pathology disciplines involved in diagnosis and investigation include andrology, clinical genetics, (cytogenetics and molecular genetics) haematology, bacteriology, virology and clinical biochemistry.

T124
a. No clinic may carry out either the process of pronuclear transfer* (PNT) or maternal spindle transfer* (MST) or part of either process, unless express provision has been made on the clinic's licence permitting it to undertake either or both processes.

b. Neither PNT nor MST may be carried out under third party, satellite or transport agreements.

c. No clinic may provide treatment using gametes or embryos which have been created using PNT or MST unless express provision has been made on the clinic's licence permitting the clinic to undertake either or both processes.

*Wherever reference is made in this licence to PNT or MST, or to the process of PNT or MST, it is to be treated as a reference to the process described in Regulation 4 or Regulation 7 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015.

T125 PNT and MST must only be carried out on premises of clinics licensed to undertake mitochondrial donation ('MD'). These processes must not be carried out on the premises of a clinic that is operating under a third party, satellite or transport agreement with a clinic that holds a licence to undertake MD.

HFEA guidance

Definition of premises

Interpretation of mandatory requirements 25A

A licence can apply only to one premises; if a centre wishes to conduct licensed activities in a building different from the licensed premises, and not subject to a third party agreement, a separate licence will be required.

The HFEA must approve all new premises or changes to existing premises before use.

25.1 The HFEA defines premises as the specific area where a centre conducts its business, as identified on a floor plan submitted by the centre to the HFEA.

25.2 The centre should provide the HFEA with a floor plan that defines the premises to be licensed, including the purpose of each room.

25.3 When setting up or altering premises, the centre should review Health Technical Memoranda and Health Building Notes (published by the Department of Health) in considering the location and the services to be provided. In particular, the centre should consider Health Building Notes on day surgery and outpatient departments.

25.4 The centre should ensure it can provide ongoing assurance that its premises are fit for purpose, and evidence of:

(a) maintenance of lifts
(b) fire safety
(c) maintenance of ventilation and heating systems
(d) electrical safety
(e) medical gas safety.

Detailed guidance on these can be found in the relevant Health Technical Memoranda.

Moving to new premises

25.5 Before moving to new premises, the centre should contact its inspector for advice. The centre should notify the HFEA in writing of the intended move by submitting an application to vary the licence with information about the new premises. The HFEA will consider the application and information, and may need to inspect the premises.

Changing existing premises

25.6 Before planning any changes to the existing premises, the centre should contact its inspector for advice. The centre should notify the HFEA in writing of any planned changes to the premises by submitting, in advance, an application for a variation of the licence with information on the planned changes.

25.7 The HFEA will consider the application and information, and may need to inspect the premises.

Acquiring additional premises

25.8 If a centre wishes to conduct licensed activities not subject to a third party agreement in premises other than those specified on the current licence (eg, in a different building), it should contact its inspector for advice and notify the HFEA in writing. The centre should also submit an application for a new licence with information about the additional premises.

Centre facilities

25.9 The centre should provide for the privacy, dignity and respect of all prospective and current patients and donors, as well as providing a safe working environment for all staff. Consultation and the exchange of personal information should be carried out in private (ie, cannot be overlooked or overheard by others).

25.10 The centre should have facilities for reception, clinical and counselling activity, laboratory work, storage of confidential records, storing gametes and embryos, and staff.

25.11 The centre should display a copy of its Certificate of Licence where it can easily be read by current and potential patients and donors.

25.12 The centre should have appropriate procedures to ensure premises comply with relevant requirements for safety and air quality, and these procedures should be validated.

25.13 The person responsible should assess how many treatment cycles can safely be accommodated by the centre. The assessment should consider the centre's premises, equipment, staffing levels and the skill mix of staff members. Activity should be adjusted according to the findings of the assessment.

Clinical facilities

25.14 The centre should ensure that its clinical facilities:

(a) provide privacy and comfort for those:

(i) considering donation and seeking treatment
(ii) undergoing examination and treatment, and
(iii) producing semen specimens.

