



Code of Practice

6th Edition

Code of Practice

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The Human Fertilisation and Embryology Authority
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Contents

| | |
|---|-----|
| Introduction | p9 |
| Interpretation Of The <i>Code Of Practice</i> | p12 |
| Part 1 Staff | |
| 1.1 General Standards | p13 |
| 1.2 The Person Responsible | p14 |
| 1.5 Medical Staff | p15 |
| 1.8 Nursing And Midwifery Staff | p15 |
| 1.9 Counselling Staff | p16 |
| 1.11 Staff Engaged In Scientific Services | p17 |
| 1.17 Continued Professional Training | p18 |
| 1.18 Conscientious Objection | p18 |
| 1.19 Criminal Convictions | p18 |
| Part 2 Facilities And Administrative Procedures | |
| 2.1 General Standards | p21 |
| 2.4 Administration | p23 |
| 2.5 Clinical Facilities | p23 |
| 2.9 Laboratory Facilities And Safe Cryopreservation | p24 |
| 2.18 Counselling Facilities | p25 |
| 2.22 Secure Storage For Gametes And Embryos | p26 |
| 2.23 Adverse Incidents | p26 |
| 2.27 Maintaining And Improving Standards | p27 |
| 2.29 Advertising | p27 |
| 2.30 Professional Standards | p27 |
| Part 3 Welfare Of The Child And The Assessment Of Those Seeking Treatment | |
| 3.1 General Obligations | p29 |
| 3.11 Welfare Of The Child | p31 |
| 3.14 Other Issues To Be Taken Into Account | p32 |
| 3.16 Surrogate Pregnancy | p32 |
| 3.18 Selection Of Donated Gametes | p32 |
| 3.20 Enquiries To Be Made | p33 |
| 3.21 Multidisciplinary Assessment | p33 |
| 3.25 Written Record In Respect Of The Welfare Of The Child | p34 |
| 3.26 Additional Information For Those Seeking Long Term Storage Of Gametes And Embryos | p34 |
| 3.28 Additional Information For Those Seeking An Egg Sharing Arrangement | p35 |

Part 4 Assessing And Screening Potential Donors

| | | |
|------|--|-----|
| 4.1 | General Standards | p37 |
| 4.4 | Family And Other Relevant History | p38 |
| 4.8 | Suitability As Donors | p39 |
| 4.9 | Potential Donors Undergoing Treatment | p39 |
| 4.10 | Scientific Tests | p39 |
| 4.22 | Age Of People Considering Donation | p41 |
| 4.26 | Payment And Expenses For People Providing Gametes For Donation | p41 |
| 4.27 | People Unsuitable As Donors | p41 |
| 4.32 | People Involved In An Egg Sharing Arrangement | p42 |

Part 5 Information

| | | |
|------|--|-----|
| 5.1 | General Obligations | p43 |
| 5.5 | Additional Information | p45 |
| 5.6 | Information Relating To The Donation Of Gametes | p46 |
| 5.6 | Information For Those Receiving Treatment With Donor Gametes/Embryos | p46 |
| 5.8 | Information For Research Donors | p50 |
| 5.11 | People Seeking Long Term Storage Of Gametes And Embryos | p51 |
| 5.12 | People Involved In An Egg Sharing Agreement | p51 |

Part 6 Consent

| | | |
|------|---|-----|
| 6.1 | Consent To Examination And Treatment | p53 |
| 6.4 | Consent To The Presence Of Observers | p54 |
| 6.5 | General Obligations | p54 |
| 6.10 | Consent By Children And Young People | p55 |
| 6.13 | Mental Capacity | p55 |
| 6.14 | Consent To Storage | p55 |
| 6.15 | Statutory Storage Period | p56 |
| 6.18 | Consent To Use | p64 |
| 6.23 | Consent To Export | p57 |
| 6.23 | Direction 1991/8 Export Of Gametes | p57 |
| 6.24 | Posthumous Use | p58 |
| 6.28 | People Seeking Treatment | p59 |
| 6.32 | Consent Of The Husband Or Male Partner And Legal Fatherhood | p60 |
| 6.39 | People Providing Gametes And Embryos For Donation | p63 |
| 6.42 | People Seeking Long Term Storage Of Gametes And Embryos | p64 |
| 6.48 | People Involved In An Egg Sharing Arrangement | p67 |

Part 7 Counselling

| | | |
|------|---|-----|
| 7.1 | General Obligations | p69 |
| 7.11 | Implications Counselling | p72 |
| 7.14 | Treatment With Donated Gametes Or Embryos | p72 |
| 7.16 | People Providing Gametes And Embryos For Donation | p73 |
| 7.19 | Support Counselling | p74 |
| 7.21 | Therapeutic Counselling | p74 |
| 7.23 | Genetic Counselling | p75 |
| 7.24 | Later Counselling | p75 |
| 7.25 | Records | p75 |
| 7.27 | People Seeking Long Term Storage Of Gametes And Embryos | p75 |
| 7.29 | People Involved In An Egg Sharing Arrangement | p75 |

Part 8 Use Of Gametes And Embryos

| | | |
|------|---|-----|
| 8.1 | Obtaining Gametes And Embryos | p77 |
| 8.4 | Clinical Use | p79 |
| 8.10 | Termination And Disposal | p82 |
| 8.13 | People Seeking Treatment | p82 |
| 8.17 | Transfer Of Eggs And Embryos | p83 |
| 8.23 | Donor Insemination | p84 |
| 8.29 | People Providing Gametes And Embryos For Donation | p86 |
| 8.33 | Export Of Gametes | p86 |
| 8.34 | Posthumous Use | p86 |

Part 9 Storage And Handling Of Gametes And Embryos

| | | |
|------|---------------------------------|-----|
| 9.1 | General Obligations | p87 |
| 9.2 | Screening | p87 |
| 9.5 | Security | p87 |
| 9.9 | Identification | p88 |
| 9.11 | Storage Review | p88 |
| 9.14 | Contamination | p88 |
| 9.15 | Transfer Of Gametes And Embryos | p89 |

