Code of Practice update October 2021

Details about this paper

Area(s) of strategy this paper relates to:	The right information
Meeting:	Authority
Agenda item:	
Paper number:	HFEA (07/07/2021)
Meeting date:	07 July 2021
Author:	Emily Tiemann, Policy Manager Joanne Anton, Head of Regulatory Policy

Annexes	**Annex 1: Guidance note 4 (Information to be provided prior to consent)** **Annex 2: Guidance note 5 (Consent to treatment, storage, donation, and disclosure of information)** **Annex 3: Guidance note 6 (Legal parenthood)** **Annex 4: Guidance note 11 (Donor recruitment, assessment and screening)** **Annex 5: Guidance note 14 (Surrogacy)** **Annex 6: Guidance note 15 (Procuring, processing and transporting gametes and embryos)** **Annex 7: Guidance note 16 (Import and exports)** **Annex 8: Guidance note 17 (Storage of gametes and embryos)** **Annex 9: Guidance note 18 (Witnessing and assuring patient and donor identification)** **Annex 10: Guidance note 19 (Traceability)** **Annex 11: Guidance note 20 (Donor assisted conception)** **Annex 12: Guidance note 25 (Premises, practices and facilities)** **Annex 13: Guidance note 26 (Equipment and materials)** **Annex 14: Guidance note 30 (Confidentiality and privacy)**

Output from this paper

For information or decision?	For decision
Recommendation:	Authority members are asked to approve the proposed amendments to the Code of Practice, to be introduced later in 2021 subject to sign off by the Minister for Health and Social Care.
Resource implications:	Within Budget
Implementation date:	We are preparing for publication in October 2021, dependent on ministerial 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
Organisational risk:	Medium

Annex I

4. Information to be provided prior to consent

Version 2.0

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 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 recording and protection of personal data and confidentiality

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

f. 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 store 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
(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 on the 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 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, 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

Data Protection Act 2018

Equality Act 2010

Gender Recognition Act 2004

The Consumer Protection from Unfair Trading Regulations 2008

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

Consumer Rights Act 2015

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

Annex 2

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

Version 2.0

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

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. …

(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),

(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 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 (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) unless effective consent is in place from each gamete provider in accordance with Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended).

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.

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

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

Procedure for obtaining consent

Interpretation of mandatory requirements 5B

The law requires that before a person 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 of their 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.

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 on removing gametes and embryos within the storage period is outlined in guidance note 17.

5.8 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).

5.9 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.

5.10 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.

5.11 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) taken 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'.

5.12 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.

5.13 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.

5.14 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.

5.15 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.

5.16 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.

5.17 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)).

5.18 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.

5.19 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.

5.20 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 10of 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.

Written consent to the storage of gametes, embryos or human admixed embryos must:

(a) specify the maximum period of storage (if less than the statutory storage period), and

(b) state what should be done with the gametes, embryos or human admixed embryos if the person giving the consent dies or cannot, because of mental incapacity, withdraw or vary the terms of the consent.

In relation to b), where consent is given following the application of the parental consent provisions in Schedule 3, the consent needs only to specify what is to be done with the embryo or the human admixed embryo if the person to whom the consent relates dies.

The consent may also specify conditions under which the gametes, embryos or human admixed embryos may remain in storage.

In certain limited circumstances involving premature infertility, gametes and embryos can be stored beyond the statutory maximum storage period.

Gametes first placed in storage before 1 August 1991

Any gametes currently in storage which were originally placed into storage before 1 August 1991 (ie, before statutory regulation) can only continue to be stored if the original 10 year storage period was properly extended under the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 (the 1991 regulations) and this extension period has not expired. Any gametes in storage as at 31 July 2001 (10 years after the storage period was deemed to start) and which were not eligible for extension of storage under the 1991 regulations should have been allowed to perish. The Schedule to the 1991 Regulations sets out how long gametes can be stored beyond the statutory maximum storage period. The appropriate period is calculated by using the gamete provider's age on the date the gametes were provided. The storage period must be calculated from 1 August 1991.

For an online tool to calculate the appropriate storage period, see CE(16)02(a).

Gametes and embryos first placed in storage between 1 August 1991 and 1 October 2009

Gametes first placed in storage between 1 August 1991 and 1 October 2009, and which are being kept lawfully, may continue to be stored beyond the statutory maximum storage period if the conditions in the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 are satisfied. The Schedule to these Regulations set out how long gametes can be stored beyond the statutory maximum storage period. The appropriate period is calculated by using the gamete provider's age on the date the gametes were provided. The storage period begins on the date that the gametes were stored. This has the effect that storage can continue beyond the gamete provider's 55th birthday but not beyond age 56.

Embryos first placed in storage between 1 August 1991 and 1 October 2009, and which are being kept lawfully, may continue to be stored beyond the statutory maximum storage period but only if both people whose gametes were used to bring about the creation of the embryo confirm in writing that they have no objection to the extension (and if the other conditions in the Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996 are satisfied). The Schedule to these Regulations sets out how long embryos can be stored beyond the statutory maximum storage period. The appropriate period is calculated by using the age of the woman being treated on the date that the embryo was first placed in storage.

For an online tool to calculate the appropriate storage period, see CE(16)02(a).

Gametes and embryos first placed in storage after 1 October 2009

Gametes or embryos first placed in storage after 1 October 2009 may continue to be stored beyond the statutory maximum storage period, to a maximum of 55 years, but only with the written consent of the gamete provider or the people whose gametes were used to bring about the creation of the embryo (and if the other conditions in the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 2009 are satisfied) (the 2009 Regulations). Gametes and embryos first stored earlier than 1 October 2009 may be stored for an extended period under the 2009 regulations but only where the gametes or embryos are either still within the statutory storage period, or are being stored subject to a lawfully extended period under the 1991 or 1996 regulations respectively

5.21 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.

5.24 The centre should ensure that they discuss the possibility of posthumous use, and the need for consent to posthumous use, with all patients, particularly those who are storing gametes before undergoing treatment 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.

5.25 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.

5.26 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.

5.27 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.

5.28 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

5.29 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.

5.30 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

5.31 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 what the specific HFEA consent forms that 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.

5.32 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.

5.33 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.

5.34 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 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 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 a qualified 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. A qualified electronic signature is defined in Article 3 of the electronic identification and trust services (eIDAS) Regulation as an electronic signature which:

(i) meets all of the following requirements of an advanced electronic signature:

(a) it is uniquely linked to the signatory,

(b) it is capable of identifying the signatory,

(c) it is created using electronic signature creation data that the signatory can, with a high level of confidence, use under their sole control, and

(d) it is linked to the date signed therewith in such a way that any subsequent change in the data is detectable.

(ii) is created by an electronic creation device and based on a qualified certificate for electronic signature.

(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.

5.35 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.

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

5.37 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 so as to prevent disruption or delay to patient's treatment.

5.38 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

5.39 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.

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

Consent to the presence of observers

5.41 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).

5.42 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.

5.43 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).

5.44 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.

5.45 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.

5.46 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.

5.47 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).

5.48 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.

5.49 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.

5.50 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.

5.51 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.

5.52 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.

5.53 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

5.54 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.

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).

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.

5.55 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 the centres, 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.

5.56 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

Annex 3

6. Legal parenthood

Version 3.0

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] husband 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 wife] or intended female 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 another woman],

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

(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.

(2) The reference in section 48(6)(b) to a civil partnership includes a reference to a void civil partnership if either or both of the parties reasonably believed at the time when they registered as civil partners of each other that the civil partnership was valid; and for this purpose 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 recording and protection of personal data and confidentiality

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

f. 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 husband'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 o 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 retain the original signed consent forms and ensure that a copy is provided to those who have given consent 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 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 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 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.

6.24 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 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 or same-sex marriage 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.

Note: The provisions relating to same-sex marriages are not in force in Northern Ireland.

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 do 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 by her wife or civil partner 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 or same-sex marriage 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 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 biological father or mother 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 unmarried male partner

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 her husband/wife/civil partner is not a legal parent because there is a judicial separation or separation order in force. because the husband/wife/civil partner does not consent to the treatment (see 6.17 and 6.21).

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, prior to the transfer of eggs, sperm or embryos 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), 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 her husband/wife/civil partner is not a legal parent because there is a judicial separation or separation order in force or because the husband/wife/civil partner does not consent to the treatment (see 6.17 and 6.21).

Where a woman is being treated together with a female partner (not her civil partner or wife) 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, prior to the transfer of eggs, sperm or embryos 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, 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:

(a) there is a judicial separation or a separation order in force, or

(b) 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.

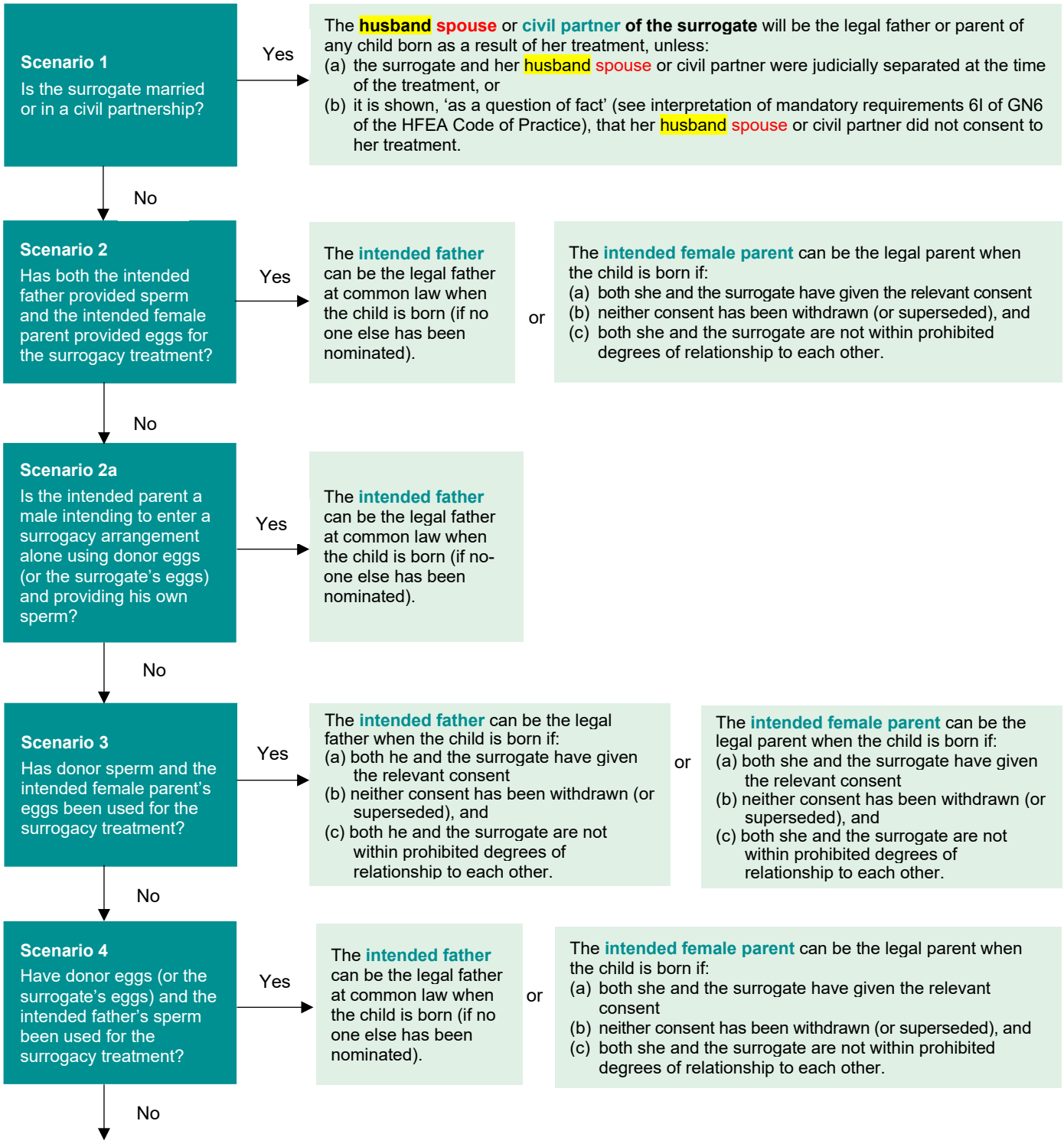
See also

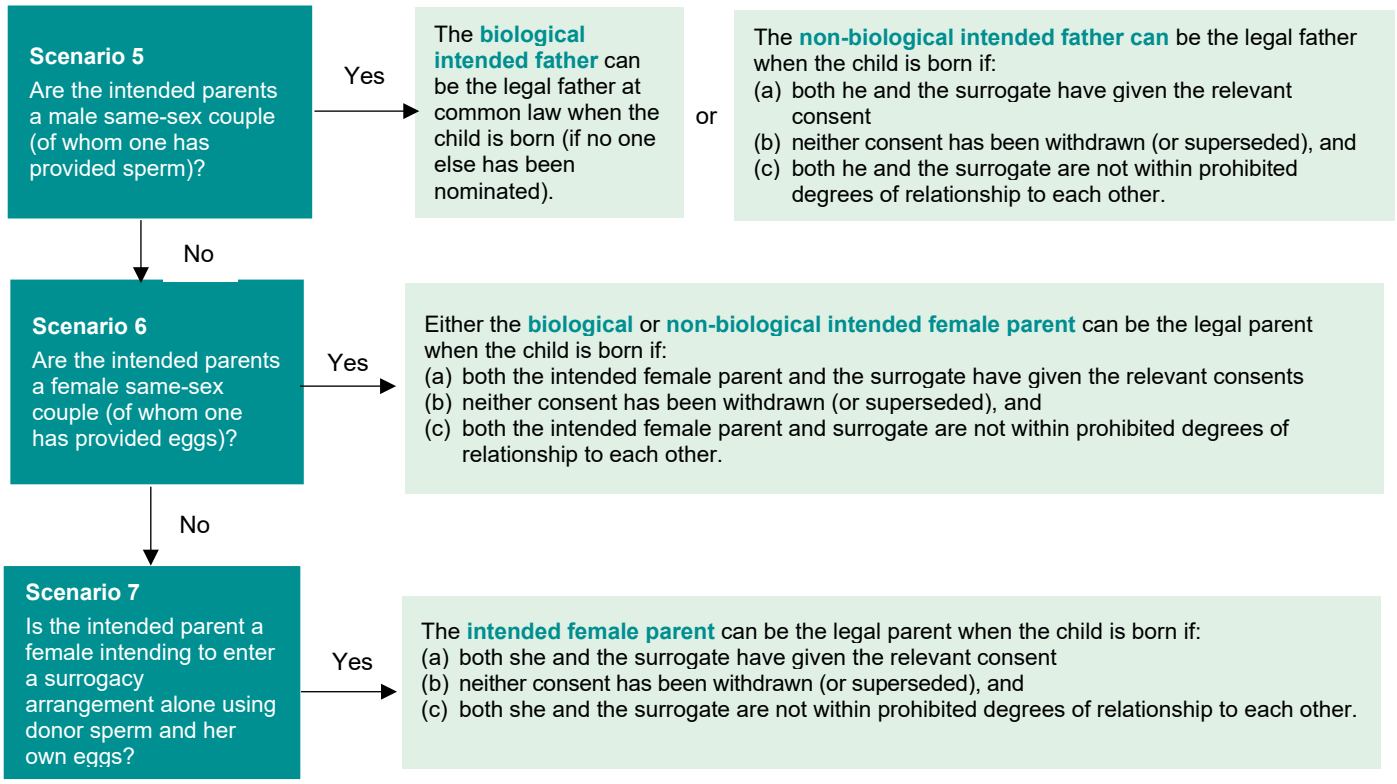
HFEA consent forms

HFEA consent form guidance

6.49 The following decision tree 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

6.46 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.

6.47 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 4

11. Donor recruitment, assessment and screening

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.

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 conditionsT52 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 With regard to donor sperm first stored in, or imported to, the UK before 19 October 2018 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 ,has suitable accreditation (for example by CPA (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.

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 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. quarantining of the gametes and re-testing of a repeat blood sample is not required. Quarantine and re-testing is also not required if the processing includes an inactivation step that has been validated for the viruses concerned.

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.

On donor sperm first stored in, or imported to, the UK after 19 October 2018, the centre must ensure that the laboratory tests required by licence condition T52 meet the following requirements, namely:

d. The test must be accredited by UKAS, the national accreditation body for the UK, carried out by a qualified laboratory, which has suitable accreditation (for example by CPA (UK) Ltd or another accreditation body recognised as accrediting to an equivalent standard). CE marked testing kits must be used where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge.

e. Blood samples must be obtained within a timeframe specified by the Authority, and

f. Donor sperm must be quarantined for a minimum of 180 days, after which repeat serological testing is required. If the blood donation 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. Quarantine and re-testing is also not required if the processing includes an inactivation step that has been validated for the viruses concerned.

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 for 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 Centres should use the current requirements in T53 (d-f) for sperm first stored in, or imported to, the UK after 19 October 2018, including where the current version of T53 has not yet been included on the clinic's licence. The requirements in T53 (a-c) still apply to donor sperm first stored in, or imported to, the UK before 19 October 2018.

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 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.

11.25 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.

11.26 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:

1. the introduction of more stringent screening requirements since the sperm to be used in their treatment was first imported and/or stored
2. the risks, if any, associated with the use of such sperm relative to sperm screened as per the revised version of SLC T53
3. 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

11.27 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.

11.28 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

11.29 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.

11.30 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.

11.31 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

11.32 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.

11.33 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.

11.34 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

11.35 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) the procedure for donors to withdraw consent for the use of their gametes, or embryos created with their gametes, and
(p) 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.

11.36 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.

11.37 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.

11.38 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.

11.39 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.

11.40 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

11.41 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).

11.42 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).

11.43 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.

11.44 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.

11.45 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.

11.46 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).

11.47 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.

11.48 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.

11.49 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.

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).

11.50 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.

11.51 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).

11.52 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.

11.53 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.

11.54 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

11.55 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).

11.56 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.

11.57 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.

11.58 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.

11.59 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.

11.60 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).

11.61 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.

11.62 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.

11.63 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.

11.64 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.

11.65 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

11.66 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.

11.67 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

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

Data Protection Act 2018

Medical Devices Regulations 2002

Equalities Act 2010

Gender Recognition Act 2004

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)

Annex 5

14. Surrogacy

Version 3.0

Mandatory requirements

Human Fertilisation and Embryology Act 2008

Part 2 – Parenthood in cases involving assisted reproduction

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 part 2

58 (1) In this part “enactment” means an enactment contained in, or in an instrument made under—

(a) an act of Parliament,

(b) an act of the Scottish Parliament,

(c) a measure or act of the National Assembly for Wales, or

(d) Northern Ireland legislation.

(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.

(3) Other expressions used in this part and in the 1990 act have the same meaning in this part as in that act.

Regulations

The Parental Orders (Human Fertilisation and Embryology) Regulations 2010

The Parental Orders (Human Fertilisation and Embryology) (Scotland) Regulations 1994

Directions

0005 – Collecting and recording information for the HFEA

HFEA guidance

Assessment and screening in surrogacy arrangements

Interpretation of mandatory requirements 14A

Intended parents providing gametes in surrogacy arrangements must be screened in line with requirements for gamete donors.

14.1 The centre should assess all those involved in surrogacy arrangements before providing treatment, in line with the welfare of the child assessment process, outlined in guidance note 8.

See also

Guidance note 8 – Welfare of the child

Guidance note 11 – Donor recruitment, assessment and screening

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

Additional information for those involved in surrogacy arrangements

14.2 The centre should ensure that those involved in surrogacy arrangements have received information about legal parenthood under the HFE Act 2008 and other relevant legislation. This information should cover who may be the legal parent(s) when the child is born, as outlined in guidance note 6.