(b) are equipped with backup and emergency clinical facilities that:

(i) are equivalent to those provided as standard practice in other medical facilities
(ii) are appropriate to the degree of risk involved in any planned procedure, and
(iii) can cope with emergencies known to occur in this clinical field.

Counselling facilities

25.15 The centre should ensure that counselling facilities provide quiet and comfortable surroundings for private, confidential and uninterrupted sessions.

See also

Guidance note 3 – Counselling and patient support

Laboratory facilities

25.16 The centre's laboratories should comply with current professional guidelines, legislation and regulations.

25.17 Procedures must be evaluated for hazards to laboratory staff, and precautions put in place to minimise potential hazards.

See also

Guidance note 15 – Procuring, processing and transporting gametes and embryos

Guidance note 24 – Third party agreements

Staff facilities

25.18 The centre should have staff amenities that are easily accessible and include:

(a) toilet facilities
(b) a rest area with basic catering facilities and a supply of drinking water
(c) a changing area and secure storage for personal belongings, and
(d) storage for protective clothing.

Infection control

25.19 When developing infection control policies and procedures, centres should consider the Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance.

25.20 Infection control policies should ensure that staff and patients are protected from acquiring infections in the course of providing treatment. In particular, these policies should ensure that:

(a) there are effective procedures in place for preventing and controlling infections, such as hand decontamination, policies on wearing sterile gloves, dress code, and the safe use and disposal of sharps
(b) staff are aware of their role in these procedures
(c) a person is identified as the infection control lead for the centre
(d) management systems are in place to ensure infection control issues are dealt with.

Management of medicines

25.21 Centres should be aware of and comply with relevant regulations, best practice, and professional body guidance pertaining to medicines management and controlled drugs. Centres should have awareness and understanding of the relevant legal requirements, and the circumstances in which these regulations apply.

25.22 Centres should have appropriate standard operating procedures in place to ensure the safe management of medicines including controlled drugs, and must be able to demonstrate good governance and accountability for medicines and controlled drugs.

25.23 Centres should ensure that they have a controlled drug register and that entries in the register satisfy the relevant legal requirements for record-keeping in respect of controlled drugs. During inspections centres must be able to demonstrate that:

(a) the particulars of every quantity of drug obtained and supplied (whether by way of administration or otherwise), and whether to patients in or outside of the UK, are recorded in chronological order
(b) every entry in the register is made on the day on which the drug is obtained or, if that is not reasonably practicable, on the following day
(c) there is either a separate register or separate part of the register for entries made in respect of each class of drugs
(d) there is a separate controlled drug register kept for each premises where drugs are stored and that this register remains on the premises to which it relates, and
(e) there is no cancellation, obliteration, or alteration of any entry made in the register (a correction to an entry should only be as a marginal note or footnote and should specify the date the correction was made).

25.24 Centres should ensure that controlled drugs are only accessible to authorised persons who are lawfully able to supply or offer them.

25.25 Centres should be aware of and comply with waste management regulations relating to the disposal of controlled drugs.

25.26 Centres should have policies and procedures in place for:

(a) storing, disposing of, and managing the wastage of medicines, ensuring medicines can be accurately identified, are within date, and are kept safely (to prevent unauthorised access)
(b) managing medicine stock, ensuring staff can identify and respond when new stock is needed
(c) prescribing and dispensing medicines, ensuring only suitably qualified staff prescribe medicines
(d) administering medicines, ensuring only suitably qualified staff do so, and patients who self-administer receive clear written and spoken instructions
(e) dealing effectively with any emergencies following the administration of medicines by developing appropriate contingency plans, and
(f) ensuring patients receive appropriate medicines and are provided with information about risks and side effects of the medication prescribed to them (taking into account factors such as medical history and allergies).