Part 10 Research

| | | |
|------|-------------------|-----|
| 10.1 | General Standards | p91 |
| 10.4 | Prohibitions | p92 |

Part 11 Records

| | | |
|------|---|-----|
| 11.1 | Accuracy | p95 |
| 11.3 | Confidentiality | p95 |
| 11.4 | Access To Health Records And The Data Protection Act 1998 | p95 |
| | Access Exemptions To The Data Protection Act 1998 | p96 |

| | | |
|----------------|--|------|
| 11.10 | The Human Fertilisation And Embryology Act 1990 | p101 |
| 11.15 | People Involved In An Egg Sharing Arrangement | p103 |
| | <i>Annex A</i> | p104 |
| | <i>Annex B</i> | p105 |
| Part 12 | Confidentiality | |
| 12.1 | General Obligations | p107 |
| 12.2 | Disclosure Without Consent | p110 |
| 12.4 | Disclosure With Consent | p110 |
| 12.9 | People Involved In Gamete Donation Or An Egg Sharing Arrangement | p112 |
| 12.9 | Additional Safeguards | p112 |
| Part 13 | Complaints | |
| 13.1 | General Obligations | p113 |
| | <i>Annex A</i> | p115 |
| | <i>Annex B</i> | p118 |
| Part 14 | Preimplantation Testing | |
| 14.1 | Definitions | p119 |
| 14.4 | Polar Body/Blastomere Biopsy | p119 |
| 14.6 | Licensing Of Preimplantation Testing | p120 |
| 14.11 | Accreditation Of Genetics Laboratories | p121 |
| | Preimplantation Genetic Diagnosis | p122 |
| 14.12 | Staff Involved | p122 |
| 14.13 | Genetic Consultation | p122 |
| 14.16 | Patient Information | p123 |
| 14.20 | Clinical Decision Making | p123 |
| 14.24 | Preimplantation Genetic Screening For Aneuploidy | p124 |
| 14.26 | Patient Information | p125 |
| 14.28 | Recording And Reporting Of Information | p126 |
| Part 15 | Witnessing Clinical And Laboratory Procedures | |
| | General | p127 |
| | Protocol For Witnessing Clinical And Laboratory Procedures | p128 |
| 15.1 | Egg Collection | p128 |
| 15.2 | Sperm Sample | p128 |
| 15.3 | Sperm Preparation | p128 |
| 15.4 | Insemination/ICSI | p128 |
| 15.5 | Fertilisation Check | p129 |
| 15.6 | Embryo Transfer | p129 |
| 15.7 | Gamete/Embryo Freezing | p129 |

| | | |
|------|-----------------------------------|------|
| 15.8 | Removal Of Cryopreserved Material | p129 |
| 15.9 | Donor Insemination | p130 |

Part 16 Intra-Cytoplasmic Sperm Injection (ICSI)

| | | |
|------|-------------------------------|------|
| | General | p131 |
| | Definitions | p131 |
| 16.1 | ICSI Practitioners | p132 |
| 16.3 | Recognised ICSI Practitioners | p132 |
| 16.4 | Licensing Obligations | p133 |
| 16.5 | Factors To Be Considered | p133 |

Appendices

| | | |
|------------|---|------|
| Appendix A | Guidance For Egg Sharing Arrangements | p135 |
| Appendix B | Consent To Disclosure Of Identifying Information About My/Our Fertility Treatment To Another Person Who Is Not Covered By A Licence | p140 |
| Appendix C | Guidance On Screening For HIV Infection | p142 |
| Appendix D | Parental Orders In Surrogacy Cases | p143 |
| Appendix E | Consent To Treatment Involving Egg Retrieval And/Or Egg Or Embryo Replacement | p145 |
| Appendix F | Guidelines From Professional Organisations | p149 |
| Appendix G | Guidance On Reasonable Expenses For Donors | p152 |
| Appendix H | Licence Conditions | p154 |
| Appendix I | The HFEA Register | p162 |

Index

| |
|------|
| p163 |
|------|

Introduction

Medical intervention or research which aims to alleviate infertility or reduce the risk of inherited abnormality intrudes upon the most sensitive parts of our existence and our most private relationships. The Human Fertilisation and Embryology Authority (HFEA) was established in response to deep public concern about the implications which new techniques for assisted reproduction might have for the perception and valuing of human life and family relationships. The Authority's principal task is to regulate, by means of a system of licensing, audit and inspection, any research or treatment which involves the creation, keeping and use of human embryos outside the body, or the storage or donation of human eggs and sperm. Section 25 of the Human Fertilisation and Embryology Act 1990 (HFE Act) requires the HFEA to maintain a *Code of Practice* giving guidance about the proper conduct of licensed activities which may also include guidance on any procedure involving the placing of eggs and sperm in a woman.

The HFE Act covers both *in vitro* fertilisation and donor insemination and imposes obligations upon centres to give and record information, provide counselling and take account of the welfare of the relevant children. The HFE Act recognises that, while those seeking assisted reproductive treatment deserve and can expect proper consideration of their medical and social needs, licensed treatments may result in children who would not otherwise have been born and whose interests must be taken into account.

The object of the HFEA *Code of Practice* is therefore wider than to secure the safety or efficacy of particular clinical or scientific practices. It is concerned with areas of practice which raise fundamental ethical and social questions. In framing the *Code of Practice*, the HFEA has been guided both by the requirements of the HFE Act and by:

- 1 The respect which is due to human life at all stages of its development
- 1 The right of people seeking assisted reproductive treatment to proper consideration of their request
- 1 A concern for the welfare of children, which cannot always be adequately protected by concern for the interests of the adults involved
and
- 1 A recognition of the benefits, both to individuals and to society, which can flow from the responsible pursuit of medical and scientific knowledge

The HFEA recognises that these considerations may sometimes conflict and has sought to reconcile them in a way which is both practicable and in accordance with the spirit and intentions of the HFE Act. The HFEA's aim is to support the best clinical and scientific practice, while guarding against the undoubted risk of exploitation of people at a time when they may be particularly vulnerable.