14.3 The centre should ensure that those involved in surrogacy arrangements have received information about the effect of the parenthood provisions in the HFE Act 2008 and in particular the Parental Orders provisions in the Act. These state that parental rights and obligations in respect of surrogacy arrangements may be transferred from the birth parent(s) to the intended parent(s), as long as certain conditions are met. One of the conditions that must be met is that the gametes of at least one of the intended parents must have been used in the creation of the embryo (ie, a single intended parent must have used their own gametes in treatment or, where the intended parents are a couple, the gametes of one or both of the individuals must have been used in treatment).In the case of mitochondria donation, the mitochondria donor is not considered to be the biological parent (ie, because their nuclear DNA is not passed on to the child). Therefore, they cannot be an

applicant for a parental order on the basis of that donation.

14.4 The centre should advise patients that surrogacy arrangements are unenforceable and that they are encouraged to seek legal advice about this and any other legal aspect of surrogacy.

14.5 The centre should satisfy itself that those involved in surrogacy arrangements have received enough information and understand the legal implications of these arrangements well enough to be able to give informed consent to treatment.

14.6 The centre should advise patients intending to travel to another country for the purpose of entering into a surrogacy arrangement that they are encouraged not to do so until they have sought legal advice about:

(a) legal parenthood of the prospective child
(b) immigration status and passport arrangements
(c) the adoption or parental orders procedures for that country, and
(d) the degree to which those procedures would be recognised under the law of the part of the United Kingdom in which the patients live.

See also

Guidance note 4 – Information to be provided prior to consent

Guidance note 6 – Legal parenthood

Discussion of implications for surrogacy arrangements

14.7 The centre should ensure that any person intending to begin treatment as a surrogate has discussed the implications of treatment as part of their preparation for treatment (see guidance note 4.1-4.4). Our expectation is that the discussion of implications should be delivered by a qualified counsellor with appropriate knowledge of surrogacy arrangements. If the surrogate has a partner they should attend the session(s) with the surrogate. If the surrogate requests additional sessions without her partner this should be made available.

14.8 The discussion of implications may be provided by the centre or by another suitable organisation or individual. Where the centre is satisfied that the surrogate has previously discussed the implications of entering a surrogacy arrangement (either at the centre or elsewhere) the centre should make the decision as to whether further discussion of is required or not before the surrogate can begin treatment. If the surrogate has previously discussed implications, but would like to undertake further discussions, this should be available. The intended parent(s) should not attend this/these implications discussion(s) and where practicable the appointment(s) should take place on a date separate to any appointment to be attended by, or with, the intended parent(s). The discussion of implications should address potential risks and implications of surrogacy, including, but not limited to:

- risks to the surrogate's physical and mental health;
- legal implications, practical and financial matters;
- the risk of the intended parent(s) not wanting to parent any child born and/or not wishing to make a parental order application after a child is born;
- the potential emotional impact on the surrogate and the surrogate's partner and/or family.

The discussion of implications should allow full opportunity for the surrogate (and her partner, where applicable) to ask questions and discuss any concerns.

14.9 The centre should ensure that any person intending to enter a surrogacy arrangement as an intended parent has discussed the implications of entering into a surrogacy arrangement (see guidance note 4.1-4.4). Our expectation is that the discussion of implications should be delivered by a qualified counsellor with appropriate knowledge of surrogacy arrangements. The surrogate

(and the surrogate's partner, if applicable) should not attend this/these session(s) and where practicable this appointment(s) should take place on a date separate to any appointment to be attended by, or with, the surrogate (or the surrogate's partner if she has one). The discussion of implications should address potential risks and implications of surrogacy, including, relevant risks outlined in 14.8, as well as the risk of the surrogate not agreeing to the legal transfer of parenthood to the intended parent(s) after a child is born and the risk of the surrogate deciding to parent the child herself after its birth. The discussion of implications should allow full opportunity for the intended parent(s) to ask questions and discuss any concerns.

14.10 In addition to the separate discussions of implications referred to at 14.7 and 14.9, the surrogate and intended parent(s) should attend (a) joint implications discussion(s). This should cover any relevant risks/considerations mentioned in 14.8 and 14.9. Both the surrogate and the intended parent(s) should have full opportunity to ask questions and discuss any concerns at this appointment.

Offer of counselling to those considering surrogacy

14.11 The centre should give all those involved in a surrogacy arrangement a suitable opportunity to receive proper counselling about the implications of the steps they are considering. The counselling requirements are outlined in guidance note 3.

14.12 Counselling may be provided by the centre or by another suitable organisation or individual. If the surrogate has previously received counselling (either at the centre or elsewhere) but would like to undertake further counselling, this should be available.

14.13 The centre should encourage those involved in a surrogacy arrangement to reflect on their decisions before it obtains their consent. The centre should provide detailed information, advice and guidance and encourage questions. The centre should be satisfied that all parties fully understand all aspects of the surrogacy arrangement and are entering into the arrangement freely and voluntarily, before obtaining their consent. This should include testing the understanding of both the intended surrogate and intended parent(s) and ensuring that information is provided clearly and at an appropriate level of complexity tailored to an individual's capacity to understand it.

14.14 The centre should exercise particular caution and sensitivity when discussing and taking consents for surrogacy arrangements and be aware of the vulnerable positions of both the surrogate and intended parent(s) and the serious implications for all concerned of a surrogacy arrangement breaking down. The centre should be alert to any sign of coercion. The centre's role should be to protect both parties from entering into a surrogacy arrangement which it suspects may be unsuitable or unethical for any reason.

Exporting gametes or embryos for patients who may be seeking commercial surrogacy abroad

14.15 Centres seeking to export gametes or embryos for patients who may be considering commercial surrogacy abroad are not precluded from doing so provided they can satisfy the requirements of General Direction 0006. The Surrogacy Arrangements Act 1985 prohibits any person, including agents and intermediaries, from negotiating surrogacy arrangements in the UK on a commercial basis, however it is not unlawful for intended parents or prospective surrogates to carry out acts that are otherwise prohibited under this Act. Similarly, it is not unlawful for not-for-profit agencies in the UK to undertake certain activities related to surrogacy that would otherwise be prohibited if undertaken by a commercial surrogacy agency. Treatment provided to a surrogate and intended parents would not be unlawful in the UK notwithstanding that they may have entered into a commercial arrangement thus, the possibility of commercial surrogacy abroad should not be an impediment to export, provided the requirements of General Direction 6 can be satisfied.

See also

Guidance note 3 – Counselling and patient support

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

Other legislation, professional guidelines and information

Legislation

Surrogacy Arrangements Act 1985

General information

Home Office: UK visas and immigration

Please note that the following two guidance documents were published before the law was changed to allow single people to apply for a parental order to transfer legal parenthood to them if they are an intended parent in respect of a surrogacy arrangement:

The Surrogacy Pathway

Care in Surrogacy

Clinic Focus articles

Clinic Focus Article: Export of gametes and embryos for surrogacy abroad (December 2020)

Annex 6

15. Procuring, processing and transporting 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.

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.

T74 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 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

b. 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.

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, has suitable accreditation (for example by CPA (UK) Ltd 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.

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 UK 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
GBXI	**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 GBXI00012300000000XX456 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 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 7

16. Imports and exports

Version 2.0

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.

Interpretation of mandatory requirements 16A, 16B, 16C, and 16.1-16.5 apply to centres in GB only.

Interpretation of mandatory requirements 16D, 16E, 16F, and 16.6-16.12 apply to centres in NI only.

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)

24 Directions as to particular matters

(3) In relation to gametes or embryos that are not intended for human application, directions may authorise, in such circumstances and subject to such conditions as may be specified in the directions, the keeping, by or on behalf of a person to whom a licence applies, of gametes or embryos in the course of their carriage to or from any premises.

(3A) In relation to gametes and embryos that are intended for human application, directions may authorise the keeping of gametes or embryos by or on behalf of a person to whom a licence applies, in the course of their carriage -

(a) between premises to which licences relate,

(b) between such premises and relevant third party premises,

(c) in relation to Northern Ireland, between premises referred to in paragraphs (a) and (b) and tissue establishments accredited, designated, authorised or licensed under the laws, or other measures, of an EEA state which implement the first, second and third Directives between premises referred to in paragraphs (a) and (b) and tissue establishments accredited, designated, authorised or licensed under the laws, or other measures, of an EEA state other than the United Kingdom or of Gibraltar which implement the first, second and third Directives, or

(d) between premises referred to in paragraphs (a) and (b) and tissue establishments in a country which is not an EEA state third country, pursuant to directions given under subsection (4), in such circumstances and subject to such conditions as may be specified in directions.

(3B) Directions may authorise, in such circumstances and subject to such conditions as may be specified in the directions, the keeping, by or on behalf of a person to whom a licence applies, of human admixed embryos in the course of their carriage to or from any premises.

(4) Directions may authorise any person to whom a licence applies to

(a) receive gametes, embryos or human admixed embryos

(i) from outside the United Kingdom, and

(ii) in respect of Northern Ireland, from Great Britain, or

(b) send gametes, embryos or human admixed embryos outside the United Kingdom in such circumstances and subject to such conditions as may be specified in the directions.

(4ZA) Directions made by virtue of this subsection (4) may provide for sections 12 to 14 of this Act to have effect with such modifications as may be specified in the directions.

(4A) In giving any directions under subsection (4) authorising any person to whom a licence applies to export from the United Kingdom to a third country, gametes or embryos intended for human application, the Authority shall -

(a) include directions specifying the measures that persons to whom a licence applies shall take to ensure that all such exports meet standards of quality and safety equivalent to those laid down in the act, and

(b) have regard to ensuring traceability.

(4AA) Directions must, in accordance with paragraph 1 of Schedule 3AA, specify requirements with which any person to whom a licence applies who proposes to make qualifying imports (other than a one-off import) must comply before the Authority gives any directions under subsection (4) authorising the person to make qualifying imports.

(4AB) Directions must, in accordance with paragraph 2 of Schedule 3AA, specify requirements with which any person to whom a licence applies who proposes to make a qualifying import which is a one-off import must comply before the Authority gives any directions under subsection (4) authorising the person to make the import.

(4AC) In giving any directions under subsection (4) authorising any person to whom a licence applies to make any qualifying imports, the Authority must include the directions specified in paragraph 3 of Schedule 3AA.

(4AD) Where the Authority gives any directions under subsection (4) authorising any person to whom a licence applies to make any qualifying imports, it must

(a) in relation to Great Britain, provide that person with a certificate of authority in such form as the Authority considers appropriate; and in the form set out in Annex II to the fourth directive.

(b) in relation to Northern Ireland, provide that person with a certificate in the form set out in Annex II to the fourth Directive.

(4AE) In subsections (4AA) and (4AB) a reference to a one-off import, in relation to gametes or embryos, is to gametes or embryos imported for the purposes of providing services to a particular person or persons on one occasion only.

(4AF) In subsections (4AA) to (4AD) and Schedule 3AA "qualifying import" means the import into the United Kingdom from a third country of gametes or embryos intended for human application.

Directions

0005 – Collecting and recording information for the HFEA

0006 – Import and export of gametes and embryos

Guidance for centres in Great Britain

Registering patients and donors in Great Britain

Interpretation of mandatory requirements 16A for centres in Great Britain

Where a centre wishes to import gametes or embryos into the UKGB, or export them from the UKGB, the person responsible must ensure that:

- a donor information form is completed in respect of any donated gametes, and
- where the gametes are exported or imported for the use of a patient, that the patient is registered with the HFEA, and the relevant registration forms are completed.

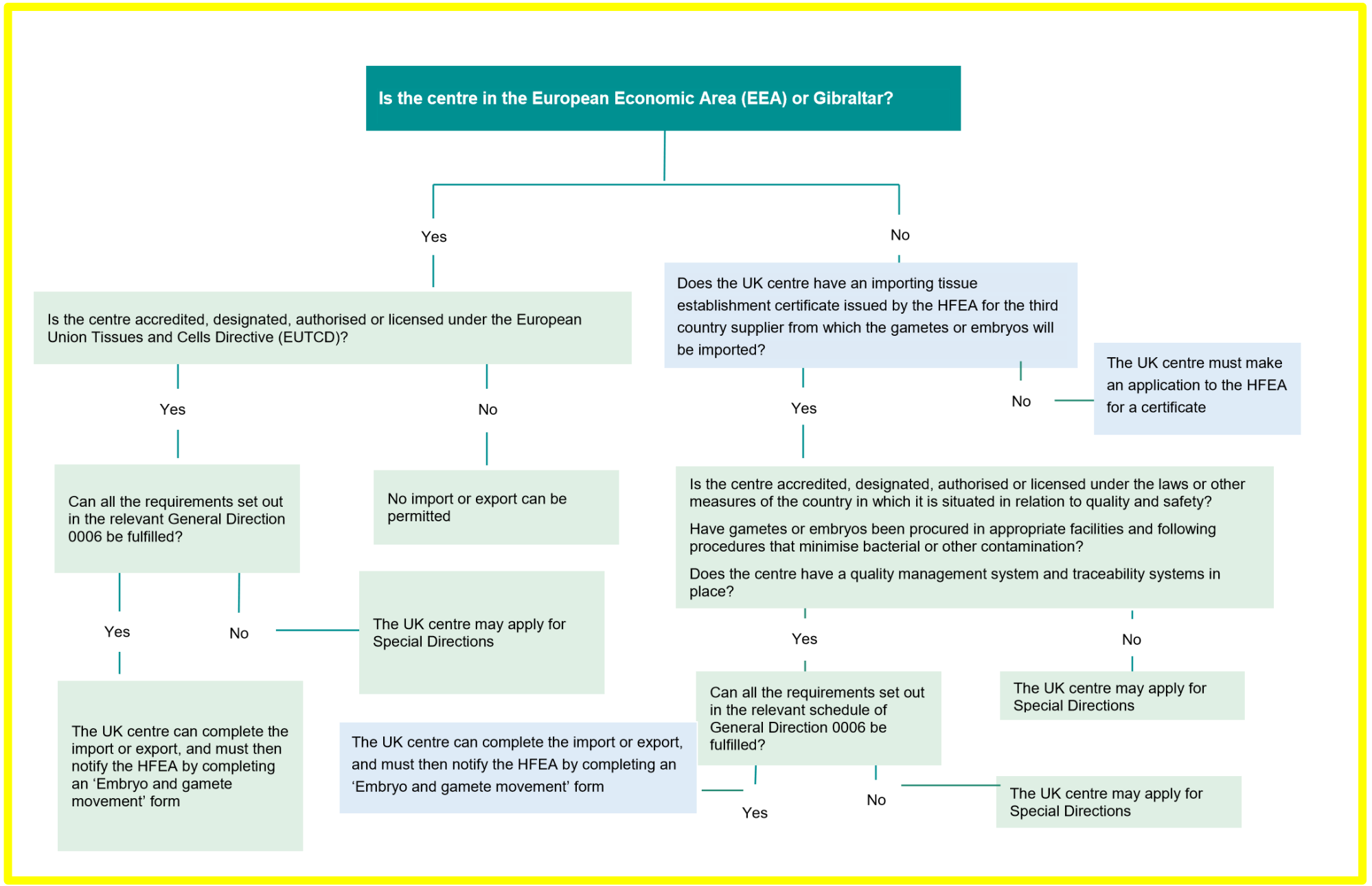
Information for patients and donors for centres in Great Britain

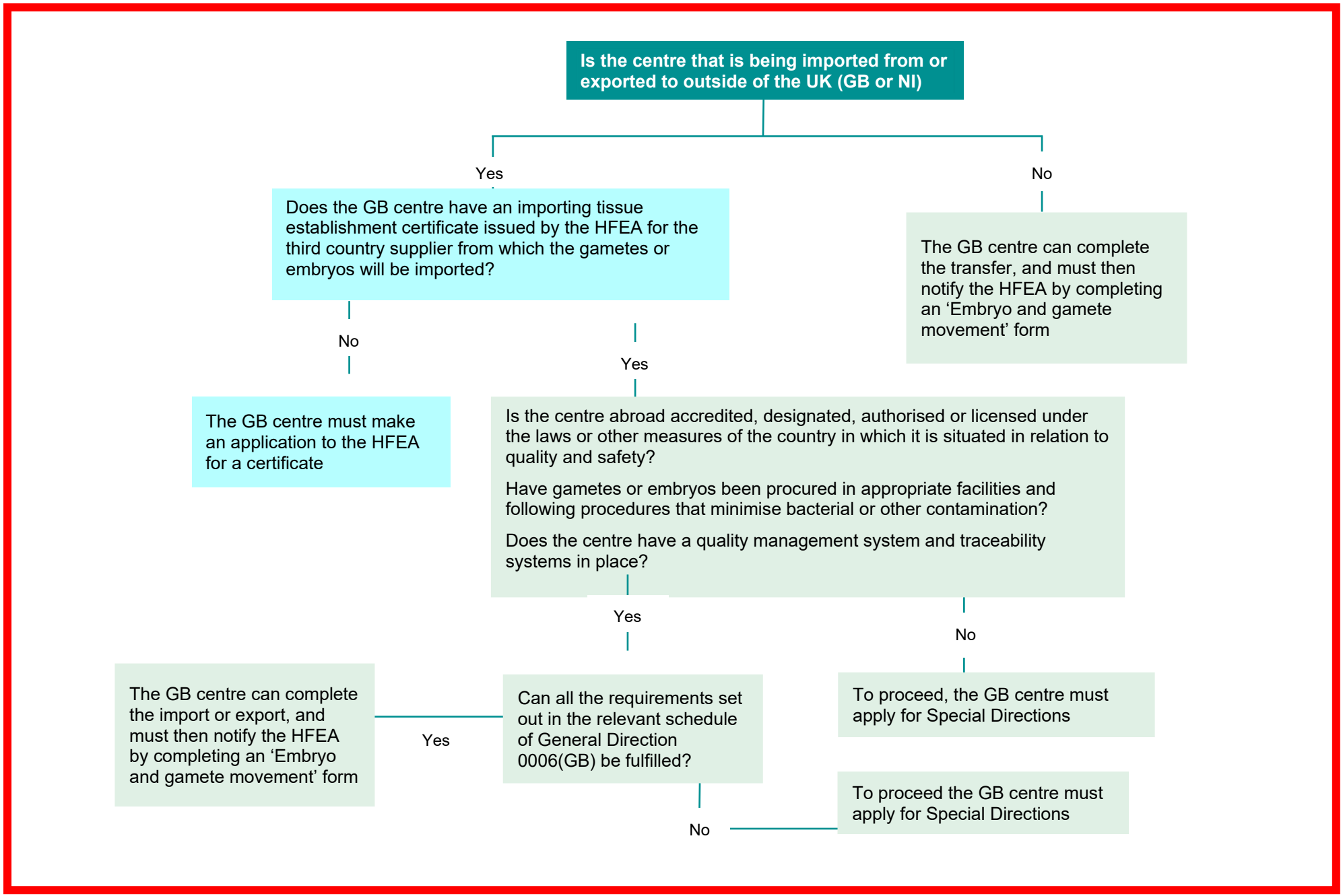
16.1 Before a patient or donor considers obtaining gametes or embryos from outside the UKGB, the centre should inform them that special criteria relating to UK standards must be met.

Imports and exports flowchart for centres in Great Britain

16.2 The flowchart on the following page summarises what centres in GB must consider when transferring gametes and embryos to or from a country outside of the UK.

(a) within the European Economic Area (EEA) and Gibraltar, or
(b) outside the EEA and Gibraltar.