25.27 Centres should ensure they keep accurate records that clearly set out the medication a patient is receiving. The centres should facilitate communication with third parties to avoid unnecessary delays to patients receiving medication. Centres should have suitable processes in place to ensure that patients are able to receive medication out of hours where necessary.

25.28 Staff competency in the management of medicines should be regularly reviewed and assessed.

The surgical pathway

25.29 Before doing an operation, centres should assess the suitability of a patient to have this, including a review of their medical history, allergies and known reactions to medicines.

25.30 The consultant anaesthetist or person administering the sedative should review the patient's notes before an operation. This review should take into account that patients having operations, under either general anaesthetic or sedation, are at risk of compromise to airway, breathing and circulation. There should be an anaesthetic chart in the patient's notes, containing information such as:

(a) known drug allergies
(b) previous problems with anaesthetics or sedatives
(c) airway assessment
(d) whether the patient is taking any regular medication
(e) any post-operative instructions (eg, whether the patient will need antibiotics).

25.31 When doing a surgical procedure, centres should ensure that they:

(a) use a theatre check list, equivalent to the WHO checklist
(b) monitor the patient before inducing the anaesthetic or sedative, and throughout the procedure
(c) have contingency plans in case problems arise during an operation, such as a severe allergic reaction or major bleeding
(d) have a discharge policy, ensuring that patients are discharged appropriately and by suitably trained staff.

25.32 All practitioners providing sedation procedures should undergo documented training in the knowledge, skills and competencies necessary for safe sedation. Centres carrying out sedation techniques should establish safe sedation processes that reflect guidance from relevant professional bodies.

25.33 Centres should keep accurate documentation about the operation undertaken, including the anaesthetic or sedative given, and details of patient monitoring and swab instruments and sharps counts undertaken.

25.34 Centres should ensure patients receive safe and appropriate post-operative care in line with

professional guidelines. Where a general anaesthetic or sedative is used, centres should have a fully equipped recovery area, staffed by recovery staff trained to professional standards. Second recovery areas should provide close and continued supervision of all patients, who should be visible to the nursing staff.

25.35 Where recovery areas are not available or not required, centres should consider how they can be sure that the relevant staff and equipment are in place for safe post-operative care.

25.36 Centres should ensure that their procedures are suitable for the type of anaesthetic or sedative provided.

25.37 Centres should ensure that only an appropriately qualified person provides an anaesthetic.

25.38 If an anaesthetic is used at remote sites, centres should have a resuscitation team led by an Advanced Life Support provider. Where this is not the case, the anaesthetists should provide competency-based evidence of their ability to provide both advanced life support and the safe transport of a patient requiring multi-system support.

Safeguarding

25.39 Centres are expected to have a policy and procedures for safeguarding those who use their services. These should set out what staff should do if they suspect that a person has been abused, neglected or harmed in any way. The policy and procedure should include:

(a) a statement of roles and responsibilities, authority and accountability that is specific enough to ensure all staff understand their roles and limitations
(b) how to deal with allegations of abuse, including procedures for providing immediate protection in emergency situations, assessing abuse and deciding when intervention is appropriate, and reporting suspicions to the police when necessary
(c) what to do if necessary action is not taken
(d) a comprehensive list of points of referral, explaining how to access support, advice and protection at all times (including outside normal working hours), with contact addresses and telephone numbers
(e) how to record allegations of abuse, any investigations and subsequent action
(f) a list of sources of expert advice
(g) a full description of channels of inter-agency communication, for example with local authorities, and procedures for decision making
(h) a list of all services that might offer victims access to support or redress.

25.40 Centres should review procedures annually, or more often to incorporate any lessons learned or changes to legislation.

25.41 Centres should provide training for staff on the safeguarding policy and their responsibilities, including:

(a) awareness that abuse can happen, and the duty to report this
(b) recognition of abuse, and responsibilities for reporting this.