This sixth edition of the *Code of Practice* has been designed for ease of use for those specialists working in licensed centres and other readers. Each Part of the *Code* is now prefaced by the relevant legislation, the practical implications of which are further explained in the following text. Where the legislation requires or empowers the HFEA to exercise its jurisdiction over certain matters through its licensing and regulatory system, the Authority's policy is explained and the relevant licence conditions or Directions which bring this into force are indicated. Finally, guidance is provided on the proper conduct of activities in licensed centres and, where appropriate, agreed standards of best practice are given. In cases in which the *Code* makes reference to guidance given by other authorities and professional bodies, this guidance is provided or referenced in an appendix. Other appendices provide a complete list of standard licence conditions and relevant General Directions.

The *Code* assumes that all those involved in providing treatment or conducting research will observe the standards and requirements of good clinical and scientific practice. The *Code* is particularly relevant to the duties of the Person Responsible in HFEA licensed clinics. Under Section 17 of the HFE Act, the Person Responsible has a number of duties, including the duty to secure that:

- ¹ Proper arrangements are made for the keeping of gametes and embryos and
- ¹ Suitable practices are used in the course of all activities

It is for a Licence Committee of the HFEA to determine whether a clinic is making proper arrangements or using suitable practices. In making that determination the Licence Committee may, and in certain circumstances must, take into account provisions in this *Code of Practice*.

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 25

- (6) A failure on the part of any person to observe any provision of the *Code* shall not of itself render the person liable to any proceedings, but –
 - (a) a Licence Committee shall, in considering whether there has been a failure to comply with the conditions of a Licence and, in particular, conditions requiring anything to be “proper” or “suitable”, take account of any relevant provision of the *Code*, and
 - (b) a Licence Committee may, in considering, where it has power to do so, whether or not to vary or revoke a licence, take into account any observance or failure to observe the provisions of the *Code*.

The *Code of Practice* is regularly reviewed and amended in light of experience and to keep pace with both the latest developments in clinical practice and evolving public concerns. The new layout of the *Code* has been designed to make it easier for the reader quickly to identify the relevant Sections of the HFE Act and *Code*. In addition, the index has been designed for quicker and more accurate cross referencing.

New additions:

- 1 ICSI
- 1 Preimplantation Testing
- 1 Witnessing Procedures

This new edition also contains substantive changes in the following areas:

- 1 An appendix of guidelines produced by professional organisations
- 1 An appendix of licence conditions
- 1 Consent
- 1 Consent to disclosure forms
- 1 Complaints
- 1 Counselling
- 1 Egg sharing
- 1 Parental orders in surrogacy cases
- 1 Posthumous use
- 1 Reporting adverse incidents
- 1 Research – payment incentives for patients
- 1 Welfare of the child assessment

This revised *Code of Practice* has been approved by the Secretary of State and laid before Parliament in accordance with Section 26 of the HFE Act.

Interpretation Of The *Code Of Practice*

To assist readers to identify what is a legal requirement in the *Code* the word “**must**” has been used. Where the law specifies a prohibition, this is identified by the negative “**must not**”, or occasionally “**may not**”. Where the words “**expected to**” or “**expected that**” are used this indicates what is to be regarded as the proper conduct of licensable activities or as suitable practice within licensed centres. Where the negative “**expected not to**” or occasionally “**expected...not**” are used, this indicates what is not to be regarded as proper conduct or suitable practice. As guidance produced by an expert body pursuant to a statutory obligation, the provisions of the *Code* must be taken fully into account by the Person Responsible at a licensed centre. Any departure from the *Code of Practice* may, and in some circumstances must, be taken into account by the HFEA and could result in the revocation of a centre’s licence.

Part 1 – Staff

General Standards

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 16

- (1) Where application is made to the Authority in a form approved for the purpose by it accompanied by the initial fee, a licence may be granted to any person by a licence committee if the requirements of subsection (2) below are met and any addition fee is paid.
- (2) The requirements mentioned in subsection (1) above are –
 - (a) that the application is for a licence designating an individual as the person under whose supervision the activities are to be authorised by the licence to be carried on,
 - (b) that either that individual is the applicant or –
 - (i) the application is made with the consent of that individual, and
 - (ii) the licence committee is satisfied that the applicant is a suitable person to hold a licence,
 - (c) that the licence committee is satisfied that the character, qualifications and experience of that individual are such as are required for the supervision of the activities and that the individual will discharge the duty under section 17 of this Act ...

Section 17

- (1) It shall be the duty of the individual under whose supervision the activities authorised by a licence are carried on (referred to in this Act as the “person responsible”) to secure –
 - (a) that the other persons to whom the licence applies are of such character, and are so qualified by training and experience, as to be suitable persons to participate in the activities authorised by the licence,
 - (b) that proper equipment is used,
 - (c) that proper arrangements are made for the keeping of gametes and embryos and for the disposal of gametes or embryos that have been allowed to perish,
 - (d) that suitable practices are used in the course of the activities, and
 - (e) that the conditions of the licence are complied with.

- (2) References in this Act to the persons to whom a licence applies are to –
 - (a) the person responsible,
 - (b) any person designated in the licence, or in a notice given to the Authority by the person who holds the licence or the person responsible, as a person to whom the licence applies, and
 - (c) any person acting under the direction of the person responsible or of any person so designated.
- (3) References below in this Act to the nominal licensee are to a person who holds a licence under which a different person is the person responsible.

1.1 High standards of integrity are required from those responsible for HFEA licensed activities – and from those taking part in those licensed activities – in order to:

- (i) Protect the interests and privacy of people seeking treatment
- (ii) Protect the interests and privacy of people considering donations
- (iii) Guard against the misuse of gametes and embryos
- (iv) Protect the welfare of potential children born as a result of treatment and any other children who may be affected by the birth.

The Person Responsible

1.2 A licence application to the HFEA must name the person under whose supervision the licensed activities will be carried out. This person is referred to as the ‘Person Responsible’.