Is the centre in the European Economic Area (EEA) or Gibraltar?
Yes
No
Is the centre accredited, designated, authorised or licensed under the European Union Tissues and Cells Directive (EUTCD)?
Yes
No
Can all the requirements set out in the relevant General Direction 0006 be fulfilled?
Yes
No
The UK centre may apply for Special Directions
The UK centre can complete the import or export, and must then notify the HFEA by completing an 'Embryo and gamete movement' form
No import or export can be permitted
Does the UK centre have an importing tissue establishment certificate issued by the HFEA for the third country supplier from which the gametes or embryos will be imported?
Yes
No
The UK centre must make an application to the HFEA for a certificate
Is the centre accredited, designated, authorised or licensed under the laws or other measures of the country in which it is situated in relation to quality and safety?
Have gametes or embryos been procured in appropriate facilities and following procedures that minimise bacterial or other contamination?
Does the centre have a quality management system and traceability systems in place?
Yes
No
Can all the requirements set out in the relevant schedule of General Direction 0006 be fulfilled?
Yes
No
The UK centre may apply for Special Directions
The UK centre can complete the import or export, and must then notify the HFEA by completing an 'Embryo and gamete movement' form
The UK centre may apply for Special Directions


Is the centre that is being imported from or exported to outside of the UK (GB or NI)
Yes
No
Does the GB centre have an importing tissue establishment certificate issued by the HFEA for the third country supplier from which the gametes or embryos will be imported?
The GB centre can complete the transfer, and must then notify the HFEA by completing an 'Embryo and gamete movement' form
No
Yes
The GB centre must make an application to the HFEA for a certificate
Is the centre abroad accredited, designated, authorised or licensed under the laws or other measures of the country in which it is situated in relation to quality and safety?
Have gametes or embryos been procured in appropriate facilities and following procedures that minimise bacterial or other contamination?
Does the centre have a quality management system and traceability systems in place?
Yes
No
The GB centre can complete the import or export, and must then notify the HFEA by completing an 'Embryo and gamete movement' form
Yes
Can all the requirements set out in the relevant schedule of General Direction 0006(GB) be fulfilled?
To proceed, the GB centre must apply for Special Directions
No
To proceed the GB centre must apply for Special Directions

General directions: evidence of compliance for centres in Great Britain

Interpretation of mandatory requirements 16B for centres in Great Britain

(a) Within the EEA and Gibraltar

Where a centre wants to export or import gametes or embryos to or from another EEA state or Gibraltar, the person responsible must obtain and retain (for three years) written evidence that the receiving or sending centre is accredited, designated, authorised or licensed in accordance with the requirements of the European Tissues and Cells Directive (EUTCD).

(b) Outside the EEA and Gibraltar

Where a centre in GB wants to export or import gametes or embryos to or from a country outside of GB or NI (a third country) the EEA or Gibraltar, the person responsible must obtain and retain (for three years) written evidence that:

(i) the receiving or sending centre is accredited, designated, authorised or licensed under the laws or other measures of the country in which it is situated in relation to quality and safety

(ii) the centre has appropriate quality management and traceability systems, and

(iii) the gametes or embryos have been procured and processed in appropriate facilities, and following procedures that minimise bacterial or other contamination.

Where a centre wants to import from a third country supplier, the person responsible at the UK GB clinic must:

(i) ensure that, before undertaking any import from a third country supplier, the UK GB clinic has an importing tissue establishment certificate issued by the HFEA for the third country supplier it proposes to import from

(ii) comply with measures specified in the direction for the purposes of ensuring that any qualifying gametes or embryos imported from a third country meet standards of quality and safety

(iii) provide the HFEA with the information specified in the relevant schedule to General Direction 0006(GB) for ongoing imports

(iv) provide the HFEA with the documents specified in the relevant schedule to General Direction 0006(GB) for one-off imports

(v) make available for inspection any documents specified in General Direction 0006(GB)

(vi) establish a written agreement with any proposed third country supplier that complies with the requirements set out in General Direction 0006(GB).

When a certificate is issued to the importing tissue establishment, the person responsible must:

(i) Seek written approval from the HFEA for any planned substantial changes to their import activities (eg, if it has previously only imported sperm, and now wishes to import oocytes, a written approval from the HFEA will be needed).

(ii) Inform the HFEA of their decision to cease their import activities in part or in full.

(iii) Inform the HFEA of any suspected or actual serious adverse events or reactions reported to them by the third country supplier and which may influence the quality and safety of the tissues and cells they import.

(iv) Notify the HFEA of any revocation or suspension of a third country supplier's authorisation to export tissues and cells

(v) Notify the HFEA of any decision taken for reasons of non compliance by the competent authority of the country that the third country supplier is based in, where the quality and safety of imported tissues and cells are affected.

(vi) Notify the HFEA if a further import is anticipated for a couple on whose behalf a one-off import has previously been made, whether by your clinic or any other clinic in the UKGB.

In each case, a copy of the information retained must be provided to the Authority on request.

In all cases, all the remaining requirements in the relevant HFEA Directions on import and export of gametes and embryos relating to identification, consent, parenthood, payment of the donor, use of the gametes and embryos, and screening must be met.

No import of eggs or embryos that have undergone maternal spindle transfer (MST) or pronuclear transfer (PNT) is permitted to the UKGB.

16.3 The systems referred to in the interpretation box above should include the traceability of all materials and equipment that could affect the quality and safety of the gametes or embryos. For transfers to or from centres within the EEA and Gibraltar, this evidence may include documented certification from the competent authority that the centre complies with the requirements of the EUTCD, is included in a national database of registered tissue establishments, or both.

See also

Guidance note 19 – Traceability

Guidance note 31 – Record keeping and document control

Guidance note 14 – Surrogacy

Special Directions: imports or exports within the EEA and Gibraltar

16.4 An application to the HFEA for Special Directions should be made when patients wish to transfer gametes or embryos to or from an EEA centre that is accredited, designated, authorised or licensed in line with the EUTCD, but where compliance with other condition(s) in the relevant General Directions cannot be assured.

16.5 The HFEA has no power to issue Special Directions to allow imports to or exports from unaccredited tissue establishments within the EEA. Centres should tell patients that imports or exports of gametes or embryos are permitted only if the EEA centre has been accredited and licensed as complying with the requirements of the EUTCD.

Special Directions: imports or exports from centres in Great Britain outside EEA and Gibraltar

16.4 If compliance with all conditions in the relevant General Directions 0006(GB) cannot be assured, then an application to the HFEA for Special Directions may must be made.

16.5 Before applying for special directions for the import of any gametes or embryos from a third country supplier (a supplier outside of GB or NI), the GBUK centre must ensure that it has an importing tissue establishment certificate issued by the HFEA for the third country supplier it proposes to import from.

See also

Special direction – import or export of gametes or embryos form (clinic portal)

Special direction – export of gametes form (clinic portal)

Special direction – import of embryos form (clinic portal)

Special direction – import of gametes form (clinic portal)

HFEA special direction application guidance

Notifying the HFEA about transfers to or from centres in Great Britain

Interpretation of mandatory requirements 16C for centres in Great Britain

When transferring gametes or embryos to or from GB UK under General Directions, the centre must complete the relevant transfer notification form. In this form, the person responsible must declare that they are satisfied that the centre to or from which the transfer is being made meets the requirements listed in the Directions. Completed forms must be returned to the HFEA no later than 10 working days after the transfer has taken place.

When transferring gametes or embryos under Special Directions, the person responsible must notify the HFEA within two working days.

See also

Embryo and gamete movement – Out (GO) form (clinic portal)

Embryo and gamete movement – In (GI) form (clinic portal)

Guidance for centres in Northern Ireland

Registering patients and donors in Northern Ireland

Interpretation of mandatory requirements 16D for centres in Northern Ireland

Where a centre in NI wishes to import gametes or embryos into NI, or export them from NI, the person responsible must ensure that:

- a donor information form is completed in respect of any donated gametes, and
- where the gametes are exported or imported for the use of a patient, that the patient is registered with the HFEA, and the relevant registration forms are completed.

Information for patients and donors for centres in Northern Ireland

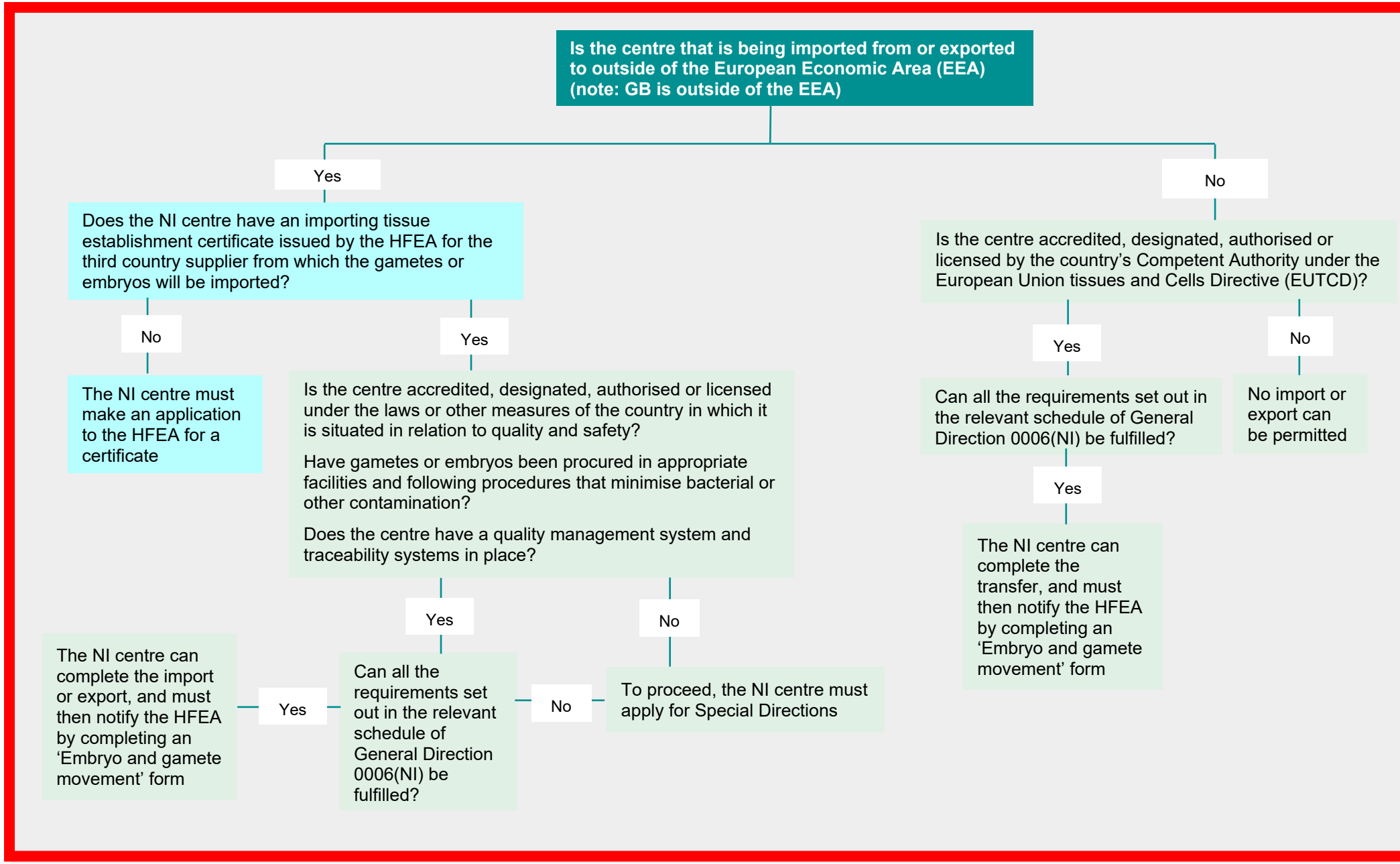
16.6 Before a patient or donor considers obtaining gametes or embryos from outside NI, the centre should inform them that special criteria relating to UK standards must be met.

Imports and exports flowchart for centres in Northern Ireland

16.7 The flowchart on the following page summarises what centres in NI must consider when transferring gametes and embryos

(a) within the European Economic Area (EEA), or

(b) outside the EEA.


Is the centre that is being imported from or exported to outside of the European Economic Area (EEA) (note: GB is outside of the EEA)
Yes
No
Does the NI centre have an importing tissue establishment certificate issued by the HFEA for the third country supplier from which the gametes or embryos will be imported?
No
Yes
The NI centre must make an application to the HFEA for a certificate
Is the centre accredited, designated, authorised or licensed under the laws or other measures of the country in which it is situated in relation to quality and safety?
Have gametes or embryos been procured in appropriate facilities and following procedures that minimise bacterial or other contamination?
Does the centre have a quality management system and traceability systems in place?
Yes
No
Can all the requirements set out in the relevant schedule of General Direction 0006(NI) be fulfilled?
Yes
No
To proceed, the NI centre must apply for Special Directions
The NI centre can complete the import or export, and must then notify the HFEA by completing an 'Embryo and gamete movement' form
Is the centre accredited, designated, authorised or licensed by the country's Competent Authority under the European Union tissues and Cells Directive (EUTCD)?
Yes
No
Can all the requirements set out in the relevant schedule of General Direction 0006(NI) be fulfilled?
No import or export can be permitted
Yes
The NI centre can complete the transfer, and must then notify the HFEA by completing an 'Embryo and gamete movement' form

General directions: evidence of compliance for centres in Northern Ireland

Interpretation of mandatory requirements 16E for centres in Northern Ireland

(a) Within the EEA

Where a centre in NI wants to import gametes or embryos from an EEA state, the person responsible must obtain and retain (for three years) written evidence that the sending centre is accredited, designated, authorised or licensed in accordance with the requirements of the European Tissues and Cells Directive (EUTCD).

Where a centre in NI wants to export gametes or embryos to an EEA state, the person responsible must obtain and retain (for three years) written evidence that:

(i) the receiving centre is accredited, designated, authorised or licensed under the laws or other measures of the country in which it is situated in relation to quality and safety

(ii) the centre has appropriate quality management and traceability systems, and

(iii) the gametes or embryos have been procured and processed in appropriate facilities, and following procedures that minimise bacterial or other contamination.

(b) Outside the EEA (a third country, which includes GB)

Where a centre in NI wants to export or import gametes or embryos to or from a country outside of EEA, the person responsible must obtain and retain (for three years) written evidence that:

(i) the receiving or sending centre is accredited, designated, authorised or licensed under the laws or other measures of the country in which it is situated in relation to quality and safety

(ii) the centre has appropriate quality management and traceability systems, and

(iii) the gametes or embryos have been procured and processed in appropriate facilities, and following procedures that minimise bacterial or other contamination.

Where a centre wants to import from a third country supplier, the person responsible at the NI clinic must:

(iv) ensure that, before undertaking any import from a third country supplier, the NI clinic has an importing tissue establishment certificate issued by the HFEA for the third country supplier it proposes to import from

(v) comply with measures specified in the direction for the purposes of ensuring that any qualifying gametes or embryos imported from a third country meet standards of quality and safety

(vi) provide the HFEA with the information specified in the relevant schedule to General Direction 0006(NI) for ongoing imports

(vii) provide the HFEA with the documents specified in the relevant schedule to General Direction 0006(NI) for one-off imports

(viii) make available for inspection any documents specified in General Direction 0006(NI)

(ix) establish a written agreement with any proposed third country supplier that complies with the requirements set out in General Direction 0006(NI).

When a certificate is issued to the importing tissue establishment, the person responsible must:

(i) Seek written approval from the HFEA for any planned substantial changes to their import activities (eg, if it has previously only imported sperm, and now wishes to import oocytes, a written approval from the HFEA will be needed).

(ii) Inform the HFEA of their decision to cease their import activities in part or in full.

(iii) Inform the HFEA of any suspected or actual serious adverse events or reactions reported to them by the third country supplier and which may influence the quality and safety of the tissues and cells they import.

(iv) Notify the HFEA of any revocation or suspension of a third country supplier's authorisation to export tissues and cells

(v) Notify the HFEA of any decision taken for reasons of non-compliance by the competent authority of the country that the third country supplier is based in, where the quality and safety of imported tissues and cells are affected.

(vi) Notify the HFEA if a further import is anticipated for a couple on whose behalf a one-off import has previously been made, whether by your clinic or any other clinic in NI.

In each case, a copy of the information retained must be provided to the Authority on request.

In all cases, all the remaining requirements in the relevant HFEA Directions on import and export of gametes and embryos relating to identification, consent, parenthood, payment of the donor, use of the gametes and embryos, and screening must be met.

No import of eggs or embryos that have undergone maternal spindle transfer (MST) or pronuclear transfer (PNT) is permitted to NI.

16.8 The systems referred to in the interpretation box above should include the traceability of all materials and equipment that could affect the quality and safety of the gametes or embryos. For transfers to or from centres within the EEA, this evidence may include documented certification from the competent authority that the centre complies with the requirements of the EUTCD, is included in a national database of registered tissue establishments, or both.

See also

Guidance note 36 – Imports and exports

Guidance note 19 – Traceability

Guidance note 31 – Record keeping and document control

Guidance note 14 - Surrogacy

Special Directions for centres in Northern Ireland: imports or exports within the EEA

16.9 An application to the HFEA for Special Directions should be made when patients wish to transfer gametes or embryos to or from an EEA centre that is accredited, designated, authorised or licensed in line with the EUTCD, but where compliance with other condition(s) in General Directions 0006(NI) cannot be assured.

16.10 The HFEA has no power to issue Special Directions to allow imports to or exports from unaccredited tissue establishments within the EEA. Centres should tell patients that imports or exports of gametes or embryos are permitted only if the EEA centre has been accredited, designated, authorised or licensed in line with the EUTCD.

Special Directions for centres in Northern Ireland: imports from or exports to the EEA (including to or from GB)

16.11 If compliance with all conditions in the General Directions 0006(NI) cannot be assured, then an application to the HFEA for Special Directions must be made in order to proceed.

16.12 Before applying for special directions for the import of any gametes or embryos from a third country supplier (any country outside of the EEA, including GB), the NI centre must ensure that it has an importing tissue establishment certificate issued by the HFEA for the third country supplier it proposes to import from.

See also

Special direction – import or export of gametes or embryos form (clinic portal)

HFEA special direction application guidance

Notifying the HFEA about transfers to or from centres in Northern Ireland

Interpretation of mandatory requirements 16F for centres in Northern Ireland

When transferring gametes or embryos to or from NI under General Directions, the centre must complete the relevant transfer notification form. In this form, the person responsible must declare that they are satisfied that the centre to or from which the transfer is being made meets the requirements listed in the Directions. Completed forms must be returned to the HFEA no later than 10 working days after the transfer has taken place.

When transferring gametes or embryos under Special Directions, the person responsible must notify the HFEA within two working days.

See also

Embryo and gamete movement – Out (GO) form (clinic portal)

Embryo and gamete movement – In (GI) form (clinic portal)

Other legislation, professional guidance and information

Legislation

The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019

The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020

Chair's letters

Chair's letter CH(20)02: Regulation changes for the end of the Implementation Period

Chair's Letter CH(21)02: New requirements come into force at the end of the transition period

General information

List of European Union (EU) and European Economic Area (EEA) countries

Annex 8

17. Storage of gametes and embryos

Version 2.0

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)

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.

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 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, shall be allowed to perish, 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 statutory storage period in respect of gametes is such period not exceeding ten years as the licence may specify.

(4) The statutory storage period in respect of embryos is such period not exceeding ten years as the licence may specify.

(4A) The statutory storage period in respect of human admixed embryos is such period not exceeding 10 years as the licence may specify.

(5) Regulations may provide that subsection (3), (4) or (4A) above shall 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 regulations, such longer period, as may be specified in the regulations.