25.42 If abuse, neglect or harm is suspected, it may be in the best interests of the individual to disclose confidential patient information. The safeguarding policy should set out the principles governing the sharing of information. These principles can be summarised as follows:

(a) Information should be shared only on a ‘need to know’ basis, when it is in the best interests of the patient or donor.
(b) Confidentiality and secrecy are two different things.
(c) The individual should give informed consent to disclosure, but if this is not possible, it may be necessary to disclose personal or sensitive personal information, despite a duty of confidentiality or legislation that would ordinarily prohibit disclosure.
(d) It is inappropriate to give assurances of absolute confidentiality in cases where there are concerns about abuse.

(e) Exchange or disclosure of personal information should be in line with current data protection legislation where this applies.

Other legislation, professional guidelines and information

Legislation

The Human Medicines Regulations 2012

as amended (2014)

The Misuse of Drugs Act 1971

The Misuse of Drugs Regulations 2001 (as amended)

The Misuse of Drugs Regulations (Northern Ireland) 2002

The Controlled Drugs (Supervision of Management and Use) Regulations 2013 (as amended 2020)

The Health Act 2006

Professional guidelines

Academy of Medical Royal Colleges: Safe sedation practice for healthcare procedures – standards and guidance (2013)

Academy of Medical Royal Colleges: Safe sedation practice for healthcare procedures update (2021)

Association of Anaesthetists - Recommendations for standards of monitoring during anaesthesia and recovery (2021)

Association of Anaesthetists of Great Britain and Ireland: Checking anaesthetic equipment (2012)

Association of Anaesthetists of Great Britain and Ireland: Controlled drugs in perioperative care (2019)

Association of Anaesthetists of Great Britain and Ireland: Immediate post-anaesthesia recovery (2013)

Association of Anaesthetists of Great Britain and Ireland: Infection control in anaesthesia (2008)

Association of Anaesthetists of Great Britain and Ireland: Pre-operative assessment and patient preparation – the role of the anaesthetist (2010)

Association of Anaesthetists - Guidelines

Care Quality Commission: Controlled drugs (2022) Department for Health: Health Building Notes (2013)

- Designing health and community care buildings HBN 00-01
- Designing stairways, lifts and corridors in health buildings HBN 00-04
- Infection control in the built environment HBN 00-09
- Design for flooring, walls and sanitaryware and windows HBN 00-10

Department for Health: Health Technical Memoranda (2013)

Department of Health: No Secrets – guidance on developing and implementing multi-agency policies and procedures to protect vulnerable adults from abuse (2000)

General Medical Council: Good practice in prescribing and managing medicines and devices (2013)

Royal College of Anaesthetists: Guidelines for the provision of anaesthetic services (GPAS) (2018)

Association for Perioperative Practice (Accountable items: swabs, instruments and sharps (2017)

Royal College of Nursing Publications (2021)

Royal College of Nursing Education and Career Progression Framework for Fertility Nursing (2021)

Royal College of Nursing - Adult Safeguarding: Roles and Competencies for Health Care Staff (2018)

United Kingdom Accreditation Service: Clinical pathology accreditation

World Health Organisation: Surgical safety checklist and implementation manual (2008)

Royal College of Paediatrics and Child Health - Safeguarding children and young people - roles and competencies (2019)

Other information

Human Fertilisation and Embryology Authority: Medicines management – supplying and dispensing medicines for self-administration (2017)

Clinic Focus articles

Clinic Focus article: Safe sedation practice for healthcare procedures (September 2019)

Clinic Focus article: Focusing on medicines management non-compliances (February 2020)

Clinic Focus article: Safe sedation practice for healthcare procedures (September 2021).

Annex 13

26. Equipment and materials

Version 3.0

The United Kingdom (UK) left the European Union (EU) on 31 January 2020, and the Implementation Period (IP) ended at 11pm on 31 December 2020. The Human Fertilisation and Embryology Act 1990 (HF&E Act) continues to apply UK wide, with some amendments, resulting in certain provisions applying to centres in Northern Ireland (NI) only and other amendments applying to centres in Great Britain (England, Wales and Scotland) only.