1.3 The Person Responsible is expected to have sufficient insight into the scientific, medical, legal, social, ethical and other aspects of the treatment centre’s work to be able to supervise its activities properly. The qualities of integrity, responsibility, managerial authority and capability are more important than any particular professional qualification. The HFEA expects the Person Responsible to take whatever specialist advice is necessary to allow him/her to continue to run the treatment centre professionally.

1.4 The Person Responsible must ensure that:

- (i) The character, qualifications and experience of those carrying out HFEA licensed activities are suited to the work they are doing at the treatment centre
- (ii) Proper equipment is used at the treatment centre
- (iii) Proper arrangements are made for the keeping and disposal of gametes and embryos at the treatment centre
- (iv) Suitable practices are used in the course of the activities
- (v) The centre complies with all the conditions of its HFEA licence

- (vi) Any adverse incident which has occurred at the treatment centre is reported in line with the requirements at paragraphs 2.23 to 2.26 of this *Code*

Medical Staff

- 1.5 At treatment centres the individual with overall clinical responsibility for treatment services using *in vitro* fertilisation is expected to:
 - (i) Be on the General Medical Council Specialist Register and
 - (ii) Have completed training recognised by the Royal College of Obstetricians and Gynaecology and
 - (iii) Participate in a recognised programme of continuing medical education and professional development
- 1.6 At treatment centres other medical staff engaged in provision of treatment are expected to be registered medical practitioners with sufficient experience under supervision to qualify them to take part in providing treatment. Medical staff who carry out laparoscopies are expected to be Fellows or Members of the Royal College of Obstetricians and Gynaecologists. Medical staff in training are expected to follow relevant training programmes under appropriate supervision.
- 1.7 Where treatment centres are licensed to provide donor insemination only, the individual with overall clinical responsibility is expected to:
 - (i) Be a registered medical practitioner and
 - (ii) Have a sufficient period of experience in an established infertility clinic to be qualified to take full charge of the centre's treatment services

Nursing and Midwifery Staff

- 1.8 All nursing and midwifery staff are expected to be appropriately qualified and registered by the Nursing and Midwifery Council, to be experienced in women's reproductive health and to be working towards:
 - (i) National and/or locally set competences to ensure appropriate standards of clinical competences and
 - (ii) A higher level award with a focus on women's reproductive health and
 - (iii) An accredited ultrasound course/qualification, if involved in that procedure

Counselling Staff

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 13

- (1) The following shall be conditions of every licence under paragraph 1 of Schedule 2 to this Act ...
- (6) A woman shall not be provided with any treatment services involving –
- (a) the use of any gametes of any person, if that person's consent is required under paragraph 5 of Schedule 3 to this Act for the use in question,
 - (b) the use of any embryo the creation of which was brought about *in vitro*, or
 - (c) the use of any embryo taken from a woman, if the consent of the woman from whom it was taken is required under paragraph 7 of that Schedule for the use in question,
- unless the woman being treated and, where she is being treated together with a man, the man have been given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and have been provided with such relevant information as is proper. ...

1.9 Treatment centres are expected to ensure that at least one member of staff is appointed to fulfil the roles of counsellor to clients and is expected to:

- (i) Hold either a recognised counselling, clinical psychology, counselling psychology or psychotherapy qualification to diploma of higher education level or above
or
- (ii) Hold an Infertility Counselling Award
or
- (iii) Hold a professional social work qualification recognised by one of the UK social care councils
or
- (iv) Be able to provide evidence of working towards accreditation through the British Infertility Counselling Association/British Fertility Society Infertility Counselling Award
and
- (v) Be able to provide evidence of membership of a recognised professional counselling body with a complaints/disciplinary procedure and has agreed to abide by an appropriate code of conduct or ethics

Staff Engaged In Scientific Services

- 1.10 All clinical scientists working in HFEA licensed centres are expected to be registered or show evidence of working towards registration with the Health Professions Council.
- 1.11 The individual with responsibility for the clinical embryology laboratory is expected to:
- (i) Possess an appropriate scientific or medical degree
and
 - (ii) Have had a sufficient period of experience in a clinical embryology laboratory consistent with the ability to supervise and be responsible for such a laboratory (see also the Association of Clinical Embryologists guidelines in Appendix F).
- 1.12 The individuals with responsibility for preimplantation genetic screening/diagnosis (both cyto and molecular genetic) are expected to:
- (i) Possess an appropriate scientific or medical degree
and
 - (ii) Have had a sufficient period of experience in an appropriately accredited medical genetics diagnostic laboratory consistent with the ability to supervise and be responsible for such a laboratory
- 1.13 Where genetic testing of those seeking treatment or considering donation is carried out, centres are expected to ensure the availability of an individual who understands:
- (i) The nature of the tests conducted
and
 - (ii) The scope and limitation of the tests
and
 - (iii) The accuracy and implications of the tests
and
 - (iv) The meaning of the test results
- 1.14 The individual with responsibility for a seminology laboratory is expected to:
- (i) Possess a degree or higher national diploma in a relevant discipline
and
 - (ii) Have had a sufficient period of experience in a seminology laboratory consistent with the ability to supervise and be responsible for such a laboratory

- 1.15 Andrologists working in licensed centres are expected to receive appropriate training.
- 1.16 The individual with responsibility for cryopreservation is expected to be appropriately trained and experienced in the relevant techniques.

Continued Professional Training

- 1.17 Where formal qualifications are insufficient, centres are expected to arrange for staff taking part in scientific, clinical, nursing or counselling activities, to receive appropriate training. All professional staff are expected to engage actively in continuing professional development activities as provided and recommended by the relevant professional associations.

Conscientious Objection

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 38

- (1) No person who has a conscientious objection to participating in any activity governed by this Act shall be under any duty, however arising, to do so.
- (2) In any legal proceedings the burden of proof of conscientious objection shall rest on the person claiming to rely on it.
- (3) In any proceedings before a court in Scotland, a statement on oath by any person to the effect that he has a conscientious objection to participating in a particular activity governed by this Act shall be sufficient evidence of that fact for the purpose of discharging the burden of proof imposed by subsection (2) above.