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 the United Kingdom Northern Ireland from an EEA state other than from the United Kingdom or from Gibraltar, 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

Regulations

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

1 Citation and coming into force

These Regulations may be cited as the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 and shall come into force on 1st October 2009

2 Interpretation

In these Regulations—

"the 1991 Regulations" means the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991;

"the 1996 Regulations" means the Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996;

"the 2020 Regulations" means the Human Fertilisation (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020;

"the Act" means the Human Fertilisation and Embryology Act 1990;

"coronavirus" means severe acute respiratory syndrome coronavirus 2 (SARS-Cov-2);

"the maximum storage period" means—

(a) in respect of an embryo, the maximum period that may by virtue of these Regulations be specified under section 14(4) of the Act in a licence; and

(b) in respect of a gamete, the maximum period that may by virtue of these Regulations be specified under section 14(3) of the Act in a licence;

"person to be treated" means—

(a) the woman whom it is intended will be provided with treatment services using the embryo or gamete in question;

(b) the woman who the embryo or gamete in question has been allocated to by a person to whom a licence applies6; or

(c) the man who the embryo or gamete in question has been allocated to by a person to whom a licence applies; and

"the relevant persons" means the two people whose gametes were used to bring about the creation of an embryo.

3. Extension of statutory storage period for premature infertility

(1) Subject to paragraphs (6) and (7), for the purpose of this regulation—

"relevant period" means ten years from the date that—

(a) the embryo in question was first placed in storage; or

(b) if later, the most recent previous written opinion was given under sub-paragraph (b) of paragraph (3).

(2) In the circumstances specified in paragraph (3), the maximum storage period for an embryo shall, subject to paragraph (4) and regulation 3A, be the period beginning with the date on which the embryo was first placed into storage and ending ten years after the date of the most recent written opinion given under sub-paragraph (b) of paragraph (3).

(3) The circumstances referred to in paragraph (2) are that—

(a) the relevant persons have consented in writing to the embryo in question being stored for a period in excess of ten years for the provision of treatment services; and

(b) on any day within the relevant period a registered medical practitioner has given a written opinion that one of the relevant persons, or, where they are not one of those persons, the person to be treated, is prematurely infertile or is likely to become prematurely infertile.

(4) Where the maximum storage period calculated in accordance with paragraph (2) would be greater than fifty five years, the maximum storage period for the purpose of that paragraph shall be fifty five years.

(5) Paragraphs (1) to (4) apply to embryos to which a maximum storage period of 10 years would otherwise apply by virtue of article 2 of the Human Fertilisation and Embryology (Supplementary Provision) Order 2009 as they apply to embryos first placed into storage after the coming into force of these Regulations.

(6) Where the statutory storage period for an embryo has been extended under regulation 3 of the 2020 Regulations, paragraph (1) applies as if *"relevant period"* means—

(a) where the statutory storage period for the embryo has not previously been extended under paragraph (2), twelve years from the date that the embryo in question was first placed in storage;

(b) where the statutory storage period for the embryo has previously been extended under paragraph (2)—

(i) twelve years from the date that the embryo in question was first placed in storage, or

(ii) if later, ten years from the date that the most recent previous written opinion was given under sub-paragraph (b) of paragraph (3).

(7) Where the statutory storage period for an embryo has been extended under regulation 3A, paragraph (1) applies as if *"relevant period"* means—

(a) where the most recent previous written opinion given under sub-paragraph (b) of paragraph (3) was given before 1st July 2020, twelve years from the date of that opinion;

(b) where the most recent previous written opinion given under sub-paragraph (b) of paragraph (3) was given on or after 1st July 2020, ten years from the date of that opinion.

3A. Extension of statutory storage period for premature infertility for a reason relating to coronavirus

(1) In the circumstances specified in paragraph (2), the maximum storage period for an embryo shall, subject to paragraph (3), be the period beginning with the date on which the embryo was first placed into storage and ending twelve years after the date of the most recent written opinion given under paragraph (3)(b) of regulation 3 ("the extended storage period").

(2) The circumstances referred to in paragraph (1) are that—

(a) the embryo in question is, on 1st July 2020, being stored, for the provision of treatment services, on premises to which a licence under paragraph 1 or 2 of Schedule 2 to the Act relates;

(b) a registered medical practitioner has, before 1st July 2020, given a written opinion under paragraph (3)(b) of regulation 3;

(c) neither of the relevant persons nor, where they are not one of those persons, the person to be treated, is, for a reason relating to coronavirus, able to obtain a further written opinion within ten years from the date that the written opinion referred to in sub-paragraph (b) was given;

(d) the relevant persons have consented in writing, whether before, on or after 1st July 2020, to the embryo being stored for at least the extended storage period for the provision of treatment services; and

(e) the statutory storage period for the embryo has not previously been extended under paragraph (1).

(3) Where the maximum storage period calculated in accordance with paragraph (1) would be greater than fifty five years, the maximum storage period for the purpose of that paragraph shall be fifty five years.

4. Extension of statutory storage period for premature infertility

(1) Subject to paragraphs (5) and (6), for the purpose of this regulation—

"relevant period" means ten years from the date that—

(a) the gamete in question was first placed in storage; or

(b) if later, the most recent previous written opinion was given under sub-paragraph (b) of paragraph (3).

(2) In the circumstances specified in paragraph (3), the maximum storage period for a gamete shall, subject to paragraph (4) and regulation 4A, be the period beginning with the date on which the gamete was first placed into storage and ending ten years after the date of the most recent written opinion given under sub-paragraph (b) of paragraph (3).

(3) The circumstances referred to in paragraph (2) are that—

(a) the person who provided the gamete in question has consented in writing to the gamete being stored for a period in excess of ten years for the provision of treatment services; and

(b) on any day within the relevant period a registered medical practitioner has given a written opinion that the person who provided the gamete or, where they are not that person, the person to be treated, is prematurely infertile or is likely to become prematurely infertile.

(4) Where the maximum storage period calculated in accordance with paragraph (2) would be greater than fifty five years, the maximum storage period for the purpose of that paragraph shall be fifty five years.

(5) Where the statutory storage period for a gamete has been extended under regulation 4 of the 2020 Regulations, paragraph (1) applies as if *"relevant period"* means—

(a) where the statutory storage period for the gamete has not previously been extended under paragraph (2), twelve years from the date that the gamete in question was first placed in storage;

(b) where the statutory storage period for the gamete has previously been extended under paragraph (2)—

(i) twelve years from the date the gamete in question was first placed in storage, or

(ii) if later, ten years from the date that the most recent previous written opinion was given under sub-paragraph (b) of paragraph (3).

(6) Where the statutory storage period for a gamete has been extended under regulation 4A, paragraph (1) applies as if *"relevant period"* means—

(a) where the most recent previous written opinion given under sub-paragraph (b) of paragraph (3) was given before 1st July 2020, twelve years from the date of that opinion;

(b) where the most recent previous written opinion given under sub-paragraph (b) of paragraph (3) was given on or after 1st July 2020, ten years from the date of that opinion.

4A. Extension of statutory storage period for premature infertility for a reason relating to coronavirus

(1) In the circumstances specified in paragraph (2), the maximum storage period for a gamete shall, subject to paragraph (3), be the period beginning with the date on which the gamete was first placed into storage and ending twelve years after the date of the most recent written opinion given under paragraph (3)(b) of regulation 4 ("the extended storage period").

(2) The circumstances referred to in paragraph (1) are that—

(a) the gamete in question is, on 1st July 2020, being stored, for the provision of treatment services, on premises to which a licence under paragraph 1 or 2 of Schedule 2 to the Act relates;

(b) a registered medical practitioner has, before 1st July 2020, given a written opinion under paragraph (3)(b) of regulation 4;

(c) neither the person who provided the gamete nor, where they are not that person, the person to be treated, is, for a reason relating to coronavirus, able to obtain a further written opinion within ten years from the date that the written opinion referred to in sub-paragraph (b) was given;

(d) the person who provided the gamete has consented in writing, whether before, on or after 1st July 2020, to the gamete being stored for at least the extended storage period for the provision of treatment services; and

(e) the statutory storage period for the gamete has not previously been extended under paragraph (1).

(3) Where the maximum storage period calculated in accordance with paragraph (1) would be greater than fifty five years, the maximum storage period for the purpose of that paragraph shall be fifty five years.

5. Transitional provision for embryos: original storage period

(1) In this regulation and regulation 6 *"original storage period"* , in respect of an embryo means the period of five years beginning with the day on which the embryo was first placed in storage.

(2) Except where regulation 6 applies, this paragraph applies to an embryo that is in storage on the date that these Regulations come into force in relation to which the original storage period has not expired.

(3) Where paragraph (2) applies the maximum storage period for the embryo in question shall be—

(a) subject to paragraph (6), where the circumstances in paragraph (4) are met, the period beginning with the date on which the embryo was first placed in storage and ending ten years after the date of the most recent written opinion given under sub-paragraph (b) of paragraph (4); or

(b) ten years where those circumstances are not met.

(4) The circumstances referred to in sub-paragraph (a) of paragraph (3) are that—

(a) the relevant persons have consented in writing whether before or after the coming into force of these Regulations to the embryo in question being stored for a period in excess of ten years for the provision of treatment services; and

(b) on any day within the relevant period, but after the coming into force of these Regulations, a registered medical practitioner has given a written opinion that one of the relevant persons, or, where they are not one of those persons, the person to be treated, is prematurely infertile or is likely to become prematurely infertile.

(5) For the purposes of sub-paragraph (b) of paragraph (4), *"the relevant period"* means—

(a) five years from the date that the embryo in question was first placed in storage; or

(b) if later, ten years from the date the most recent previous written opinion was given under sub-paragraph (b) of paragraph (4).

(6) Where the [maximum] storage period calculated in accordance with sub-paragraph (a) of paragraph (3) would be greater than fifty five years, the [maximum] storage period for the purpose of that sub-paragraph shall be fifty five years.

6. Transitional provision for embryos: extended storage period

(1) This paragraph applies to an embryo that is in storage on the date that these Regulations come into force in relation to which a storage period in excess of the original storage period applies by virtue of the 1996 Regulations ("the extended storage period").

(2) Where paragraph (1) applies the [maximum] storage period for the embryo in question shall be—

(a) subject to paragraph (5), where the circumstances in paragraph (3) are met, the period beginning with the date on which the embryo was first placed in storage and ending ten years after the date of the most recent written opinion given under sub-paragraph (b) of paragraph (3); or

(b) the extended storage period where those circumstances are not met.

(3) The circumstances referred to in sub-paragraph (a) of paragraph (2) are that—

(a) the relevant persons have consented in writing whether before or after the coming into force of these Regulations to the embryo in question being stored for a period in excess of ten years for the provision of treatment services; and

(b) on any day within the relevant period, but after the coming into force of these Regulations, a registered medical practitioner has given a written opinion that one of the relevant persons, or, where they are not one of those persons, the person to be treated, is prematurely infertile or is likely to become prematurely infertile.

(4) For the purposes of sub-paragraph (b) of paragraph (3), *"the relevant period"* means—

(a) the extended storage period; or

(b) if later, ten years from the date the most recent previous written opinion was given under sub-paragraph (b) of paragraph (3).

(5) Where the [maximum] storage period calculated in accordance with sub-paragraph (a) of paragraph (2) would be greater than fifty five years, the [maximum] storage period for the purpose of that sub-paragraph shall be fifty five years.

7. Transitional provision for gametes: statutory storage period

(1) Except where regulation 8 applies, this paragraph applies to any gamete that is in storage on the date that these Regulations come into force.

(2) Where paragraph (1) applies, the maximum storage period for any gamete shall be—

(a) subject to paragraph (5), where the circumstances in paragraph (3) are met, the period beginning with the date on which the gamete was first placed in storage and ending ten years after the date of the most recent written opinion given under sub-paragraph (b) of paragraph (3); or

(b) ten years where those circumstances are not met.

(3) The circumstances referred to in sub-paragraph (a) of paragraph (2) are that—

(a) the person who provided the gamete in question has consented in writing, whether before or after the coming into force of these Regulations, to the gamete being stored for a period in excess of ten years for the provision of treatment services; and

(b) on any day within the relevant period, but after the coming into force of these Regulations, a registered medical practitioner has given a written opinion that the gamete provider, or, where they are not that person, the person to be treated, is prematurely infertile or is likely to become prematurely infertile.

(4) For the purposes of sub-paragraph (b) of paragraph (3), *"the relevant period"* means ten years from the date that—

(a) the gamete in question was first placed in storage; or

(b) if later, the most recent previous written opinion was given under sub-paragraph (b) of paragraph (3).

(5) Where the [maximum] storage period calculated in accordance with sub-paragraph (a) of paragraph (2) would be greater than fifty five years, the maximum storage period for the purpose of that paragraph shall be fifty five years.

8. Transitional provision for gametes: extended storage period

(1) This paragraph applies to any gamete that is in storage on the date that these Regulations come into force in relation to which a storage period in excess of ten years applies by virtue of the 1991 Regulations ("the extended storage period").

(2) Where paragraph (1) applies the maximum storage period for the gamete shall be—

(a) subject to paragraph (5), where the circumstances in paragraph (3) are met, the period beginning with the date on which the gamete was first placed in storage and ending ten years after the date of the most recent written opinion given under sub-paragraph (b) of paragraph (3); or

(b) the extended storage period where those circumstances are not met.

(3) The circumstances referred to in sub-paragraph (a) of paragraph (2) are that—

(a) the person who provided the gamete in question has consented in writing, whether before or after the coming into force of these Regulations, to the gamete being stored for a period in excess of ten years for the provision of treatment services; and

(b) on any day within the relevant period, but after the coming into force of these Regulations, a registered medical practitioner has given a written opinion that the gamete provider, or, where they are not that person, the person to be treated, is prematurely infertile or is likely to become prematurely infertile.

(4) For the purposes of sub-paragraph (b) of paragraph (3), *"the relevant period"* means—

(a) the extended storage period; or

(b) if later, ten years from the date the most recent previous written opinion was given under sub-paragraph (b) of paragraph (3).

(5) Where the maximum storage period calculated in accordance with sub-paragraph (a) of paragraph (2) would be greater than fifty five years, the maximum storage period for the purpose of that paragraph shall be fifty five years.

9. Revocations and savings

(1) Subject to paragraphs (2) and (3) the 1991 Regulations and the 1996 Regulations are revoked.

(2) The 1991 Regulations shall continue to have effect for the purposes of regulation 8.

(3) The 1996 Regulations shall continue to have effect for the purposes of regulation 6

The Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991

The Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996

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

The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020

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

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.

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, has suitable accreditation (for example by CPA (UK) Ltd 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.

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:

c. 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

d. 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).

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 No gametes or embryos must 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.

T80 The statutory storage period in respect of gametes is such period not exceeding ten years as the licence may specify.

T81 The statutory storage period in respect of embryos is such period not exceeding ten years as the licence may specify.

T82 Regulations may provide that licence conditions T80 and T81 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.

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

Facilities and documented procedures

17.1 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.

17.2 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.

17.3 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.

17.4 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

17.5 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.

17.6 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.

17.7 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 17A

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.

17.8 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.

17.9 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 17B

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

17.10 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

17.11 The statutory storage period of 10 years for gametes and embryos is calculated from when these are first placed in storage at a UK centre.

17.12 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. Gametes or embryos must not be stored for longer than the period of storage that patients have consented to.

17.13 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.

Information for those seeking storage of gametes or embryos

17.14 If the treatment involves the creation of embryos in vitro, the centre should give people seeking treatment information about the availability of facilities for freezing embryos, and about the implications of storing and then using stored embryos.

17.15 When a centre enters into a contractual agreement with a patient regarding the practicalities of storage (eg, an agreement to pay storage fees or store whilst funding is available) the patient 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. This agreement should be separate from the consent provided by the patient – see guidance note 5 – information for those seeking storage of gametes or embryos. Depending on the terms of the agreement, the centre should provide information about the circumstances in which the patient's gametes or embryos could be removed from storage 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.

17.16 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, the centre should give those providing the gametes or embryos relevant information about:

(a) the possible deterioration or loss of viability of gametes or embryos as a result of storage, and the potential risk of cross-contamination between samples
(b) statutory storage periods for gametes and embryos which permit patients to store for a maximum of 10 years, and regulations for extending storage periods up to a maximum of 55 years. In the case of embryos, patients should also be given relevant information about the requirement for both gamete providers to consent to any extension of storage
(c) the likelihood of a live birth resulting from previously cryopreserved embryos or gametes, and
(d) screening tests to be done, the cost of these, the reason for them and the implications of the tests for the gamete providers.

Oncology patients and other patients requiring long-term storage should be given specific information tailored to their needs and circumstances. Where relevant, this should include information appropriate for children and young people. This information should include the options available if the patient dies and, in particular:

(i) the consequences for posthumous use in cases where they have not provided written consent to their gametes or embryos being used in the treatment of a named partner in the event of their death, and
(ii) the maximum storage period, subject to satisfying the regulations and the fact that gametes or embryos cannot be used posthumously for longer than the storage period to which the gamete provider has consented.

17.17 The centre should ensure that, before someone consents to gametes or embryos being stored, they are told:

(a) the options available if a person providing gametes or resulting embryos dies or becomes mentally incapacitated
(b) that it may be possible to register a deceased partner as the parent of a child resulting from treatment, and the conditions for doing so, and
(c) that it is unlawful to store embryos and gametes beyond the period of consent, the centre having a legal obligation to dispose of them once consent has expired.

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

17.18 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 17C

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, and 11 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. (and has sufficient capacity and competence to do so).

In certain limited circumstances involving premature infertility, gametes and embryos can be stored beyond the statutory maximum storage period. **Gametes first placed in storage before 1 August 1991**

Any gametes currently in storage which were originally placed into storage before 1 August 1991 (ie, before statutory regulation), can only continue to be stored if the original 10 year storage period was properly extended under the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 (the 1991 regulations) and that extended period has not expired. Any gametes in storage as at 31 July 2001 (10 years after the storage period was deemed to start) and which were not eligible for extension of storage under the 1991 regulations should have been allowed to perish. The Schedule to the 1991 regulations sets out how long gametes can be stored beyond the statutory maximum storage period. The appropriate period is calculated by using the gamete provider's age on the date the gametes were provided. The storage period must be calculated from 1 August 1991.

For an online tool to calculate the appropriate storage period, see **CE(16)02(a)**.

Gametes and embryos first placed in storage between 1 August 1991 and 1 October 2009

Gametes first placed in storage between 1 August 1991 and 1 October 2009, and which are being kept lawfully, may continue to be stored beyond the statutory maximum storage period if the conditions in the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 are satisfied. The Schedule to these Regulations set out how long gametes can be stored beyond the statutory maximum storage period. The appropriate period is calculated by using the gamete provider's age on the date the gametes were provided. The storage period begins on the date that the gametes were stored. This has the effect that storage can continue beyond the gamete provider's 55th birthday but not beyond age 56.

Embryos first placed in storage between 1 August 1991 and 1 October 2009, and which are being kept lawfully, may continue to be stored beyond the statutory maximum storage period but only if both people whose gametes were used to bring about the creation of the embryo confirm in writing that they have no objection to the extension (and if the other conditions in the Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996 are satisfied). The Schedule to these Regulations set out how long embryos can be stored beyond the statutory maximum storage period. The appropriate period is calculated by using the age of the woman being treated on the date that the embryo was first placed in storage.

For an online tool to calculate the appropriate storage period, see **CE(16)02(a)**.

Gametes and embryos first placed in storage after 1 October 2009

Gametes or embryos first placed in storage after 1 October 2009 may continue to be stored beyond the statutory maximum storage period, to a maximum of 55 years, but only with the written consent of the gamete provider or the people whose gametes were used to bring about the creation of the embryo (and if the other conditions in the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 2009 ('the 2009 Regulations') are satisfied). Gametes and embryos first stored earlier than 1 October 2009 may be stored for an extended period under the 2009 regulations but only where the gametes or

embryos are either still within the statutory storage period, or are being stored subject to a lawfully extended period under the 1991 or 1996 regulations respectively.