Where there are distinct Licence Conditions or guidance for centres in NI, the NI guidance has been highlighted below, within a light grey box.

Except in those cases where different requirements are highlighted, requirements and guidance in the Code apply to clinics in both NI and GB.

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

17 Person responsible

(1) It shall be the duty of the individual under whose supervision the activities authorised by a licence are carried on (referred to in this Act as the "person responsible") to secure—

…

(b) that proper equipment is used,

…

Licence conditions

T22 For every critical activity, identifying information about all of the materials and equipment must be documented.

T23 Activities must be carried out using equipment and materials designated for the purpose and maintained to suit their intended purpose and must minimise any hazard to patients and/or staff.

T24 All critical equipment and technical devices must be identified and validated, regularly inspected and maintained in accordance with the manufacturer's instructions. Where equipment or materials affect critical processing or storage parameters (eg, temperature, pressure, particle counts, microbial contamination levels) they must be identified and be the subject of appropriate monitoring, alerts, alarms and corrective action, as required, to detect malfunctions and defects, and to ensure that the critical parameters are maintained within acceptable limits at all times. All equipment with critical measuring function must be calibrated against a traceable standard if available.

T25 New, repaired and recommissioned equipment must be tested and validated before use. Test results must be documented.

T26 Maintenance, servicing, cleaning, disinfection and sanitation of all critical equipment and premises must be performed regularly and recorded accordingly.

T27 Procedures for the operation of each piece of critical equipment must be established and these procedures must document the action to be taken in the event of malfunctions or failure.

T28 Sterile instruments and devices must be used for the procurement of gametes and embryos. Instruments or devices must be of good quality, validated or specifically certified and regularly maintained for the procurement of tissues and cells.

T29 When reusable instruments are used, a validated cleaning and sterilisation procedure for removal of infectious agents has to be in place.

T30 for clinics in Great Britain

T30 Wherever possible only CE marked, CE and UK(NI) marked, or UKCA marked medical devices must be used.

NOTE: CE marked medical devices will continue to be accepted on the UK market until 30 June 2023. Medical devices placed on the GB market after 30 June 2023 must be UKCA marked rather than CE marked, as set out in the Medical Devices Regulations 2002 (as amended). This requirement does not prevent centres from continuing (after 30 June 2023) to use CE marked medical devices which were on the market prior to 1 July 2023. The UK Government has guaranteed unfettered access for NI businesses to the rest of the UK internal market. This means that any conformity mark held by a NI business which validates a medical device for sale on the NI market is valid for the whole of the UK. Accordingly, NI businesses can continue to place CE marked and CE and UK(NI) marked devices on the GB market after 30 June 2023.

NOTE: The Government has announced that the deadline for manufacturers placing CE marked devices on the GB market will be extended beyond 30 June 2023.

This means that, despite the wording of the notes under Standard Licence Conditions T30, T51, T53,R59 and R67 centres can continue to use CE marked devices placed on the GB market after 30 June 2023. See February 2023 Clinic Focus.

T30 for clinics in Northern Ireland

T30 Wherever possible only CE marked or CE and UK(NI) marked medical devices must be used.

NOTE: The UKCA mark is not available for devices placed on the NI market. Medical devices used in NI should be CE marked if certified by a notified body in the EU. Medical devices certified for the market in NI by a UK notified body should be both CE and UK(NI) marked as set out in the Medical Devices Regulation 2002 (as amended).

T31 The procedures for licensable activities must detail the specifications for all critical materials and reagents. In particular, specifications for additives (eg, solutions) and packaging materials must be defined. Critical reagents and materials must meet documented requirements and specifications and, when applicable, the requirements of the Medical Devices Regulation 2002 (as amended).

HFEA guidance

Scope

26.1 For the purpose of this Code of Practice, 'equipment and materials' includes all equipment, disposables, reagents, and calibrations and control materials used in the conduct of assisted conception process.

Protection and hygiene

26.2 The centre should provide proper clothing and equipment for the personal protection and hygiene of staff carrying out licensed activities, together with written instructions for their use.