- 1.18 Prospective employees at an HFEA licensed treatment or research centre are expected to be provided with full descriptions of the centre's activities. The interviewers are expected to raise the issue of conscientious objection with the prospective employee and draw their attention to the relevant provisions for conscientious objection in the HFE Act.

Criminal Convictions

- 1.19 Centres are expected to require all prospective and existing staff to report promptly any relevant criminal convictions to the Person Responsible. In deciding whether or not an individual is suitable to take part in an HFEA licensed activity at a treatment or research centre the Person Responsible is expected to take into account relevant previous convictions or breaches of regulations. Where an individual has a relevant previous conviction or is known to

have breached relevant regulations, that individual is expected not to be appointed to a post which involves:

- (i) Access to people considering donation
or
- (ii) Access to people seeking treatment
or
- (iii) Access to gametes or embryos or records relating to gametes or embryos

Unless the Person Responsible is satisfied that the applicant is suitable for the post in question.

The Person Responsible is expected to decide what is a “relevant previous conviction” and much will depend upon the position to be held and the gravity of the offence. It is for the Person Responsible to decide what action is required in the event of being made aware of such a conviction.

Part 2 – Facilities And Administrative Procedures

General Standards

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 17

- (1) It shall be the duty of the individual under whose supervision the activities authorised by a licence are carried on (referred to in this Act as the “person responsible”) to secure –
 - (a) that the other persons to whom the licence applies are of such character, and are so qualified by training and experience, as to be suitable persons to participate in the activities authorised by the licence,
 - (b) that proper equipment is used,
 - (c) that proper arrangements are made for the keeping of gametes and embryos and for the disposal of gametes or embryos that have been allowed to perish,
 - (d) that suitable practices are used in the course of the activities, and
 - (e) that the conditions of the licence are complied with.
- (2) References in this Act to the persons to whom a licence applies are to –
 - (a) the person responsible,
 - (b) any person designated in the licence, or in a notice given to the Authority by the person who holds the licence or the person responsible, as a person to whom the licence applies, and
 - (c) any person acting under the direction of the person responsible or of any person so designated.
- (3) References below in this Act to the nominal licensee are to a person who holds a licence under which a different person is the person responsible.

- 2.1 The Person Responsible must ensure that proper equipment and suitable practices are used in all service provision and support to patients.

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 12

The following shall be conditions of every licence granted under this Act –

- (a) that the activities authorised by the licence shall be carried on only on the premises to which the licence relates and under the supervision of the person responsible

2.2 If a centre decides to use outside facilities, the Person Responsible is expected to be satisfied that those facilities comply with any relevant provisions of this *Code*. Licensed activities must only take place on the licensed premises.

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 13

- (1) The following shall be conditions of every licence under paragraph 1 of Schedule 2 to this Act.
- (2) Such information shall be recorded as the Authority may specify in directions about the following...
 - (e) any mixing of egg and sperm and any taking of an embryo from a woman or other acquisition of an embryo, and
 - (f) such other matters as the Authority may specify in directions.

Section 14

- (1) The following shall be conditions of every licence authorising the storage of gametes or embryos –
- (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.

Section 15

- (1) The following shall be conditions of every licence under paragraph 3 of Schedule 2 to this Act –
- (2) The records maintained in pursuance of the licence shall include such information as the Authority may specify in directions about such matters as the Authority may so specify.

Section 24

- (1) If, in the case of any information about persons for whom treatment services were provided, the person responsible does not know that any child was born following the treatment, the period specified in directions by virtue of section 13(4) of this Act shall not expire less than 50 years after the information was first recorded.
- (2) In the case of every licence under paragraph 1 of Schedule 2 to this Act, directions shall require information to be recorded and given to the Authority about each of the matters referred to in section 13(2)(a) to (e) of this Act.
- (3) 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.

- 2.3 Treatment centres must operate transport and satellite IVF arrangements in accordance with Directions given by the HFEA. Suitable arrangements are expected to be made to ensure that patients having treatment through satellite and transport centres to have appropriate access to counselling provided by an appropriately qualified counsellor at the centre in which they are receiving treatment.

Administration

- 2.4 Treatment centres are expected to have appropriate clinical governance procedures in place. In NHS treatment centres/clinics, these procedures are expected to be in accordance with standards required of NHS services and as set out in this *Code of Practice*. In private treatment centres/clinics, the procedures are expected to be in accordance with the standards required by the National Care Standards Commission in England, or the Care Commission in Scotland or the Care Standards Inspectorate Wales, or the relevant successor body, and as set out in this *Code of Practice*.¹

Clinical Facilities

- 2.5 Treatment centres are expected to have backup and emergency clinical facilities equivalent to those which are standard practice in other medical service provision and appropriate to the degree of risk involved in any planned procedures. Appropriately qualified staff are expected to also be available e.g. with the ability to resuscitate a patient during egg recovery, if necessary.
- 2.6 Local facilities are expected to be available to cater for predictable emergencies.
- 2.7 Treatment centres are expected to take reasonable steps to ensure that acceptable facilities are available and be sensitive to the needs for both privacy and comfort of those considering

¹ There is no equivalent body to the NCSC in Northern Ireland.

donation and seeking treatment. In particular, treatment centres are expected to provide a completely private and comfortable room for examination and treatment, and similarly private facilities for the production of semen specimens.

- 2.8 Where a treatment centre is licensed to provide treatment services using *in vitro* fertilisation, a member of staff is expected to be available at all times for those patients receiving treatment.