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

Extension of storage

Interpretation of mandatory requirements 17D

The statutory storage period for embryos and gametes is 10 years under section 14(3) and (4) of the HFE Act 1990. The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020 ('the Coronavirus Regulations') provided that in exceptional circumstances relating to coronavirus, section 14(3) and (4) shall have effect as if for 10 years there were substituted 12 years.

Regulation 3 (embryos) and Regulation 4 (gametes) of the Coronavirus Regulations defined the exceptional circumstances in which the 12 year period as -

- the gametes or embryos were in storage on 1 July 2020 at premises to which a treatment, storage or research licence applied, and
- the gamete provider in the case of gametes or the relevant persons in the case of embryos consent in writing to their gametes or embryos being stored for at least 12 years. This consent can be provided before, on or after 1 July 2020.

The 12 year period will be substituted for 10 years on one occasion only. Consent should be obtained and recorded using the correct HFEA consent form - Your consent to extending the storage of your gametes or embryos as a result of the COVID-19 pandemic' (CVS form)

Keeping gametes or embryos in storage for longer than 10 years (or 12 years, where the above exceptional circumstances apply) is prohibited. However, in certain limited circumstances generally involving premature infertility, the statutory storage period can be extended. Those circumstances are set out in the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 ('the 2009 Regulations') which came into effect on 1 October 2009. The 2009 Regulations revoked the earlier Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 ('the 1991 Regulations') and Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996 ('the 1996 Regulations'). The 1991 and 1996 Regulations continue to have effect for the limited purposes described in Regulations 6 and 8 of the 2009 Regulations. Accordingly, centres should refer to the 2009 Regulations (as amended) as the primary source for determining the applicable storage period.

Applying the 2009 Regulations

Extending storage of gametes or embryos which were first stored after 1 October 2009

Depending on whether the centre is dealing with gametes or embryos, either Regulation 3 (embryos) or Regulation 4 (gametes) of the 2009 Regulations will be applicable. Under Regulation 3 or 4 embryos or gametes that were first placed in storage after 1 October 2009 can continue to be stored for successive ten-year periods, up to a maximum of 55 years, provided that certain conditions are met.

There are two conditions that must be satisfied to extend storage, and these are set out in paragraphs 3(3) (embryos) and 4(3) (gametes) of the 2009 Regulations. The first condition is that the gamete provider(s) must have provided written consent to the gametes or embryos being stored for treatment purposes for longer than 10 years.

The second condition is that on any day within the 'relevant period', a registered medical practitioner must have given a written opinion that the gamete provider, or the person to be treated, is prematurely infertile or likely to become prematurely infertile. The medical opinion must have been provided within 'the relevant period' which means within 10 years from the date the gametes or embryos were first placed in storage i.e. before expiry of the 10 year statutory storage period, or where storage has previously been extended, within 10 years of the date of the most recent medical opinion i.e. before expiry of 10 years from the date of the previous medical opinion. If the medical opinion is provided after the 10-year statutory storage period has expired or more than 10 years after the date of the last medical opinion, it will not be possible to extend storage.

The medical opinion must be provided by a medical practitioner who is registered with the General Medical Council. The opinion must address premature infertility or the likelihood of premature infertility. Patients whose fertility has declined naturally with age will not be able to satisfy the requirement as to premature infertility.

Extension of statutory storage period for premature infertility for a reason relating to coronavirus

In certain circumstances, patients who are or are likely to become prematurely infertile and whose treatment was impacted by coronavirus may, under Regulation 3A (embryos) or Regulation 4A (gametes) of the 2009 Regulations, be eligible for an extended storage period of 12 years.

The circumstances that must be satisfied in order to benefit from the 12 year extended storage period are set out in Regulation 3A (2) and 4A (2). These include that the embryos or gametes were stored on licensed premises (premises holding a treatment or storage licence) for the provision of treatment; before 1 July 2020, a registered medical practitioner must have provided the necessary written opinion as to premature infertility; neither the gamete provider(s) nor the person to be treated is, for a reason relating to coronavirus, able to obtain a further written medical opinion within 10 years from the date of the previous medical opinion; the person(s) who provided the gametes has consented in writing either before or after 1 July 2020 to the gametes or embryos being stored for at least 12 years for the provision of treatment; and the statutory storage period has not previously been extended for a reason relating to coronavirus.

This is a one-off 12-year extension and thereafter, those who satisfy the conditions of Regulation 3 (embryos) or 4 (gametes) may be able to store for successive ten-year periods up to a maximum of 55 years.

Gametes or embryos first placed in storage between 1 August 1991 and 1 October 2009 (i.e. before the 2009 Regulations came into effect)

1 August 1991 was the day statutory regulation began. Any gametes or embryos that were in storage prior to 1 August 1991 were deemed to have been placed in storage on that date.

Gametes or embryos first placed in storage (or deemed to have been placed in storage) between 1 August 1991 and 1 October 2009 may be stored for an extended period, but that period will depend on whether Regulation 5 or 6 of the 2009 Regulations in the case of embryos, or Regulation 7 or 8 in the case of gametes, is applicable.

Regulation 5 (embryos) or 7 (gametes) will apply where the embryos or gametes were in storage on 1 October 2009, but where the conditions for extending storage under the 1991 or 1996 Regulations were not satisfied by this date. In this scenario, the maximum storage period may be as short as 10 years.

Regulation 6 (embryos) or 8 (gametes) will apply if the conditions for extending storage under the 1991 or 1996 Regulations had already been satisfied on 1 October 2009. In this scenario, the maximum storage period will either be 10 years after the date of the most recent medical opinion on infertility (up to a maximum of 55 years), or it will be the extended storage period under the 1991 or 1996 Regulations, which is calculated by reference to the gamete provider's age on the date the gametes were provided or

the embryos placed in storage. This has the effect that storage can continue beyond the gamete provider's 55th birthday but not beyond age 56.

If the conditions for extending storage under the 1991 or 1996 Regulations were not satisfied on 1 October 2009, those older regulations do not apply at all and centres must then have reference to either Regulation 5 or 7 of the 2009 Regulations.

Note that only in those rare cases where the conditions for extending storage under the 1991 or 1996 Regulations were satisfied on 1 October 2009, the storage period should be calculated by reference to the Schedule to the relevant regulations.

The Schedule to the 1991 Regulations sets out how long gametes can be stored beyond the statutory maximum storage period. The appropriate period is calculated by using the gamete provider's age on the date the gametes were provided. For material in storage prior to 1 August 1991, the storage period must be calculated from 1 August 1991. For material placed in storage between 1 August 1991 and 1 October 2009, it must be calculated based on the date the material was placed in storage.

The Schedule to the 1996 Regulations sets out how long embryos can be stored beyond the statutory maximum storage period. The appropriate period is calculated by using the age of the woman being treated on the date that the embryo was first placed in storage.

For an online tool to calculate the appropriate storage period under the 1991 or 1996 Regulations, see **CE(16)02(a)**.

The Human Fertilisation and Embryology (Statutory Storage Period) Regulations 2009 ('the 2009 Regulations') allow gametes or embryos to be stored for longer than the 10 year standard storage period, up to a maximum of 55 years, provided that the conditions set out in those Regulations have been met.

There are two statutory criteria that must be met: the first is that the relevant person(s) have provided written consent to the gametes or embryos being stored for treatment purposes for longer than 10 years. The second is that, on any day within the relevant period, a registered medical practitioner gave a written opinion that the person who provided the gametes (or in the case of embryos, one of the persons whose gametes were used to create the embryos), or the person to be treated, is prematurely infertile or likely to become prematurely infertile.

To satisfy the first statutory requirement, the written consent to storage for a period of more than 10 years must be given before expiry of the original 10-year statutory storage period or, in the case of gametes or embryos which have already been stored pursuant to an extended period under the 2009 Regulations, before expiry of that extended period.

To satisfy the second statutory requirement, the written opinion on premature infertility must be provided by a medical practitioner who is registered with the General Medical Council and must be provided within 10 years from the date that the gametes or embryos were first placed in storage or, in the case of gametes or embryos which are being stored pursuant to an extended period under the 2009 Regulations, within 10 years of the date of the most recent medical opinion.

The statement from the medical practitioner must be renewed for every 10-year storage period beyond the initial statutory period.

17.19 The centre should inform patients wishing to store gametes or embryos for more than 10 years of the criteria set out in the 2009 Regulations and how these must be satisfied. It is important that, in the case of patients who wish to store gametes or embryos for more than 10 years, centres take steps to satisfy the requirements of the 2009 Regulations before the patient's current storage period expires.

17.20 To satisfy the requirements for extended storage periods, the centre should seek a written medical opinion certifying that one of the gamete providers, the woman who is to be treated with the gametes, or the person who the gametes or embryos have been allocated to, is prematurely infertile or likely to become prematurely infertile. This medical opinion should be obtained before the current storage period expires. In those cases where the gametes or embryos are being stored for an extended storage period, the further medical opinion must be obtained within 10

years of the previous medical opinion i.e. before expiry of 10 years from the date of the previous medical opinion. The opinion must be provided by a medical practitioner registered with the General Medical Council (GMC). A medical opinion from an overseas medical practitioner who is not registered with the GMC does not satisfy the requirements of the 2009 Regulations.

17.21 The centre should seek the written medical opinion on premature infertility whilst the gamete provider is alive. However, if the gamete provider (who has provided consent to extended storage) dies before a medical opinion is in place, the medical opinion may be sought after death provided it is based on evidence that the person would have satisfied the premature infertility criteria when they were alive. Although the medical opinion may be provided after the gamete provider's death, it must nevertheless be provided within the relevant period; that is within the 10 year statutory storage period, or in the case of gametes or embryos that are being stored pursuant to an extended period under the 2009 Regulations, within 10 years of the most recent medical opinion.

17.22 Whether a person is, or is likely to become, prematurely infertile is a clinical judgment taking into account all relevant considerations and information known to the clinician at the time. Patients whose fertility has declined naturally with age will not be able to satisfy the requirement as to premature infertility.

17.23 Provided the requirements of the 2009 Regulations have been met, the centre can store the gametes and embryos for a further 10 years from the date the criteria are met. The centre can extend the storage period by further 10-year periods (up to the maximum of 55 years) if it is shown at any time within each extended storage period that the criteria continue to be met.

17.24 As a result of the impact that coronavirus had on patients, in July 2020 the Coronavirus Regulations were introduced. The Coronavirus Regulations provide for the 10-year statutory storage period to be substituted by 12 years. However, this is only in the case of embryos or gametes that were in storage at a licensed centre on 1 July 2020 and where the gamete providers have consented in writing, either before, on or after 1 July 2020, to their gametes or embryos being stored for at least 12 years. Centres should ensure that patients who have not already consented to storage for 12 years or more and who wish to do so provide written consent to extend.

If patients had embryos created in July 2011 and consented to storage of the embryos for 10 years, then the statutory storage period would expire in July 2021. The patients would satisfy the requirements under Regulation 3 of the Coronavirus Regulations, so the storage period is extended to 12 years, meaning that storage would expire in July 2023. If the egg provider in this case is prematurely infertile and a written opinion on premature infertility is provided in January 2023, this will be within 12 years of the date the embryo was first placed in storage (i.e., within the 'relevant period' as defined by Regulation 3(6)(a) of the 2009 Regulations. As such, the storage period can be extended by a further 10 years to January 2033 (under Regulation 3(2) of the 2009 Regulations).

17.25 Patients who, as of 1 July 2020, satisfied the requirements of the 2009 Regulations and whose gametes or embryos were in storage for an extended period, are entitled to extend the 10-year storage period to 12 years from the date of the most recent medical opinion.

If patients who placed embryos in storage in January 2002 consented to storage for 10 years, then the statutory storage period would have expired in January 2012. If a written medical opinion was given in September 2010 (before January 2012) and the patients consented to a further 10 years' storage, then under the 2009 Regulations, the storage period would be extended for 10 years and would expire in September 2020. If the patients were unable to obtain a further written opinion within this 10-year extended storage period before September 2020 due to reasons relating to the Coronavirus, then under Regulation 3A of the 2009 Regulations, the patients are entitled to extend the 10-year storage period to 12 years. For these patients, the 12 years is calculated from the date of the most recent previous medical opinion given in September 2010, which means their 12-year storage period will expire in September 2022.

17.26 It is important to note that the Coronavirus Regulations provide for a one-off extension of 'the relevant period' to 12 years due to the coronavirus and thereafter, the 2009 Regulations to continue to apply as they always have i.e. providing for storage to be extended for up to 10 years in cases of premature infertility.

See also

The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020

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

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.

Interpretation of mandatory requirements 17E

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).

Where one of the gamete providers whose gametes were used to create the embryos withdraws his or her consent to The law allows embryos to be the storage of the embryo(s), the storage will remain stored lawful for 12 months beginning from the date that the centre receives notice of withdrawal of consent, unless the centre receives notice from each person who has been notified of the withdrawal of consent stating that they consent to the destruction of the embryo before the end of 12 months. 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.

For guidance about the withdrawal of consent see **guidance note 5 – Consent to treatment, storage, donation, and disclosure of information.**

Ongoing storage when legal proceedings are threatened or commenced

17.27 There may be circumstances in which patients threaten legal proceedings or commence legal proceedings. This may be because they have been advised by the centre that a gamete provider has withdrawn consent to storage and the centre therefore intends removing the gametes or embryos from storage and allowing them to perish.

17.28 In these circumstances ongoing storage may be lawful if the 12-month cooling-off period can be invoked. However, where that is not possible or if the 12- month cooling-off period has lapsed, ongoing storage may be unlawful. Centres are reminded that it is a condition of their licence that the consent requirements set out in Schedule 3 of the 1990 Act are complied with, including the requirement that gametes or embryos must not be kept in storage unless there is consent by each relevant person and storage must be in accordance with the consent given.

17.29 If an Order from a Court is obtained requiring that the centre continue to store the gametes or embryos, the centre should comply with that Order.

17.30 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.

See also

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

HFEA consent forms

Storage review

17.31 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, and
(iii) 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

17.32 The centre should operate a bring-forward system in order to ensure sufficient advance notice of the end of the statutory storage period (or such 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 clinical processes regarding extension of storage periods.

End of storage

Interpretation of mandatory requirements 17F

No centre may keep embryos or store gametes after the expiry of the statutory storage period, or after the end of any shorter the 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.

17.33 The centre should make efforts to stay in contact with patients who have gametes or embryos in storage for their own treatment, and with any woman to be treated with stored gametes or embryos (where she is not a gamete provider.) The centre should also explain to gamete providers and current patients the importance of informing the centre of any change in their contact details, including that their gametes or embryos may be removed from storage if they do not keep their contact details up to date.

17.34 The centre should establish and use documented procedures to contact patients who have gametes or embryos in storage for their own treatment when the end of the permitted storage period is approaching but long enough in advance to allow the centre and patient to take any steps necessary to comply with the 2009 Regulations (as amended) where extension of storage is an option for the patients. The centre should use all contact details available to them, including at least one written form of contact. Patients should be provided with information about the options available to them as the end of their permitted storage period approaches. They should 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 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.

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 (201908)

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 limit for frozen eggs, sperm and embryos extended during coronavirus outbreak (June 2020)

Clinic Focus article: Storage period for imported gametes (July 2019)

Information on HTLV screening, issued in Clinic Focus (November 2010)

Chief Executive's letters

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

Chair's letters

Chair's Letter CH(03)03: Withdrawal of consent to storage (May 2003)

Chair's Letter CH(20)01: COVID-19 storage extension Regulations (June 2020)

Annex 9

18. Witnessing and assuring patient and donor identification

Version 1.0

Mandatory requirements

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

Act guidance section

Licence conditions

T71 Centres must have in place robust and effective processes to ensure that no mismatches of gametes or embryos or identification errors occur. Centres must double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process. These checks must be completed and recorded at the time the relevant clinical or laboratory process/procedure takes place. A record must be kept in each patient's/donor's medical record.

HFEA guidance

Witnessing clinical and laboratory procedures

18.1 Witnessing protocols should ensure that every sample of gametes or embryos can be identified at all stages of the laboratory and treatment process to prevent any mismatches of gametes or embryos.

18.2 Centres are responsible for ensuring that witnessing protocols are relevant to their local systems and conditions, based on HFEA model protocols. Where appropriate, clinics may adapt HFEA model protocols to take into account their local systems.

See also

Relevant HFEA model protocols

18.3 Electronic systems such as barcoding and radio frequency identification (RFID) for assisted conception are appropriate, subject to a risk assessment as set out at 18.34–18.43.

18.4 Witnessing protocols should be followed when any of the following clinical or laboratory procedures take place:

(a) Collecting eggs

- Cross-check identifying information that the egg provider gives against patient records and laboratory data sheets, or cross-check information entered into the electronic system and the allocation of the barcode or RFID tag.
- Cross-check information marked on egg collection dishes against the patient's records. This step does not need to be manually witnessed if an electronic system (barcoding or RFID) is being used.

(b) Collecting sperm

- Cross-check identifying information that the sperm provider gives against patient records, the laboratory data sheet and sperm receptacle, or cross-check information entered into the system and the allocation of the barcode or RFID tag.

(c) Preparing sperm

- Cross-check information on tubes against the patient records and information on the sperm receptacle (when the sperm sample is transferred onto a preparation column). This step does not need to be manually witnessed if an electronic system (barcoding or RFID) is being used.

(d) Mixing sperm and eggs or injecting sperm into eggs

- Verify identifying information on the dishes and tubes and confirm that the sperm and eggs should be mixed or the sperm injected into eggs.

(e) Transferring gametes or embryos between tubes or dishes

- Cross-check information marked on dishes and tubes against the patient or donor records, and the information marked on the dishes and tubes that the gametes or embryos are being transferred from.

(f) Transferring embryos into a woman

- Cross-check identifying information that the patient provides against the patient records or the electronic system (or both) and the laboratory data sheet.
- Cross-check information marked on the embryo-transfer dish against the patient records.

(g) Inseminating a woman with sperm prepared in the laboratory

- Cross-check identifying information that the patient provides against the patient records, or cross-check information entered into the electronic system and the allocation of a barcode or RFID tag.
- Verify the sperm provider's identifying information in their records, the electronic system and on the sperm container, and confirm that this is the correct sperm provider.

(h) Placing gametes or embryos into cryopreservation

- Cross-check identifying information on the storage container against the patient or donor records and the information on the tube or dish that the gametes or embryos are being transferred from.
- Cross-check where in the dewar the gametes or embryos are placed.

(i) Removing gametes or embryos from cryopreservation

- Cross-check information on the storage container against information in the patient or donor records to confirm they are the correct gametes or embryos to remove.

- Cross-refer information from the storage container and the patient or donor records or their information on the electronic system against the thaw dish or tube (and, if applicable, attach a barcode or RFID tag to the thaw dish or tube).

(j) Disposing of gametes or embryos

- Cross-check information on the storage container against information in the patient or donor records to confirm they are the correct gametes or embryos to dispose of.

(k) Transporting gametes or embryos

- Cross-check information on the storage container against information in the patient records to check that these are the correct gametes or embryos to transport.
- Check that information on the storage container is correct.

(l) Transferring nuclear material from one egg/embryo to another, for the purposes of mitochondrial donation.

- Verify identifying information on the dishes and tubes and confirm that the nuclear material should be moved from one egg or embryo to another.

(m) Allocating donor gametes or embryos for treatment

- Verify that the correct donor has been allocated to a patient's treatment cycle by cross checking patient records and information recorded on laboratory data sheets.

18.5 Each stage of the witnessing trail should check the patient's or donor's full name and their two unique identifiers identifying code.

18.6 Centres performing embryo biopsy should have witnessing protocols in place to ensure that embryos and the material removed from them for analysis are labelled.