Managing equipment and material

26.3 The centre should establish documented procedures for managing equipment and materials, including:

(a) selecting and procuring equipment and materials

(b) ensuring the traceability of any products or materials that come into contact with gametes or embryos and that affect their quality and safety, and
(c) maintaining inventory information and records for stock control.
(d) ensuring software-driven equipment is effectively validated, and revalidated after any software update.

CE marking, CE and UK(NI) marking and UKCA marking

NOTE: The Government has announced that the deadline for manufacturers placing CE marked devices on the GB market will be extended beyond 30 June 2023.

This means that, despite the wording of the notes under Standard Licence Conditions T30, T51, T53, R59 and R67 centres can continue to use CE marked devices placed on the GB market after 30 June 2023. See February 2023 Clinic Focus.

26.4 Centres in GB should use only media and consumables that have been CE marked, CE and UK(NI) marked or UKCA marked as a classification suitable for their intended purpose. Modifying existing devices (for example, adding calcium ionophore to culture medium) or using them 'off label' for purposes not intended by the manufacturer (for example, using a medium for a different purpose from that specified) has safety implications. It may also count as manufacture of a new device under the Medical Devices Regulations 2002 (as amended).

26.5 Following the UK's departure from the EU, CE marked medical devices will continue to be accepted on the UK market until 30 June 2023. New medical devices placed on the market in GB after 30 June 2023 must be UKCA marked or, if placed on the market by a NI business, may be CE or CE and UK(NI) marked.

26.6 Centres in NI should use only media and consumables that have been CE marked or CE and UK(NI) marked as a classification suitable for their intended purpose. Modifying existing devices (for example, adding calcium ionophore to culture medium) or using them 'off label' for purposes not intended by the manufacturer (for example, using a medium for a different purpose from that specified) has safety implications. It may also count as manufacture of a new device under the Medical Devices Regulations 2002 (as amended).

26.7 Following the UK's departure from the EU, medical devices that are CE marked can continue to be used in NI if certified by a notified body in the EU. New medical devices certified for the market in NI by a UK notified body should be both CE and UK(NI) marked. The UKCA mark is not available for devices placed on the market in NI.

26.8 If a centre does choose to modify an existing product or use a product 'off label', it should (as the 'manufacturer') complete a risk analysis and validation to ensure the product or process is safe.

See also

Guidance note 19 – Traceability

Guidance note 27 – Adverse incidents

Guidance note 31 – Record keeping and document control

Safety of equipment used to store cryopreserved gametes and embryos

26.9 All centres storing gametes and embryos should have effective alarms and monitoring systems to ensure the safety of cryopreserved gametes and embryos. These systems should have:

(a) local alarms (ie, on individual dewars for either temperature or liquid nitrogen level)
(b) an auto-dial facility or similar (eg, link to fire-alarm board) to contact staff outside normal working hours
(c) adequate staffing and funding to implement formal emergency procedures, including having on-call arrangements, and
(d) adequate spare storage space or vessels to enable transfer of samples if a vessel fails.

See also

Guidance note 17 – Storage of gametes and embryos

Other legislation, professional guidelines and information

Legislation

The Medical Devices Regulations 2002

General information

Medicines and Healthcare products Regulatory Agency: Alerts and recalls for drugs and medical devices

Clinic Focus articles

Clinic Focus article: Incidents case study - a cautionary tale on the use of benchtop incubators (January 2015)

Clinic Focus article: For action - off-label use of intralipid infusions (July 2015)

Clinic Focus article: Learning from the inspection of medicines management (July 2015)

Clinic Focus article: FAQs on the use of CE marked products (January 2016)

Clinic Focus article: CE marked devices in GB can be used after 30 June 2023 (February 2023)

Annex 14

28. Complaints

Version 2.0

HFEA guidance

Relevant legislation

Interpretation of mandatory requirements 28A

The law requires NHS and some private centres to have, and adhere to, a complaints procedure. References to the relevant legislation can be found in the 'Other legislation, professional guidelines and information' box at the end of this guidance note.