Laboratory Facilities And Safe Cryopreservation

- 2.9 HFEA licensed centres using laboratories for research or clinical services must follow good laboratory practice.
- 2.10 Centres are expected to be fully aware of the microbiological hazards of handling gametes and embryos and comply with Control of Substances Hazardous to Health regulations.
- 2.11 All blood products, other than those of the woman receiving treatment, with which gametes or embryos might come into contact are expected to be pre-tested for HIV, Hepatitis B and Hepatitis C.
- 2.12 The location used for egg collection for *in vitro* fertilisation is expected to be as close as is practical to the laboratory where fertilisation is to take place.
- 2.13 Facilities for the cryopreservation of gametes and embryos are expected to be:
- (i) Customised, secure and dedicated
and
 - (ii) Adequate for the volume and types of activities to be carried out
- 2.14 Appropriate emergency procedures are expected to be in place in all centres to respond to damage to storage vessels and failures in storage systems.
- 2.15 Written procedures are expected to provide for the safe use of straws and ampoules to minimise the risk of sample losses or contamination.
- 2.16 Centres are expected to have written standard itemised operating procedures as follows:
- (i) Cleaning vessels
 - (ii) Filling vessels
 - (iii) Securing vessels
 - (iv) Freezing and thawing procedures
 - (v) Location and duration of storage
 - (vi) Handling of contaminated samples

- 2.17 Centres are expected to also take steps to minimise risks arising from the transfer of material between centres.

Counselling Facilities

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 13

The following shall be conditions of every licence under paragraph 1 of Schedule 2 to this Act.

- (6) A woman shall not be provided with any treatment services involving –
- (a) the use of any gametes of any person, if that person's consent is required under paragraph 65 of Schedule 3 to this Act for the use in question,
 - (b) the use of any embryo the creation of which was brought about *in vitro*, or
 - (c) the use of any embryo taken from a woman, if the consent of the woman from whom it was taken is required under paragraph 7 of that Schedule for the use in question,
- unless the woman being treated and, where she is being treated together with a man, the man have been given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and have been provided with such relevant information as is proper.

Schedule 3

Paragraph 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 below.

Paragraph 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 or embryo to which the consent is relevant.
- (2) 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, or
 - (b) for the purposes of any project of research.

- 2.18 Treatment centres are expected to provide a private and comfortable room for counselling which ensures confidentiality.
- 2.19 Centres are expected to maintain good relationships with independent counselling organisations so that those considering donation and seeking treatment may be given the maximum assistance in obtaining appropriate counselling, in addition, or as an alternative, to the resources available at the centre itself.
- 2.20 Centres are expected to maintain up-to-date lists of different types of locally available and accessible counselling and local and national organisations that can provide relevant information, and make those lists available to those seeking counselling outside the treatment centre.
- 2.21 Centres are expected to designate a responsible individual who will ensure that the counselling facilities accord with the expectations of counselling services outlined in Parts 1, 7 and 13 of this *Code of Practice*.

Secure Storage For Gametes And Embryos

- 2.22 Centres are expected to provide secure, controlled access storage facilities for gametes and embryos. (Detailed guidance on storage of gametes and embryos is provided in Part 9 of this *Code of Practice*.)

Adverse Incidents

- 2.23 Each treatment centre is expected to have a written policy and procedure for dealing with adverse incidents. Centres must report all adverse incidents occurring at the treatment centre to the HFEA by telephone within 12 working hours of the identification of the incident and submit an Incident Report Form within 24 working hours.
- 2.24 Adverse incidents are defined as any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos and/or gametes, or to staff or a licensed centre.
- 2.25 All breaches of the HFE Act and/or breaches of the HFEA *Code of Practice* must be reported as adverse incidents to the HFEA. The HFEA will also investigate patient complaints that relate to adverse incidents. [See also Part 13.]

2.26 Where an adverse incident has occurred, centres are expected to:

- (i) Review relevant procedures in order to minimise the risk of any reoccurrence of the incident
and
- (ii) Inform the HFEA of the revised procedures

Maintaining And Improving Standards

- 2.27 Centres are expected to establish an effective system for monitoring and assessing laboratory, clinical and counselling practice, and are expected to be able to demonstrate that procedures and outcomes are satisfactory, judged by the highest standards of professional colleagues in relevant disciplines elsewhere. This monitoring system is expected to include an opportunity for feedback from people seeking treatment, people considering donation and people seeking storage of gametes and embryos.
- 2.28 Centres are expected to establish procedures for improving and updating laboratory, clinical and counselling practice in order to comply with paragraph 2.26 above.

Advertising

- 2.29 Centres may wish to circulate information about the variety of treatments they offer. Publicity materials are expected to conform to the general principles set out in the guidelines of the General Medical Council and the Code of Professional Conduct of the Nursing and Midwifery Council. Publicity materials are expected to also be designed and written with regard to the particularly sensitive issues involved in recruiting donors.

Such advertisements are expected to conform with the requirements of the British Advertising Standards Authority. (Included data is expected to comply with instructions in Part 5 of this *Code of Practice*.)

Professional Standards

- 2.30 This *Code of Practice* sets out the minimum standards which the HFEA expects licensed treatment centres to meet and which are expected to be demonstrated at the times of HFEA inspections of treatment centres. Some specialised organisations produce professional standards which relate to their specific areas of expertise (see Appendix F).

Part 3 – Welfare Of The Child And The Assessment Of Those Seeking Treatment

General Obligations

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 13

- (1) The following shall be conditions of every licence under paragraph 1 of Schedule 2 to this Act ...
- (5) A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for a father) and of any other child who may be affected by the birth.

- 3.1 When considering the treatment of any woman, treatment centres must take into account the welfare of the child that may be born as a result of treatment. Treatment centres are expected to also consider the welfare of any children the woman may already have responsibility for and the effect that treatment could have on these children. Treatment centre staff are expected to be aware of the need to show both care and sensitivity in this decision making process. Consideration is expected to be taken regarding the wishes and needs of those seeking treatment and the needs of any children involved.
- 3.2 Treatment centres are expected to take reasonable steps to ensure:
 - (i) The safety of those seeking treatment
and
 - (ii) The protection of any resulting or affected child or children
- 3.3 Treatment centres are expected to ensure that they have clear written criteria for assessing the welfare of any child or children which may be born or which may be affected by the birth of such child or children. Those criteria are expected to include the importance of a stable and supportive environment for any and all children who are part of an existing or prospective family group.