Keeping a record of witnessing

18.7 The checking of identifying samples, patients and donors, and the witnessing of these checks, should be recorded when the clinical and laboratory procedures take place. This means that embryologists performing procedures that need to be witnessed cannot work alone. In particular, when performing procedures that cannot be reversed (eg, thawing gametes or embryos, and mixing gametes), centres should ensure witnessing checks have taken place beforehand. This will ensure that the witnessing protocol has the maximum potential to identify errors in the treatment process at the time the procedures take place.

18.8 When a witnessing check takes place, a record should be made in the patient or donor notes stating:

(a) the witnessing check
(b) the date and time of the witnessing check
(c) the signature of the person doing the check, and
(d) the signature of the witness.

18.9 There should be a separate record of the name, job title and signature of everyone who carries out or witnesses laboratory and clinical procedures.

Witnessing training

18.10 Centres should have an induction programme for new staff to ensure they understand the principles of witnessing and follow the centre's protocols. Staff should receive refresher training as the centre decides is appropriate.

18.11 Staff should receive appropriate training if a new system for witnessing is introduced.

See also

Guidance note 2 – Staff

Appropriate person to witness

18.12 Centres should consider who is the most appropriate person to witness clinical and laboratory procedures. This will usually be someone who has completed the centre's training programme for new staff, and refresher training (as appropriate), to ensure they fully understand the principles of witnessing checks and follow the centre's protocols. For exceptions to this, refer to paragraphs 18.14 and 18.15.

18.13 At egg collection and embryo transfer, the appropriate person to witness is another embryologist, clinician or nurse.

18.14 At sperm collection, centres may consider the patient or donor to be the appropriate person to witness the cross-checking of their identifying information against their records, the laboratory data sheet and the sperm receptacle.

18.15 Insemination centres performing intrauterine insemination (IUI) with partner sperm may consider the patient to be the appropriate person to verify the sperm provider's details.

Interruptions and distractions in the clinic and laboratory

18.16 The centre should consider the implications of distractions in the clinic and laboratory, such as from phones and external noise, and ensure they are minimised.

18.17 When considering the protocol it uses for witnessing procedures, and the most appropriate person to witness checks, the centre may wish to take into account the implications of interruptions to the work of laboratory and clinical staff, particularly embryologists performing critical procedures. Interrupting and returning to a task is a common source of error.

Patient and donor identification

18.18 Centres should establish procedures to ensure patients, donors, and their gametes and embryos are accurately identified.

At the assessment stage, centres should use appropriate evidence to verify the identity of donors and self-referred patients seeking treatment (eg, passport or photocard driving licence).

18.19 When collecting eggs or sperm, transferring embryos and carrying out insemination, staff should ask patients and donors to give their own identifying information (full name and date of birth), rather than asking the donor or patient to confirm or reject information read out to them.

18.20 Centres should consider how patients and donors with disabilities or whose first language is not English will be asked to identify themselves. If possible, centres should provide an independent interpreter for patients and donors whose first language is not English.

18.21 Centres should ensure that each sample of gametes and embryos is uniquely identified. All samples of gametes and embryos should be labelled with at least the patient's or donor's full name and a further two identifiers. If, when using donor gametes, it is not possible to label the dishes or tubes with the donor name:

(a) the dishes or tubes should be labelled with the donor code to uniquely identify that donor, and

(b) the dishes or tubes should be labelled with the female patient's name and further identifier as soon as possible.

18.22 To uniquely identify each sample of gametes and embryos, centres should use the patient's or donor's full name and two one or more of the following identifiers:

(a) the patient's or donor's date of birth
(b) hospital number
(c) NHS number/CHI (Community Health Index) number
(d) a patient or donor code.

18.23 Centres should be aware that a patient's or donor's full name and one further identifier, such as date of birth, may not be uniquely identifying. If centres routinely use only these two identifiers, they should ensure they:

(a) have robust systems in place to identify when they have two patients with the same details
(b) take steps to be able to uniquely identify those samples.

Alternatively, centres may choose to use a patient's full name and two identifiers from the list in 18.22 to uniquely identify each sample.

18.23 Centres should consider the most appropriate way to label dishes or tubes when they are likely to be seen by the patient.

18.24 Centres should consider when to change the labelling from showing the donor's or male partner's identifying information to the female patient's identifying information. Centres may consider it appropriate to label all dishes and tubes with both partners' names and identifying codes throughout.

18.25 Centres should ensure that other patients' or donors' gametes or embryos are not introduced into the critical working area until the procedure is complete.

See also

Guidance note 19 – Traceability

Risk assessment

18.26 Centres should consider how this witnessing guidance applies to their local environment, and the risks involved with departing from the guidance.

18.27 Centres should conduct a formal risk assessment before introducing or changing witnessing protocols, or departing from HFEA guidance. In doing so, they may wish to consider:

(a) why they are making the change
(b) the impact of any error
(c) what barriers or safeguards are in place to avoid errors, and
(d) any risks in changing procedures, and how to reduce these.

Centres should monitor new protocols to ensure they are effective.

18.28 Centres should consider the integration of witnessing protocols into the whole laboratory and clinical process, and into risk-reduction procedures. They may wish to identify points at which mismatching of gametes and embryos is most likely to occur.

18.29 Centres should be aware of the risks associated with staff doing repetitive activities. The risk of mismatching gametes and embryos is higher when repetitive activities are taking place. Centres should bear this in mind when selecting the most appropriate person to witness

procedures. Similarly, when using witnesses, centres should consider staff workload and hours, and should ensure staff take regular breaks.

18.30 Centres should have formal risk control measures to minimise the risk of writing incorrect or incomplete identifying data on patient records. There is a risk of error when copying details from sample containers and the patient records to other records. The risk is particularly high when a record sheet becomes separated from the patient records and is relied on during a witnessed step.

18.31 As part of a quality review, audits of the patient records should include checking for transcription errors (or omissions) in patient identifiers, such as the misspelling of names and the absence of unique identifiers on a record sheet, particularly in laboratory records.

18.32 Centres should check their compliance with witnessing protocols regularly, including during the audit of their quality management system.

See also

Guidance note 23 – The quality management system

Risk assessment: electronic witnessing systems

18.33 Before introducing new electronic systems or protocols for witnessing, centres should do a risk assessment covering the following:

(a) Centres should ensure that any system will not harm gametes and embryos. In establishing that this is the case, centres should consider what the supplier or manufacturer has done to satisfy itself that the system will not harm gametes and embryos (eg, commissioned independent reports or carried out irradiance readings)
(b) Centres should be aware that the reliability and safety of different electronic systems may vary
(c) Centres should evaluate the evidence that the supplier or manufacturer provides to support the safety and reliability of its system (eg, false positive and negative matches and breakdown), plus any other relevant studies
(d) Any software should be fully tested, quality assured and risk assessed, and
(e) Centres should consider what the manufacturer has done to ensure that any labels and tags will continue to be effective when placed in long-term cryostorage.

18.34 Electronic systems rely on people entering accurate information. Centres should therefore consider how they can ensure the quality of information through system validation, staff training and audit.

18.35 Centres should be aware that although they cannot completely eliminate the potential for error in any electronic witnessing system, effective risk assessment should mitigate this.

18.36 Electronic systems record all errors that occur. The person operating the system must resolve any errors, and record an explanation or description of this before continuing with the procedure. Centres should review any mismatches that electronic systems have identified, and be able to show they have taken steps to avoid them in the future.

18.37 If centres use an electronic system (barcode or RFID) with 'forcing functions' (which prevent the user omitting key matching tasks in the process by preventing them from proceeding with subsequent task steps), then as part of their risk assessment they may wish to consider that manually witnessing transfer steps between containers is not necessary. This exemption should not apply however to mixing sperm and eggs; injecting sperm into eggs; and placing gametes or embryos into and removing them from cryopreservation.

18.38 Centres should consider any potential loopholes in the system that could allow users to circumvent key steps, thus negating safeguards against error. Centres should consider implementing a system that allocates a unique identifier to each system user.

18.49 Centres should not rely solely on electronic systems to check the identity of patients, donors and samples. Centres should follow protocols for witnessing in line with HFEA model protocols; these include several manual witnessing steps.

18.40 Centres should have procedures to ensure that all witnessing steps can still be done if the electronic system fails, and that witnessing staff maintain their manual witnessing skills for all critical steps.

18.41 In addition to using the electronic system of identification (information stored on barcodes or RFID tags), centres should continue to manually label all culture dishes, tubes and straws with the patient's full name and two unique identifiers. If the electronic identification fails (for example losing a barcode label or RFID tag from a sample), centres should revert to manual identification.

18.42 Centres should consider whether the barcode or RFID tags are suitable for use on storage containers (ie, are able to withstand long periods of cryopreservation).

Risk assessment: barcoding

18.43 Centres considering installing a barcode system should consider as part of their risk assessment:

(a) the type and power of light used in the barcode equipment
(b) the length of time the gametes and embryos are likely to be exposed to it, and
(c) whether exposure to this light is likely to harm the gametes and embryos.

18.44 Although there is substantial evidence about using barcodes with human tissue, as far as the HFEA is aware no independent studies have yet been done on the effect of light on human gametes and embryos. So the HFEA does not have enough evidence to consider barcoding to be risk free.

18.45 Barcoding equipment may use a range of light sources. The HFEA is aware of two types of barcoding systems marketed for use in assisted conception: those using white-light-emitting diodes and those using laser light.

18.46 Considering the evidence of damage to human cells from some powers of laser light, centres must weigh up the degree of possible risk of using laser light barcoding systems. Centres should only consider using class 1 or 2 lasers.

18.47 Barcode equipment that uses ultraviolet or infrared light should not be used. These sources of radiation are known to heat, and so potentially damage, human cells.

Risk assessment: radio frequency identification systems

18.48 Centres considering installing an RFID system should, as part of their risk assessment, consider the frequency of the radio waves used in the RFID system and whether exposure to them is likely to harm gametes and embryos. Centres should be aware that detectable changes in temperature may result in DNA damage. Centres should do this risk assessment in the context of other risk factors in the centre and the environment (eg, mobile phone signals).

18.49 Although there is evidence for the use of RFID in a medical setting, as far as the HFEA is aware no independent studies have yet been done on the effect of electromagnetic radiation on human gametes and embryos. So there is not yet a compelling evidence base to enable the HFEA to consider RFID systems to be risk free.

Establishing, maintaining and documenting the quality management system

18.50 Centres should identify and evaluate risks and the impact of work processes. Any potential failures that may affect patient safety should be taken into account. A risk should be:

(a) adequately identified
(b) assessed
(c) entered into a risk register
(d) maintained and reviewed in accordance with the level of risk identified
(e) all decisions and actions in response to a risk should be adequately documented
(f) written documentation should be available to support and oversee the process.

Other legislation, professional guidelines and information

Clinic Focus articles

Clinic Focus article: Witnessing guidance clarification (September 2013)

Annex 10

19. Traceability

Version 2.0

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 and coding system

1 Licence conditions shall require that all persons to whom a licence applies adopt such

systems as the Authority considers appropriate to secure in relation to traceability compliance with the requirements of Article 8 of the first Directive (traceability) and Article 9 of the third Directive (traceability). and

(b) in relation to the coding of information, compliance with the requirements of Article 25 (coding of information) of the first Directive and Article 10 (European coding system) of the third Directive.

2 Licence conditions imposed in accordance with paragraph 1 may specify the coding system which must be applied in relation to gametes and embryos intended for human application.

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, including the Single European Code applied to each set of gametes and embryos when required by General Direction 0006

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. Containers holding gametes and embryos or the paperwork attaching to any containers must be labelled with a SEC in those circumstances specified in General Direction 0006.

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 SEC 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 thirty 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**.

Single European Code (SEC)

19.5 For details on the SEC, please see **guidance note 15**.

Annex 11

20. Donor assisted conception

Version 2.0

Mandatory requirements

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

Conditions of licences for treatment

13 (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.

13 (13) The person responsible shall comply with any requirement imposed on that person by section 31ZD.

31ZA Request for information as to genetic parentage or mitochondrial donors etc.

(1) A person who has attained the age of 16 ("the applicant") may by notice to the Authority require the Authority to comply with a request under subsection (2) or (2A).

(2) The applicant may request the Authority to give the applicant notice stating whether or not the information contained in the register shows that a person (“the donor”) other than a parent of the applicant would or might, but for the relevant statutory provisions, be the parent of the applicant, and if it does show that -

(a) giving the applicant so much of that information as relates to the donor as the Authority is required by regulations to give (but no other information), or

(b) stating whether or not that information shows that there are other persons of whom the donor is not the parent but would or might, but for the relevant statutory provisions, be the parent and if so -

(i) the number of those other persons,

(ii) the sex of each of them, and

(iii) the year of birth of each of them.

(2A) The applicant may request the Authority to give the applicant notice stating whether or not the information contained in the register shows that a person is the applicant’s mitochondrial donor, and if it does show that, giving the applicant the following information contained in the

register —

(a) the screening tests carried out on the mitochondrial donor and information on that donor's personal and family medical history,

(b) matters contained in any description of the mitochondrial donor as a person which that donor has provided, and

(c) any additional matter which the mitochondrial donor has provided with the intention that it be made available to a person who requests information under this section, but not giving any information which may identify the mitochondrial donor or any person who was or may have been born in consequence of treatment services using genetic material from the applicant's mitochondrial donor, by itself or in combination with any other information which is in, or is likely to come into, the possession of the applicant.

(3) The Authority shall comply with a request under subsection (2) if--

(a) the information contained in the register shows that the applicant is a relevant individual, and

(b) the applicant has been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.

(3A) The Authority must comply with a request under subsection (2A) if—

(a) the information contained in the register shows that the applicant is a mitochondrial donor-conceived person, and

(b) the applicant has been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.

31ZB Request for information as to intended spouse etc.

(1) Subject to subsection (4), a person ("the applicant") may by notice to the Authority require the Authority to comply with a request under subsection (2).

(2) The applicant may request the Authority to give the applicant notice stating whether or not information contained in the register shows that, but for the relevant statutory provisions, the applicant would or might be related to a person specified in the request ("the specified person") as -

(a) a person whom the applicant proposes to marry,

(b) a person with whom the applicant proposes to enter into a civil partnership, or

(c) a person with whom the applicant is in an intimate physical relationship or with whom the applicant proposes to enter into an intimate physical relationship.

(3) Subject to subsection (5), the Authority shall comply with a request under subsection (2) if -

(a) the information contained in the register shows that the applicant is a relevant individual,

(b) the Authority receives notice in writing from the specified person consenting to the request being made and that notice has not been withdrawn, and

(c) the applicant and the specified person have each been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.

(4) A request may not be made under subsection (2)(c) by a person who has not attained the age of 16.

(5) Where a request is made under subsection (2)(c) and the specified person has not attained the age of 16 when the applicant gives notice to the Authority under subsection (1), the Authority must not comply with the request.

(6A) For the purposes of this section, in a case where the information contained in the register shows that the applicant is a mitochondrial donor-conceived person, the applicant is not a

person who, but for the relevant statutory provisions, would or might be related to—

(a) the applicant's mitochondrial donor, or

(b) any person who was or may have been born in consequence of treatment services using genetic material from the applicant's mitochondrial donor.

31ZD Provision to donor of information about resulting children

(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 the persons falling within paragraphs (a) to (c) of subsection (3).

31ZE Provision of information about donor-conceived genetic siblings

(1) For the purposes of this section two relevant individuals are donor-conceived genetic siblings of each other if a person ("the donor") who is not the parent of either of them would or might, but for the relevant statutory provisions, be the parent of both of them.

(1A) Subsection (1B) applies in respect of a mitochondrial donor-conceived person ("P") and P's mitochondrial donor ("D").

(1B) For the purposes of this section, D is not a person who would or might, but for the relevant statutory provisions, be the parent of P.

(2) Where -

(a) the information on the register shows that a relevant individual ("A") is the donor-conceived genetic sibling of another relevant individual ("B"),

(b) A has provided information to the Authority ("the agreed information") which consists of or includes information which enables A to be identified with the request that it should be disclosed to –

(i) any donor-conceived genetic sibling of A, or

(ii) such siblings of A of a specified description which includes B, and

(c) the conditions in subsection (3) are satisfied, then, subject to subsection (4), the Authority shall disclose the agreed information to B.

(3) The conditions referred to in subsection (2)(c) are –

(a) that each of A and B has attained the age of 18,

(b) that B had requested the disclosure to B of information about any donor-conceived genetic sibling of B, and

(c) that each of A and B has been given a suitable opportunity to receive proper counselling about the implications of disclosure under subsection (2).

(4) The Authority need not disclose any information under subsection (2) if it considers that the disclosure of information will lead to A or B identifying the donor unless -

(a) the donor has consented to the donor's identity being disclosed to A or B, or

(b) were A or B to make a request under section 31ZA(2)(a), the Authority would be required by regulations under that provision to give A or B information which would identify the donor.

Regulations

The Human Fertilisation and Embryology Authority (Disclosure of Information) Regulations 2004

Information that the Authority is required to give

2 (1) Subject to paragraph (4), the information contained in the register which the Authority is required to give an applicant by virtue of section 31(4)(a) of the Act is any information to which paragraph (2) or (3) applies.

(2) This paragraph applies to information as to -

(a) the sex, height, weight, ethnic group, eye colour, hair colour, skin colour, year of birth, country of birth and marital status of the donor;

(b) whether the donor was adopted;

(c) the ethnic group or groups of the donor's parents;

(d) the screening tests carried out on the donor and information on his personal and family medical history;

(e) where the donor has a child, the sex of that child and where the donor has children, the number of those children and the sex of each of them;

(f) the donor's religion, occupation, interests and skills and why the donor provided sperm, eggs or embryos;

(g) matters contained in any description of himself as a person which the donor has provided;

(h) any additional matter which the donor has provided with the intention that it be made available to an applicant;

but does not include information which may identify the donor by itself or in combination with any other information which is in, or is likely to come into, the possession of the applicant.

(3) This paragraph applies to information from which the donor may be identified which he provides after 31st March 2005 to a person to whom a licence applies, being information as to -

(a) any matter specified in sub-paragraphs (a) to (h) of paragraph (2);

(b) the surname and each forename of the donor and, if different, the surname and each forename of the donor used for the registration of his birth;

(c) the date of birth of the donor and the town or district in which he was born;

(d) the appearance of the donor;

(e) the last known postal address of the donor.

(4) The information which the Authority is required to give to the applicant does not include any information which at the time of his request the applicant indicates that he does not wish to receive.

Licence conditions

T54 Gametes from non-identifiable donors must not be used in licensed treatment except in the following circumstances:

a. The gametes were supplied to the centre before 1 April 2005; and

b. The woman having treatment (or the person that she is having treatment with) has a child

that was conceived from the gametes before 1 April 2006; and

c. The gametes are to be used to create a genetically related sibling for that child

Embryos from non-identifiable donors must not be used in licensed treatment except in the following circumstances:

a. The embryos were created before 1 April 2005; and

b. The woman having treatment (or the person that she is having treatment with) has a child that was conceived from the embryos before 1 April 2006; and

c. The embryo is to be used to create a genetically related sibling for that child

Embryos which were created before 1 April 2006, and which were created using the gametes of the woman to be treated (or the person that she is being treated with) and the gametes of a non-identifiable donor, may continue to be used in treatment (regardless of whether or not there are any existing genetically related siblings).

HFEA guidance

Information for people seeking treatment with donated gametes and embryos

20.1 The centre should give people seeking treatment with donated gametes or embryos:

(a) non-identifying information about donors whose gametes are available to them, including the goodwill message and the pen-portrait (if available),
(b) information about genetic inheritance and, in particular, the likelihood of inheriting physical characteristics from the donor, and
(c) information about the age of the donor and the associated risk of miscarriage and chromosomal abnormalities.