Complaints procedure

28.1 The centre should ensure that staff understand the complaints procedure and the right of people to complain.

28.2 It may be appropriate to deal with a complaint as soon as it arises, without using a formal complaints procedure. In such cases, staff should deal promptly and thoroughly with issues as they are raised. Staff should treat all complaints seriously and show the complainant due respect, however minor the complaint may appear. Staff should not deter people from making formal complaints if they wish to do so.

28.3 The centre should ensure that staff are given appropriate training in complaints handling and that there are written procedures for:

(a) acknowledging and investigating complaints, and
(b) collecting suggestions and compliments.

The complaints officer and complaints register

28.4 The centre should nominate a member of staff to act as complaints officer. The complaints officer should be:

(a) the first point of contact when a person makes a formal complaint, and
(b) responsible for investigating complaints and ensuring the complaints procedure operates effectively.

28.5 The centre should display notices prominently to explain the complaints procedure and give the complaints officer's name and contact details. This information should also be given to patients and donors.

28.6 The centre should ensure there is someone else of at least equivalent seniority available to deal with complaints in case a person feels unable to complain to the complaints officer.

28.7 The centre's complaints officer should keep an accurate complaints register. For each complaint, the following should be recorded in the register:

(a) what has been done to resolve the complaint
(b) all communication with the complainant (including verbal), and
(c) the outcome, and any action taken as a result.

28.8 The centre's complaints register should be made available to HFEA inspectors during inspections.

Investigating complaints

28.9 Complaints should be investigated by staff who were not involved in the circumstances that gave rise to the complaint.

28.10 If a complainant is unhappy with the outcome of the investigation of their complaint, they should be informed of further action they could take (eg, going to the Health Commissioner in the NHS, the HFEA, or the Ombudsman).

28.11 In NHS centres, the complaints procedure should comply with standards required of NHS services. In private centres, the procedures should comply with this Code of Practice and with the standards required by:
(a) the Care Quality Commission (England)
(b) the Care Commission (Scotland)
(c) the Care and Social Services Standards Inspectorate Wales (Wales)
(d) the Regulation and Quality Improvement Authority (Northern Ireland), or
(e) relevant successor bodies.

Dispute resolution

28.12 In line with Competition and Markets Authority (CMA) recommendations set out in their 2022 Compliance Review Findings Report, centres that treat self-funded patients should join an independent Alternative Dispute Resolution (ADR) scheme to enable all self-funded patients and NHS-funded patients receiving treatment in a private facility to access an ADR scheme where a patient has a complaint that cannot be resolved by the centre.

28.13 Patients treated in an NHS facility or funded by the NHS can access an ADR scheme by submitting complaints to the relevant ombudsman once they have followed the centre's internal complaints or Patient Advice and Liaison Service (PALS) procedure.

28.14 Centres should ensure that all patients are given sufficient information about the routes available to them to escalate complaints where a complaint cannot be resolved by the centre involved.

Other legislation, professional guidelines and information

Legislation

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

The National Health Service (Complaints) Regulations 2004

Local Authority Social Services and National Health Service Complaints (England) Regulations 2009

The Private and Voluntary Health Care (England) Regulations 2001

Patient Rights (Scotland) Act 2011

Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011

The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011

The Independent Health Care (Wales) Regulations 2011

The Health and Social Care Complaints Procedure Directions (Northern Ireland) 2009 (as amended)

Independent Health Care Regulations (Northern Ireland) 2005/174

General information

Care Quality Commission (England)

Healthcare Improvement Scotland (Scotland)

Healthcare Inspectorate Wales (Wales)

The Regulation and Quality Improvement Authority (Northern Ireland)

Competition and Markets Authority - Fertility treatment: A guide for Clinics

Competition and Markets Authority - Consumer law compliance review of fertility clinics- Findings report (Sept 2022)