- 3.4 Best practice is expected to include an assessment of the welfare of the child upon first contact for licensed treatment with the prospective patients. If there is a delay before treatment takes place, treatment centres are expected to establish that no changes of circumstances have occurred since the original assessment of the welfare of the child before proceeding with treatment.
- 3.5 Treatment centres are expected to repeat the welfare of the child assessment where there has been:
- (i) A gap of two years or more in contact between the clinic and the patient(s)
or
 - (ii) A change of partner
or
 - (iii) A child born to the patient(s) since the previous assessment
or
 - (iv) A significant change in the prospective patient's medical or social circumstances
- 3.6 Treatment centres are expected to take all reasonable steps to verify the identity of those seeking treatment. This might be achieved through information from both partners' GP. However, if consent to this disclosure of information from both partners' GP is not given, or the patient(s) are from abroad, the patient is expected to be required to provide additional confirmation of identity e.g. birth certificate, passport.
- 3.7 Women over 35 and men over 45 are expected – like all patients – to be offered clinical advice and counselling at the outset. Advice and counselling is expected to focus on the implications of age for success in treatment. Gametes of patients in these age groups are expected to be used only for their own or their partner's treatment.
- 3.8 Gametes for use in treatment may only be taken from patients under the age of 18 in the following exceptional circumstances:
- (i) If it is the intention to use such gametes for the patient's own treatment or for the use of the patient's partner
and
 - (ii) If the centre is able to satisfy itself that the patient is capable of giving and actually gives effective consent to the use or storage of those gametes
- 3.9 Sperm to be used for the purposes of research may be taken from a male under the age of 18 only if the centre is able to satisfy itself that the donor is capable of giving, and actually gives, effective consent to such use.
- 3.10 It is expected that eggs shall not to be taken from a female under the age of 18 for the purposes of storage or licensed research without informing the HFEA.

Welfare Of The Child

3.11 Treatment centres are expected to:

- (i) Take reasonable steps to determine who will have parental responsibility for the child or children which may be born as a result of treatment and
- (ii) Take reasonable steps to determine the person or persons responsible for raising such child or children and
- (iii) Take particular care where the child is to be raised in another country and where the law may be different from that in this jurisdiction. In such cases patients are expected to have counselling on the implications for the potential child and all others who could be affected (particularly when using donated gametes) especially if the treatment requested is considered illegal in the country of origin

3.12 Those seeking treatment are entitled to a fair assessment. Treatment centres are expected to conduct the assessment with skill and care, and have regard to the wishes and sensitivities of all those involved. This assessment is expected to take into account the following factors relating to patients:

- (i) The commitment to raise children
- (ii) The ability to provide a stable and supportive environment for a child/children
- (iii) Immediate and family medical histories
- (iv) The age, health and ability to provide for the needs of a child/children
- (v) The risk of harm to children including:
 - (a) inherited disorders or transmissible disease
 - (b) multiple births
 - (c) problems arising during pregnancy
 - (d) neglect or abuse
 - (e) the effect of a new baby or babies upon any existing child of the family

3.13 Where donated gametes are used, treatment centres are expected to take into account the following additional factors:

- (i) A child's potential need to know about their origins and whether or not the prospective parents are prepared for the questions which may arise while the child is growing up
- (ii) Family attitudes towards such a child
- (iii) Implications which may arise if the donor is known within the child's family or social circle
- (iv) The possibility of disputed fatherhood

Other Issues To Be Taken Into Account

- 3.14 **Where the child will have no legal father** the treatment centre is expected to assess the prospective mother's ability to meet the child's/children's needs and the ability of other persons within the family or social circle willing to share responsibility for those needs.
- 3.15 **Where the couple are not married** couples are expected to be advised that their legal position as parents, whether or not donated gametes are used, may require legal advice in order for full parental responsibility to be achieved.

Surrogate Pregnancy²

- 3.16 **Where the child will not be raised by the carrying mother** all involved parties are expected to be made aware that the child's legal parent will be the carrying mother (and in certain circumstances could be her husband or partner) unless relevant court proceedings are carried out. Treatment centres are expected to – where possible – assess the possibility of a dispute in such circumstances and the effect upon the child, and the effect of any proposed arrangement upon a child or children of the family of the carrying mother or commissioning parents.
- 3.17 Treatment centres are expected to consider the use of assisted conception techniques to produce a surrogate pregnancy only where the commissioning mother is unable for physical or other medical reasons to carry a child or where her health may be impaired by doing so.

Selection Of Donated Gametes

- 3.18 Where treatment is provided for a man and woman together, treatment centres are expected to strive as far as possible to match the physical characteristics and ethnic background of the donor to those of the infertile partner, or in the case of embryo donation, to both partners, unless there are good reasons for departing from this procedure.
- 3.19 When discussing the selection of potential donors, treatment centres are expected to be sensitive to the wishes of those seeking treatment for information, whilst avoiding the possibility that this information could be used to select a donor possessing certain

² The attention of treatment centres is drawn to the Parental Orders (Human Fertilisation and Embryology) Regulations 1994 and (in Scotland) the Parental Orders (Human Fertilisation and Embryology) (Scotland) Regulations, which provide that parental rights and obligations in respect of surrogacy arrangements may be transferred from the birth parents to the commissioning parents. Appendix D of this Code of Practice sets out the conditions which must be fulfilled before an application may be made, and also contains information about birth registration in these circumstances.

characteristics for reasons that are incompatible with or not relevant to the welfare of the child. For example, those seeking treatment are expected not to be treated with gametes provided by a donor of different physical characteristics unless there are compelling reasons for doing so. Those seeking treatment with donated gametes (or embryos) are expected to be advised that no guarantees can be given where an attempt is made to match physical characteristics.