See also

Guidance note 4 – Information to be provided prior to consent

20.2 The centre should provide information to people seeking treatment with donated gametes or embryos about legal parenthood, and the collection and provision of information, specifically:

(a) 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 anyone 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 UK)
(b) information that centres must collect and register with the HFEA about the donors
(c) what information may be disclosed to people born as a result of donation and in what circumstances, and
(d) a donor-conceived person's right to access:
    (i) anonymous information about the donor and any donor-conceived genetic siblings, from the age of 16
    (ii) identifying information about the donor (where applicable), from the age of 18
    (iii) identifying information about donor-conceived genetic siblings, with mutual consent, from the age of 18
    (iv) information about the possibility of being related to the person they intend to marry or enter into a civil partnership with, at any age, and
    (v) information about the possibility of being related to the person they intend to enter into an intimate physical relationship with, from the age of 16.

20.3 The centre should give people seeking treatment with donated gametes or embryos information about genetic and other screening of people providing gametes. This information should include details about:

(a) the sensitivity and suitability of the tests
(b) the possibility that a screened provider of gametes may be a carrier of a genetic disease or infection, and
(c) in the case of fresh egg donation, the screening requirement of the donor and the risk of infection for the recipient

20.4 The centre should provide information that explains the limitations of testing procedures and the risks of treatment to anyone seeking treatment with donated gametes or embryos. The centre should make available appropriate counselling.

See also

Guidance note 3 – Counselling and patient support

20.5 If a woman is to receive donor insemination treatment, then, before treatment commences, the centre should discuss with her the number of treatment cycles to be attempted if she does not conceive initially. The centre and the woman should together review this situation regularly.

20.6 Women should not be treated with gametes, or with embryos derived from gametes, of more than one man or more than one woman during any treatment cycle (except for in treatment involving mitochondrial donation where embryos are created using gametes of two women and one man).

The importance of informing children of their donor origins

Interpretation of mandatory requirements 20A

The centre must give patients seeking treatment with donor gametes and embryos information about the importance of telling any resultant children, at an early age, of their donor-conceived origins. The centre must also give patients information on suitable methods of informing children of their donor-conceived origins.

20.7 The centre should encourage and prepare patients to be open with their children from an early age about how they were conceived. The centre should give patients information about how counselling may allow them to explore the implications of treatment, in particular how information may be shared with any resultant children.

Implications of donor conception and the provision of counselling

20.8 If it is likely that patients may require treatment with donated gametes or embryos, the centre should discuss this with the person or couple seeking treatment before their treatment starts. The centre should allow people enough time prior to treatment to consider the implications of using donated gametes or embryos, and to receive counselling before giving consent. The discussion of implications should be delivered by a qualified counsellor.

20.9 As part of this discussion about the implications of using donated gametes or embryos, the centre should explain the 10-family limit and how a family is defined (see Guidance Note 11), including that:

- a donor's gametes may be used to create up to 10 families at UK licensed centres and that each family could include one or more donor-conceived siblings or half siblings
- the donor may also have donated gametes abroad and/or may have donated in the UK but

outside of licensed centres
- the HFEA does not hold any information about the number of donor-conceived children born abroad nor how many may have been born through donation outside of licensed centres in the UK, and it will therefore not be possible for parents or donor-conceived people themselves to obtain information about donor-conceived siblings born in these circumstances from the HFEA
- the donor may also have their own children, or may have children of their own in the future, who will be genetic half siblings of any child born using the donor's gametes.

20.10 As part of this discussion about the implications of using donated gametes or embryos, the centre should explain that:

- at age 168 donor-conceived people have a right to apply to the HFEA for non-identifying information about their donor, and at age 18 they may apply for identifying information however,
- given the growing use of direct to consumer DNA testing and matching websites, it is now also possible that donors and donor-conceived people, and/or their close genetic relatives, may become identifiable to each other outside of the HFEA's managed system of information provision.

The centre should explain that this could be through intentional searching using direct to consumer DNA testing and matching services possibly in combination with social media sites, or inadvertently, when the donor or donor-conceived person is using these services or sites for another purpose, such as researching their family ancestry, ethnicity, or seeking genetic health information.

20.11 People who are not aware that they are donor-conceived may become aware of their donor-conceived status for the first time through their use of direct to consumer DNA testing and matching services. Furthermore, 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. 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.

See also

Guidance note 3 – Counselling and patient support

Access to information for donors, donor-conceived people and parents

Interpretation of mandatory requirements 20B

A donor may request information from a centre as to the number, sex, and birth year of any children born by means of their gametes or embryos (including mitochondrial donation). If the centre holds that information, it must provide it, unless the person responsible considers that special circumstances increase the likelihood of the donor being able to identify any of those children.

20.12 The centre should inform people seeking treatment with donated gametes or embryos (including mitochondrial donation) that the donor will be able to request the following information about any children born as a result of their donated gametes or embryos:

(a) the number of children born

(b) their sex, and
(c) their year of birth.

20.13 The centre should inform people seeking treatment with donated gametes or embryos that any resulting children will have access to the following non-identifying information about the donor (if the donor has provided it) 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 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).

20.14 The centre should inform people seeking treatment with gametes or embryos donated after 31 March 2005, with those donated before this date by a donor who subsequently re-registered as identifiable, that any children born as a result of the donation will have access to the following identifying information about the donor, 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).

20.15 The centre should inform people seeking treatment with donated gametes or embryos that, once they give birth to a child as a result of that donation, they will be entitled to access:

(a) all non-identifying information about the donor.
(b) information about the number, sex and year of birth of their children's genetically related donor-conceived siblings.

It is recommended that this information is shared with the child born as a result of donation. If the centre is unable to provide this information, it should direct parents to the HFEA.

20.16 Centres should inform parents seeking information about their child's donor or genetically related donor-conceived siblings that they may find counselling, or similar support services, on the implications of receiving such information helpful.

Other legislation, professional guidelines and information

Professional guidelines

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

Royal College of Obstetricians and Gynaecologists: Reproductive ageing (Scientific Impact Paper No. 24) (2011)

Other information

Donor Conception Network: Telling your child

Annex 12

25. Premises, practices and facilities

Version 2.0

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 and Directive 2003/94/EC). 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 obtain accreditation by CPA(UK) Ltd or another body 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. have a controlled drugs accountable officer registered with the Care Quality Commission.

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, patients are given information on the risks and side effects, and patients receive appropriate medicines (taking into account factors such as medical history and allergies)
(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
(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 Centres should keep accurate documentation about the operation undertaken, including the anaesthetic or sedative given, and details of patient monitoring.

25.33 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.

25.34 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.

25.35 Centres should ensure that their procedures are suitable for the type of anaesthetic or sedative provided.

25.36 Centres should ensure that only an appropriately qualified person provides an anaesthetic.

25.37 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

25.38 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.

25.39 Centres should review procedures annually, or more often to incorporate any lessons learned or changes to legislation.

25.40 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.

25.41 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

Data Protection Act 2018General Data Protection Regulation (EU) 2016/679 (GDPR)

The Human Medicines Regulations 2012

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)

The Health Act 2006

Professional guidelines

Academy of Medical Royal Colleges: Safe sedation practice for healthcare procedures – standards and guidance (2013)

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 (201906)

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)

Care Quality Commission: Controlled drugs

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)

Nursing and Midwifery Council: Standards for medicine management (2007)

Royal College of Anaesthetists: Guidelines for the provision of anaesthetic services (GPAS) (2018)

Department for Health: Health Technical Memoranda (2013)

- Management and disposal of healthcare waste (HTM 07-01)
- Safe water in healthcare premises (HTM 04-01)
- Managing healthcare fire safety (HTM 05-01)

Royal College of Radiologists: Standards for the reporting and interpretation of imaging investigations

United Kingdom Accreditation Service: Clinical pathology accreditation

World Health Organisation: Surgical safety checklist and implementation manual (2008)

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)

Annex 13

26. Equipment and materials

Version 2.0

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.

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 Medical Devices Regulation 2002 (as amended).Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and Directive 98/79/EC of the European Parliament under the Council of 27 October 1998 on In vitro Diagnostic Medical Devices.

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

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)

Annex 14

30. Confidentiality and privacy

Version 3.0

Mandatory requirements

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

31 Register information

(1) The Authority shall keep a register which is to contain any information which falls within subsection (2) and which -

(a) immediately before the coming into force of section 24 of the Human Fertilisation and Embryology Act 2008, was contained in the register kept under this section by the Authority, or

(b) is obtained by the Authority.

(2) Subject to subsection (3), information falls within this subsection if it relates to -

(a) the provision for any identifiable individual of treatment services other than basic partner treatment services,

(b) the procurement or distribution of any sperm, other than sperm which is partner-donated sperm and has not been stored, in the course of providing non-medical fertility services for any identifiable individual,

(c) the keeping of the gametes of any identifiable individual or of an embryo taken from any identifiable woman,

(d) the use of the gametes of any identifiable individual other than their use for the purpose of basic partner treatment services, or

(e) the use of an embryo taken from any identifiable woman, or if it shows that any identifiable individual is a relevant individual.

(3) Information does not fall within subsection (2) if it is provided to the Authority for the purposes of any voluntary contact register as defined by section 31ZF(1).

(4) In this section “relevant individual” means an individual who was or may have been born in consequence of -

(a) treatment services, other than basic partner treatment services, or

(b) the procurement or distribution of any sperm (other than partner donated sperm which has not been stored) in the course of providing non-medical fertility services.

33A Disclosure of information

(1) No person shall disclose any information falling within section 31(2) which the person obtained (whether before or after the coming into force of section 24 of the Human Fertilisation and Embryology Act 2008) in the person's capacity as -

(a) a member or employee of the Authority,

(b) any person exercising functions of the Authority by virtue of section 8B or 8C of this Act (including a person exercising such functions by virtue of either of those sections as a member of staff or as an employee),

(c) any person engaged by the Authority to provide services to the Authority,

(d) any person employed by, or engaged to provide services to, a person mentioned in paragraph (c),

(e) a person to whom a licence applies,

(f) a person to whom a third party agreement applies, or

(g) a person to whom Directions have been given.

(2) Subsection (1) does not apply where -

(a) the disclosure is made to a person as a member or employee of the Authority or as a person exercising functions of the Authority as mentioned in subsection (1)(b),

(b) the disclosure is made to or by a person falling within subsection (1)(c) for the purpose of the provision of services which that person is engaged to provide to the Authority,

(c) the disclosure is made by a person mentioned in subsection (1)(d) for the purpose of enabling a person falling within subsection (1)(c) to provide services which that person is engaged to provide to the Authority,

(d) the disclosure is made to a person to whom a licence applies for the purpose of that person's functions as such,

(e) the disclosure is made to a person to whom a third party agreement applies for the purpose of that person's functions under that agreement,

(f) the disclosure is made in pursuance of Directions given by virtue of section 24,

(g) the disclosure is made so that no individual can be identified from the information,

(h) the disclosure is of information other than identifying donor information and is made with the consent required by section 33B,

(i) the disclosure -

(i) is made by a person who is satisfied that it is necessary to make the disclosure to avert an imminent danger to the health of an individual (''P''),

(ii) is of information falling within section 31(2)(a) which could be disclosed by virtue of paragraph (h) with P's consent or could be disclosed to P by virtue of subsection (5), and

(iii) is made in circumstances where it is not reasonably practicable to obtain P's consent.

(j) the disclosure is of information which has been lawfully made available to the public before the disclosure is made,

(k) the disclosure is made in accordance with sections 31ZA to 31ZE,

(l) the disclosure is required or authorised to be made -

(i) under regulations made under section 33D, or

(ii) in relation to any time before the coming into force of the first regulations under that section, under regulations made under section 251 of the National Health Service Act 2006,

(m) in relation to Northern Ireland, the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) for the purpose of carrying out the Authority's duties under section 8A,

(n) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) in pursuance of an order of a court under section 34 or 35,

(o) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) to the Registrar General in pursuance of a request under section 32,

(p) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) to any body or person discharging a regulatory function for the purpose of assisting that body or person to carry out that function,

(q) the disclosure is made for the purpose of establishing in any proceedings relating to an application for an order under subsection (1) of section 54 of the Human Fertilisation and Embryology Act 2008 whether the condition specified in paragraph (a) or (b) of that subsection is met,

(r) the disclosure is made under section 3 of the Access to Health Records Act 1990,

(s) the disclosure is made under Article 5 of the Access to Health Records (Northern Ireland) Order 1993, or

(t) the disclosure is made necessarily for -

(i) the purpose of the investigation of any offence (or suspected offence), or

(ii) any purpose preliminary to proceedings, or for the purposes of, or in connection with, any proceedings.

(3) Subsection (1) does not apply to the disclosure of information in so far as -

(a) the information identifies a person who, but for sections 27 to 29 of this Act or sections 33 to 47 of the Human Fertilisation and Embryology Act 2008, would or might be a parent of a person who instituted proceedings under section 1A of the Congenital Disabilities (Civil Liability) Act 1976, and

(b) the disclosure is made for the purpose of defending such proceedings, or instituting connected proceedings for compensation against that parent.

(4) Paragraph (t) of subsection (2), so far as relating to disclosure for the purpose of the investigation of an offence or suspected offence, or for any purpose preliminary to, or in connection with proceedings, does not apply -

(a) to disclosure of identifying donor information, or

(b) to disclosure, in circumstances in which subsection (1) of section 34 of this Act applies, of information relevant to the determination of the question mentioned in that subsection, made by any person acting in a capacity mentioned in any of paragraphs (c) to (g) of subsection (1).

(5) Subsection (1) does not apply to the disclosure to any individual of information which -

(a) falls within subsection (2) of section 31 of this Act by virtue of any of paragraphs (a) to (e) of that subsection, and

(b) relates only to that individual or, in the case of an individual who is treated together with, or gives a notice under section 37 or 44 of the Human Fertilisation and Embryology Act 2008 in respect of, another, only to that individual and that other.

(6) In subsection (2) -

(i) in paragraph (p) “regulatory function” has the same meaning as in section 32 of the Legislative and Regulatory Reform Act 2006, and

(ii) in paragraph (t) references to “proceedings” include any formal procedure for dealing with a complaint.

(7) In this section ‘‘identifying donor information’’ means information enabling a person to be identified as a person whose gametes were used in accordance with consent given under paragraph 5 of Schedule 3 for the purposes of treatment services or non-medical fertility services in consequence of which an identifiable individual was, or may have been, born.

33C Power to provide for additional exceptions from section 33A(1)

(1) Power to provide for additional exceptions from section 33A(1)

(2) No exception may be made under this section for -

(a) disclosure of a kind mentioned in paragraph (a) or (b) of subsection (4) of section 33A, or

(b) disclosure in circumstances in which section 32 of this Act applies of information having the tendency mentioned in subsection (2) of that section, made by any person acting in a capacity mentioned in any of paragraphs (c) to (g) of subsection (1) of section 33A.

34 Disclosure in interests of justice

(1) Where in any proceedings before a court the question whether a person is or is not the parent of a child by virtue of sections 27 to 29 of this Act or sections 33 to 47 of the Human Fertilisation and Embryology Act 2008 falls to be determined, the court may on the application of any party to the proceedings make an order requiring the Authority -

(a) to disclose whether or not any information relevant to that question is contained in the register kept in pursuance of section 31 of this Act, and

(b) if it is, to disclose so much of it as is specified in the order, but such an order may not require the Authority to disclose any information falling within section 31(2) (c) to (e) of this Act.

(2) The court must not make an order under subsection (1) above unless it is satisfied that the interests of justice require it to do so, taking into account -

(a) any representations made by any individual who may be affected by the disclosure, and

(b) the welfare of the child, if under 18 years old, and of any other person under that age who may be affected by the disclosure.

(3) If the proceedings before the court are civil proceedings, it -

(a) may direct that the whole or any part of the proceedings on the application for an order under subsection (2) above shall be heard in camera, and

(b) if it makes such an order, may then or later direct that the whole or any part of any later stage of the proceedings shall be heard in camera.

(4) An application for a direction under subsection (3) above shall be heard in camera unless the court otherwise directs.

35 Disclosure in interests of justice: congenital disabilities, etc

(1) Where for the purpose of instituting proceedings under section 1 of the Congenital Disabilities (Civil Liability) Act 1976 (civil liability to child born disabled) it is necessary to identify a person who would or might be the parent of a child but for the relevant statutory provisions, the court may, on the application of the child, make an order requiring the Authority to disclose any information contained in the register kept in pursuance of section 31 of this act identifying that person.

(2) Where, for the purposes of any action for damages in Scotland (including any such action which is likely to be brought) in which the damages claimed consist of or include damages or

solatium in respect of personal injury (including any disease and any impairment of physical or mental condition), it is necessary to identify a person who would or might be the parent of a child but for the relevant statutory provisions, the court may, on the application of any party to the action or, if the proceedings have not been commenced, the prospective pursuer, make an order requiring the Authority to disclose any information contained in the register kept in pursuance of section 31 of this act identifying that person.

(2A) In subsections (1) and (2) “the relevant statutory provisions” means -

(a) sections 27 to 29 of this act, and

(b) sections 33 to 47 of the Human Fertilisation and Embryology Act 2008.

(3) Subsections (2) to (4) of section 34 of this act apply for the purposes of this section as they apply for the purposes of that.

(4) After section 4(4) of the Congenital Disabilities (Civil Liability) Act 1976 there is inserted -

"(4A) In any case where a child carried by a woman as the result of the placing in her of an embryo or of sperm and eggs or her artificial insemination is born disabled, any reference in section 1 of this Act to a parent includes a reference to a person who would be a parent but for sections 27 to 29 of the Human Fertilisation and Embryology Act 1990."

41 Offences

(5) A person who discloses any information in contravention of section 33A of this act is guilty of an offence and liable -

(a) on conviction on indictment, to imprisonment for a term not exceeding two years or a fine or both, and

(b) on summary conviction, to imprisonment for a term not exceeding six months or a fine not exceeding the statutory maximum or both.

Regulations

Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004

Licence conditions

T43 The centre must ensure that all information is kept confidential and only disclosed in circumstances permitted by law.

T44 The centre must have processes in place to ensure that access to a centre’s health data and records is secure at all times; conforms with legislative requirements; and is only available to persons named on a centre’s licence or authorised by the person responsible. Such processes shall include:

a. establishing and maintaining data security measures and safeguards against any unauthorised data additions, deletions or modifications to patient/donor files or records, and the transfer of information

b. establishing and maintaining procedures to resolve all data discrepancies

c. preventing unauthorised disclosure of information whilst guaranteeing the traceability of gamete, embryo or tissue (cell) donations

d. considering and responding to applications for access to confidential records and correctly identifying applicants, and

e. receiving, checking and arranging authorised access to confidential data and records.

T45 Access to registers and data must be restricted to persons authorised by the PR and to the Authority for the purpose of inspection and control measures.

HFEA guidance

Confidentiality

30.1 Centres should be aware that whilst confidentiality and data protection share a number of overlapping and similar legal considerations, they are distinct, separate concepts and all uses of personal information relating to individuals must be compliant with both. A centre should not assume that compliance with confidentiality obligations necessarily entails compliance with data protection requirements, and vice-versa. The respective considerations in relation to each are addressed separately in this guidance note.

30.2 Centres must treat all patients with dignity and respect and must take appropriate measures to maintain their confidentiality.The centre should ensure that confidential information, including all information relating to donors, patients and children born as a result of treatment, is kept confidential and disclosed only in circumstances permitted or required by law. The centre should ensure that patients, their partners, and donors do not have access to any other person's records without first getting that person's consent.

30.3 If the centre is in doubt about whether a proposed disclosure is lawful, it should seek independent legal advice.

30.4 In relation to the treatment of trans patients and donors, there are additional points on confidentiality that must be taken into consideration. The centre should be aware that under the current data protection legislation, information about a person's gender reassignment or any other information relating to a person's gender history will be classed as 'special category data' as this may reveal information about a person's health, and the centre should ensure that appropriate safeguards are in place for processing this data. This includes, among other things, the information should not be used, shared or otherwise disclosed unless the relevant requirements of the HFE Act 1990, Data Protection Act 2018, UK General Data Protection Regulation (UK GDPR) and the common law duty of confidentiality have been considered and the relevant provisions complied with. Special category data entails additional compliance obligations for centres before they are able to lawfully use, share or otherwise disclose it.

The centre should also take appropriate measures to ensure that they comply with strict prohibitions set out under the Gender Recognition Act 2004 on the disclosure of information concerning a patient or a donor who has applied for a gender recognition certificate (GRC), or about the gender history of a person who has a GRC.

Centres should seek independent legal advice if they are uncertain about the lawful use, sharing or disclosure of the personal data, including special category data, relating to transgender patients.

30.5 In relation to the treatment of patients and donors entering into surrogacy arrangements, centres must ensure that appropriate arrangements are in place to maintain confidentiality. The centre must keep separate up-to-date records for the surrogate and the intended parent(s).

The centre should provide separate counselling sessions for the surrogate and the intended parent(s), on different dates. Throughout treatment, the clinic should allow opportunity for separate consultations with the surrogate and with the intended parent(s). During any appointment or occasion where both the surrogate and intended parent(s) are present, the centre should ensure that consideration is given to their confidentiality and ensure that both parties are offered an opportunity to speak to members of staff in private should they wish to.

See also

Guidance note 29 – Treating people fairly

Breach of confidentiality

30.6 If confidentiality is breached (including disclosure of information in breach of either the HFE Act 1990 the General Data Protection Regulation (EU) 2016/679 GDPR or the Gender Recognition Act 2004), the centre should consider it an adverse incident and therefore investigate the cause(s) of the breach, take appropriate remedial action, and notify and submit a full explanation to the HFEA that includes what mitigating actions have been put in place to prevent a similar breach taking place. Consideration should also be given, depending on the level of risk to the data subject, to whether the breach meets the relevant threshold under the UK GDPR for reporting to the Information Commissioner, and/or any patients affected by the breach. Breach notification requirements under the UK GDPR are considered in 30.18 and 30.19 below, but the key issue in determining whether they arise is the level of risk posed to the patient (the data subject) which is likely to be a particular concern if any their sensitive personal data including 'special category data has been disclosed or if there is a risk of detriment to the patient.

30.7 The centre should be aware that certain breaches of confidentiality pertaining to a person's gender reassignment or gender history may also amount to a criminal offence. For example, the disclosure of certain information in breach of the provisions of section 33A of the HFE Act 1990 (as set out above) and section 22 of the Gender Recognition Act 2004. The centre should consider circumstances where they may need to disclose a person's gender reassignment or gender history (e.g., 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 it needs to obtain the person's consent to disclose this information.

See also

Guidance note 27 – Adverse incidents

Access to medical records

30.8 A health record as set out in section 205 of the Data Protection Act 2018 (DPA 2018), is defined as a record which:

(a) consists of data concerning health, and

(b) has been made by or on behalf of a health professional in connection with the diagnosis, care or treatment of the individual to whom the data relates.

For the purposes of this Code of Practice, a record is defined as information created, received and maintained as evidence by a centre or person, in meeting legal obligations or in transacting business. Records can be in any form or medium provided they are readily accessible, legible and indelible.

30.9 The centre must establish a documented procedure and policy for controlling access to medical records. As a minimum, this should ensure that arrangements are in place for:

(a) properly verifying the identity of applicants seeking access to their medical records,
(b) promptly considering and responding to applications for access to confidential records which, in the case of patients seeking to access their own records, are likely to constitute a subject access request under the UK DPA 2018 and in respect of which specific legal obligations arise for the centre when responding,
(c) a designated individual in the centre being responsible for receiving, checking and arranging authorised access to confidential records,
(d) notifying the Information Commissioner about high-risk data breaches in line with data protection legislation,

(e) giving all individual donors and recipients who provide information about themselves access to their own records and an opportunity to correct any information that is incorrect,
(f) ensuring proper procedures are in place to maintain confidentiality when records are stored off site,
(g) ensuring that individuals are aware of their rights under data protection legislation to access their own medical records, and
(h) keeping an audit trail of who has accessed what record and what changes have been made to that record.

Note: When the centre is part of a group organisation, the appropriate department of the parent organisation may undertake some or all of these procedures on behalf of the centre, where appropriate to do so. However, care must be taken to ensure that there are appropriate data sharing arrangements in place between different legal entities within a group and that any intra-group data sharing is lawful.

30.10 The centre should have clear security procedures and policies to prevent unauthorised access to records, and take particular care if records are kept outside the licensed premises (e.g., when counselling takes place outside of the centre). The security procedures and policies should be appropriate to the record keeping system, whether paper-based, electronic or in any other format. Extra scrutiny is recommended if the centre has laboratory equipment that stores patient-identifying information electronically.

30.11 To mitigate the risks of unauthorised people inadvertently gaining access to patient-identifying information through electronic records, the centre should:

(a) ensure that such information cannot be transferred, downloaded, altered or deleted where there is no legitimate organisational reason to do so to portable media-storage devices
(b) ensure that access rights to personal data granted to specific users must be understood, limited to those users who reasonably need such access to perform their function and removed when no longer needed
(c) appropriately authenticate and authorise users that can access personal data
(d) have a robust password policy
(e) ensure that when hardware is removed from the premises, identifying information has been removed. If the centre chooses to use a specialist service provider to remove and dispose of hardware, it should have clear details in its security policy as to how this is managed. Hardware should not leave the premises before the centre has established who is responsible for deleting personal data contained on it, whether that is someone within the centre or the specialist third party provider as part of its service
(f) consider making it a policy that no data is stored on any third-party device unless there is a process for anonymising, pseudoanonymising or removing any personal data
(g) understand, document and manage access to personal data and systems that process this data, including recording and auditing potential access to identifying information
(h) have systems proportionate security measures in place to protect personal data against cyber-attack or other malicious access to personal data; these systems should include anti-virus software, firewalls, and network segmentation (including user-/network-level usernames and passwords) centres should assess their systems and implement specific technical controls as laid out in appropriate frameworks (such as Cyber Essentials), and should undertake regular testing to evaluate the effectiveness of security measures
(i) maintain a record of what software is installed on centre systems
(j) ensure agreements/contracts with the relevant providers set out expectations in relation to data security, patient confidentiality and the respective roles and responsibilities of the data controller and data processor, and
(k) maintain a retention schedule to ensure information is not retained for any longer than needed.

30.12 If the centre's service providers require access to identifying information to do their job, then the centre must take steps to ensure that any person accessing data legitimately requires access to the data in question and is subject to appropriate duties of confidence when accessing it is suitable.

30.13 A person whose medical records are held by the centre is entitled to request a copy of their own medical records on the basis of their subject access rights under the DPA 2018. Such a request need not necessarily be made in writing and can be communicated verbally, although individuals should be encouraged (but not forced) to make their request so long as they ask in writing (including by electronic means). The source of the information and an explanation of any unusual or technical terms should be given.

See also

Guidance note 4 – Information to be provided prior to consent

Guidance note 31 – Record keeping and document control

UK General Data Protection Regulation (EU UK GDPR) and Data Protection Act 2018 2016/679 (GDPR)

30.14 The General Data Protection Regulation, which came into force in May 2018, has now been implemented into UK law by the EU (Withdrawal) Act 2018 as the UK GDPR which is supplemented by the Data Protection Act 2018 (DPA 2018) to comprise the primary data protection regime in the UK. All organisations who process personal data, which is any information from which an individual can be identified either directly or indirectly, must ensure they comply with the UK GDPR and the DPA 2018 when using that data. There are also additional obligations in respect of more sensitive forms of data, such as information relating to health, which is known as special category data. also came into force, repealing and replacing the Data Protection Act 1998 (DPA 1998). Many of the requirements of the GDPR are similar to those in the Data Protection DPA 1998. However, GDPR does introduce some new requirements and significant enhancements to existing requirements. The UK GDPR introduces much more severe provides for significant financial penalties for organisations that get it wrong fail to comply with its requirements. Each centre is responsible for ensuring that it complies with the legislation, including giving full effect to data subject rights. Data subjects may include, but are not limited to, patients, their partners where applicable, donors and members of staff.

30.15 The UK GDPR gives data subjects a number of rights over how their personal data is processed. However some data subject rights introduces some new rights for individuals and enhances other rights, but in general an individual's rights under GDPR are not absolute and will only apply in certain circumstances. For example, although UK GDPR introduces a right for individuals to have personal data erased, that right does not apply if the processing of the individual's personal data is necessary to comply with a legal obligation. In other words, centres will not need to comply with a patient's request for erasure of their IVF treatment records given that it is a legal requirement, by virtue of General Direction 0012, that the centre retains those records for at least 30 years. Matters which raise questions about the application of UK GDPR and the HFE Act 1990 should be considered on a case by case basis and centres should consult the Information Commissioner's Office website for guidance and take their own legal advice where necessary.

DPA 2018 and UK GDPR apply to both NHS and private centres and all centres are expected to do an audit of their current data protection arrangements against the new requirements of the new legislation to determine whether they are fully compliant. Where indicated, centres must make the necessary changes to bring practices and procedures in line with the new legal requirements.

The audit should assess, amongst other things:

what personal data is collected and when the legal basis for the processing of personal data (for example to fulfil legal obligations to report certain personal data, including data about treatment, to the HFEA or for employment purposes)

where data is stored and what measures are in place to protect it, and whether it is shared with

third parties and why it is shared

30.16 The UK GDPR and DPA 2018 imposes a range of obligations on centres in respect of their use of personal data, and it is beyond the scope of this Code to outline them all. It is for centres to familiarise themselves with data protection obligations, and ensure that they meet them. This includes, but not limited to, ensuring that:

(a) they maintain an up to date data processing register which documents key aspects such as legal bases for processing, retention period, sharing data with third parties and associated risks with the process
(b) they appoint a Data Protection Officer to oversee compliance with the data protection law
(c) they carry out data protection impact assessments where required, which may include any new processes which involve use of personal data
(d) identified the legal basis for processing under Article 6 of UK GDPR, and an additional basis under Article 9 of the UK GDPR and Schedule 1 of DPA 2018 where processing special category data, and
(e) they put in place processes to ensure data protection by design and default before processing personal data.

30.17 Centres should also regularly review practices to ensure that all individuals are provided with sufficient information about why the centre collects their personal data, what the centre does with their personal data, how long it will be kept for and who it will be shared with. This is called 'privacy information' and must be given to individuals at the time their personal information is collected. Centres must provide privacy information to anyone who personal data they process which is likely to include patients, their partners where applicable, donors and members of staff. Where indicated by the audit, centres should revise processes and procedures to ensure that they are fully compliant with all the individual rights set out in UK GDPR.

30.18 UK GDPR requires data controllers to report personal data breaches to the Information Commissioner's Office (ICO), unless the breach does not give rise to a risk to data subjects. Centres must report notifiable breaches to the ICO without undue delay and where feasible within 72 hours of becoming aware of the breach.

If the breach is likely to result in a high risk to the rights and freedoms of individuals then centres must also inform the affected individuals without undue delay.

30.19 Centres should ensure that they have robust procedures for detecting and investigating any data breaches. This should include a clear procedure for staff to alert the affected individuals of any personal data breaches and a procedure for notifying the ICO of reportable breaches. A record should be kept of any personal data breaches, regardless of whether the centre is required to report the breach.

30.20 The centre should comply promptly with 'subject access requests' (SARs) made by individuals under the DPA 2018. An individual can make a SAR verbally or in writing, including on social media. Usually, such requests will be for copies of medical records. The centre must verify the identity of the person making the request and may also request written consent to disclosure and proof of identity from the partners of applicants if the medical record contains information relating to them.

30.21 When proof of identity has been received, the centre should respond to the request without undue delay and at least within one month. The centre can extend the time to respond by a further two months if the request is complex or it has received a number of requests from the individual. The centre should ensure it has considered whether any exemptions from the right of access apply before responding to a SAR.

30.22 The centre should be aware that some requests for information may fall under different information access regimes and they must ensure that they comply within the appropriate timeframes. For example, if a centre is subject to the Freedom of Information Act 2000 and the

Environmental Information Regulations 2004, and it is not relying on an exemption, it must respond to a request promptly and within 20 working days (eg, 20 working days under the Freedom of Information Act 2000 and the Environmental Information Regulations 2004).

30.23 The centre should take into account any other applicable legislation including the HFE Act 1990, DPA 2018, UK GDPR and the common law before giving access to any information that has been requested.

Disclosing non-identifying information: general

30.24 The centre may disclose information that does not identify or could not reasonably be expected to lead to the identification of a person owed a duty of confidentiality. If the centre is unsure whether information it proposes to disclose could identify the person, it should seek independent legal advice.

Disclosure authorised by statute

Interpretation of mandatory requirements 30A

A centre may hold information that could lead to the identification of:

(a) an individual donor or recipient of gametes or embryos (including mitochondrial donation)

(b) an individual or couple seeking or receiving treatment services (other than basic partner services), or

(c) an individual who may have been born as a result of such services or as a result of donated sperm.

The centre may disclose this information only in the specific circumstances set out in the HFE Act 1990 (as amended). The information may, for example, be disclosed:

(a) to anyone, provided that it is disclosed in such a way that no individual can be identified from it

(b) to the Authority

(c) to another licensed centre to enable that centre to carry out its functions under its licence

(d) to the person to whom the information relates, and to their partner (if they are being treated together, or their partner has served notice of consent to be treated as the legal parent of any resulting child)

(e) with the consent of each person who could be identified from the information (although disclosure in this case is limited to information other than that from which a donor of gametes could be identified)

(f) in connection with specific proceedings, including, for example, in relation to the formal complaints procedure, or

(g) in an emergency, if disclosure is necessary to avert imminent danger to the health of the person to whom the information relates, and it is not reasonably practicable to obtain their consent to disclosure.

If the centre is in doubt about whether a proposed disclosure is lawful, it should seek independent legal advice.

30.25 If the centre refers a person seeking treatment to another licensed centre, it should provide relevant information in line with good clinical practice. The centre must always supply information relevant to the welfare of the child.

30.26 Centres should be aware that a donor, and a person born from this donation, could potentially access identifying information about each other outside of the managed system of information access described in this guidance note, through the use of direct to consumer DNA testing. This

could also happen even if they are not users of such a service, as any closely-related genetic relatives using a service like this could potentially access this information. Centre staff should familiarise themselves with direct to consumer DNA sites and should have a basic understanding of how they operate, so that they are able to provide appropriate information to donors and patients. Centres should provide information in line with the requirements of the HFE Act only.

See also

Guidance note 8 – Welfare of the child

Disclosing information to gamete and embryo donors

Interpretation of mandatory requirements 30B

A donor may request information from a centre about the number, sex and birth year of any children born using their gametes or embryos (including mitochondrial donation). If the centre holds that information, it must provide it unless the person responsible considers that special circumstances exist that increase the likelihood of the donor being able to identify any of those children.

Once a person conceived using donor gametes reaches the age of 16, they may ask the Authority to give them certain non-identifying information about the donor and the number, sex and year of birth of any donor-conceived siblings.

Once a person conceived using donor gametes reaches the age of 18, they may also ask the Authority for certain identifying information about the donor, where that information was provided to the centre after the Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004 came into force.

30.27 The HFEA will seek to inform donors of gametes and embryos that it has received an application by a donor-conceived person for identifying information about them. The HFEA will not give the donor any information about the person making the application.

Disclosing information to recipients of donated gametes and embryos

30.28 The centre may give non-identifying information about the donor to those who receive donor-assisted conception treatment or treatment involving mitochondrial donation and those who have received such treatment in the past.

30.29 The HFEA may also disclose the information that centres may disclose in these circumstances, if that information is contained on its Register.

30.30 The centre should:

(a) reassure donors and potential donors that they may ask at any time how many children have resulted from their donation
(b) reassure identifiable donors that attempts will be made to contact them before their identity is disclosed to a donor-conceived person
(c) encourage identifiable donors to provide up-to-date contact details to help this, and
(d) respond as fully as possible to patients' requests for non-identifying information about the donor(s) used in their treatment.

Consent to disclose identifying information

Interpretation of mandatory requirements 30C

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 storage of their 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 storage. For example, if a patient's partner could be incidentally identified through disclosure of information about a 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 necessarily incidental to the disclosure of 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).

30.31 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 disclosed
(c) the reasons for disclosure (e.g., 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.

30.32 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 (to enable them to provide the patient or the patient's partner with the best possible medical care)
(c) auditors or administrative staff outside of the centre (to enable them to perform functions designated to them 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).

30.33 The centre should renew consent to disclosure if the nature of the 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).

30.34 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 5 – Consent to treatment, storage, donation and disclosure of information

Guidance note 31 – Record keeping and document control

HFEA consent forms

Disclosure of medical records of a deceased patient

30.35 The UK GDPR and DPA 2018 do not apply to deceased patients, but the duty of confidentiality does survive death. Sections 33A(2)(r) and 33A(2)(s) of the HFE Act 1990 permits disclosure of a deceased patient's medical records where disclosure is made under section 3 of the Access to Health Records Act 1990 (AHRA) or under Article 5 of the Access to Health Records Act (Northern Ireland) Order 1993 (AHRA(NI)). Sections 3(1)(f) of the AHRA and Article 5(1)(e) of the AHRA(NI) give a patient's personal representative and any person who may have a claim arising out of the patient's death a right to apply to access a deceased patient's medical records. In respect of the latter, section 5(4) of the AHRA and article 7(4) of the AHRA(NI) limit the right of access to those parts of the record which are irrelevant to the claim.

30.36 When a centre receives a request for disclosure of a deceased patient's medical records, it should seek legal advice to assist it in reaching a view as to whether disclosure would be lawful and if so, what records or information can be disclosed. Before making disclosure, the centre and its legal advisors should consider:

(a) whether there is sufficient evidence that the person making the request is in fact a personal representative (the executor or administrator of the deceased person's estate) or a person who may have a claim arising out of the patient's death (which could be a relative or another person),
(b) whether any individual, other than the deceased patient, could be identified by the deceased's patients medical records and if so, whether that information should be redacted although noting that it is assumed reasonable to disclose personal information relating to health or social care professionals,
(c) whether there is any other legal reason why the disclosure should not be made, such as written notice from the patient to withhold the disclosure
(d) where a request has been made for the disclosure of a donor's medical records, information pertaining to a donor or the use of a donor's gamete in treatment must be considered carefully and with reference to section 33A(2)(h) read with section 33A(7) before making a disclosure, and
(e) keeping an appropriate record of what information it discloses as well as any information it does not disclose.

Other legislation, professional guidelines and information

Legislation

Access to Health Records Act 1990

The Access to Health Records (Northern Ireland) Order 1993

Data Protection Act 2018

General Data Protection Regulation (GDPR)

European (Withdrawal) Act 2018

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

The Data Protection (Subject Access Modification) (Health) Order 2000

European Convention for the Protection of Human Rights and Fundamental Freedoms

Equality Act 2010

Gender Recognition Act 2004

Human Rights Act 1998

Professional guidelines

Care Quality Commission: Code of Practice – confidential personal information (2016)

National Health Service: Code of Practice – confidentiality (2003)

General Medical Council: Confidentiality: good practice in handling patient information (2017)

Information Commissioner's Office: upholds information rights in the public interest

National Health Service Digital: Code of Practice for health and social care – records management (2016)

Clinic Focus articles

Clinic Focus article: Disclosure of medical records of a deceased patient (August 2020)