Enquiries To Be Made

3.20 In their assessment of prospective patients, treatment centres are expected to:

- (i) Take medical and social histories from each prospective parent and see each couple together and separately
- (ii) Obtain the patients' consent to make enquiries of each of their GPs. Refusal by the patients, or either of them, to give such consent is a factor to be taken into consideration in the decision to provide treatment. In such circumstances, the treatment centre is expected to ask the patient's reason for the refusal and record the answer in the patient's medical records. In the absence of such consent, treatment centres are expected to seek to establish the identity of the patient(s) by appropriate evidence e.g. passport, photocard driving licence and birth certificate
- (iii) Once the relevant consents have been received from the prospective patients, ask the GP of both partners if he/she knows of any reason why the patient(s) might not be suitable for treatment and if he/she knows of anything which might adversely affect the welfare of any resulting child
- (iv) Where unsatisfactory responses or no responses to enquiries are received, obtain the further consent from the prospective patient(s) to approach any individuals, agencies or authorities for such further information as the centre deems to be required for a satisfactory assessment. (A response may be deemed to be unsatisfactory, for example, where prospective parents have had children removed from their care or committed a relevant criminal offence.) Refusal by the prospective parents or either of them to give such consent is a factor to be taken into consideration in the decision whether or not to provide treatment

Multidisciplinary Assessment

- 3.21 In deciding whether to provide treatment, treatment centres are expected to take into account views from the staff who have had involvement with the prospective patients. Those seeking treatment are expected to be given the opportunity to respond to adverse comments and objections before a final decision is made.
- 3.22 Where adverse information has been provided in confidence to a member of staff at the treatment centre, consent is expected to be sought from the information provider to discuss it

with other members of staff. Where such consent is refused but the member of staff considers the matter as crucial to the decision to be taken, treatment centres are expected to use their discretion based upon good professional practice before breaking that confidence.

3.23 Treatment centres are expected to base their decision to refuse to provide treatment upon all available information. Treatment may be refused if the treatment centre concludes:

- (i) That it would not be in the interests of any resulting child
or
- (ii) That it would not be in the interests of any other child
or
- (iii) That it is unable to obtain sufficient information or advice upon which to base a proper assessment
or
- (iv) That, having regard to all the circumstances, it is inappropriate to offer such treatment

3.24 Where treatment is refused treatment centres are expected to:

- (i) Explain the reasons for such refusal to the woman and – where appropriate – her partner, together with any circumstances which may cause the treatment centre to reconsider its decision
and
- (ii) Explain any remaining options
and
- (iii) Explain opportunities for obtaining appropriate counselling

Written Record In Respect Of The Welfare Of The Child

3.25 Treatment centres are expected to record in writing information that has been considered in respect of the welfare of the child. This record is expected to reflect the views of those who were consulted in reaching the decision and the views of those seeking treatment.

Additional Information For Those Seeking Long Term Storage Of Gametes And Embryos

3.26 Centres are expected to seek to obtain the clients' consent to approach the GPs of each partner. Failure to give such consent is expected to be taken into account in the decision whether or not to store or accept gametes or embryos for treatment or research.

3.27 Where such consent is given, centres are expected to ask the GP(s) if they have information relevant to the storage of such gametes or embryos which they are prepared to disclose to the HFEA.

Additional Information For Those Seeking An Egg Sharing Arrangement

3.28 In addition to considering the general advice given above (paragraphs 3.1 – 3.10), treatment centres are expected to have clear written procedures for welfare of the child assessments in respect of:

- (i) The egg provider
- (ii) The egg recipient(s)
- (iii) The partners of the egg provider and the egg recipient

3.29 Treatment centres are expected to ensure that:

- (i) Care is taken in the selection of egg providers in egg sharing arrangements and
- (ii) Egg providers are fully assessed and medically suitable and
- (iii) The treatment offered is the most suitable available to satisfy the needs of the egg provider and recipient(s)

3.30 Treatment centres are expected to offer counselling to egg providers and recipients and to the partners of women donating and receiving eggs and any other individuals directly affected. There is expected to be the opportunity for the donor to receive counselling from a different counsellor from the one providing counselling to the recipient.

3.31 Treatment centres are expected to provide any additional impartial support (e.g. a member of the nursing staff not involved in the treatment of either donor or recipient) to all parties during the egg sharing cycle.

Part 4 – Assessing And Screening Potential Donors

General Standards

- 4.1 Where individuals are considering donation, from the outset treatment centres are expected to:
- (i) Ensure that those individuals considering donation understand which tests must be carried out and why they are necessary
and
 - (ii) Inform these individuals that the tests may reveal previously unsuspected conditions, including low sperm counts, genetic anomalies and HIV infection
and
 - (iii) Enquire of these individuals whether they have previously provided gametes at a different treatment centre, and if so, establish that the limit of 10 live birth events per donor will not be exceeded (see also paragraph 8.30).
and
 - (iv) Inform them that they can withdraw from the process of donation at any time until embryos or gametes have been used in treatment
and
 - (v) Ensure that no pressure or undue influence is applied to donate sperm, eggs or embryos by clinic staff, friends or relatives
and
 - (vi) Give full, up-to-date advice on the position of the HFEA Register regarding circumstances under which donors' information, both identifying and non-identifying, might be disclosed
and
 - (vii) Ensure that any donor and their partner are given the opportunity to be seen by an independent counsellor to explore the implications of donation for all concerned.

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 12

The following shall be conditions of every licence granted under this Act –

- (e) that no money or other benefit shall be given or received in respect of any supply of gametes or embryos unless authorised by directions.

- 4.2 Payments or benefits may be provided in exchange for gametes or embryos only in accordance with Directions made by the HFEA (see 4.26 below). These include those payments or benefits which, to the knowledge of the treatment centre, have been made to an agency or other intermediary.
- 4.3 Reasonable expenses incurred by an egg donor who becomes ill as a direct result of donating, may also be reimbursed by the treatment centre.

Family And Other Relevant History

- 4.4 Before gametes are provided, medical and family histories are expected to be taken and are expected to include details of previous donations. Donors are also expected to be encouraged to provide as much other non-identifying biographical information as possible, so that it may be available to prospective parents and resulting children. If a donor cannot give a full and accurate family history, treatment centres are expected to record this fact.
- 4.5 Treatment centres are expected to, wherever possible, ask prospective donors' GPs if they know of any reason why the prospective donor should not donate for the treatment of others. Failure to obtain relevant information is expected to be taken into account when deciding whether or not to accept gametes or embryos for treatment.
- 4.6 Before approaching the relevant GP, treatment centres are expected to obtain the donor's consent. Failure to give such consent or obtain relevant information is expected to be taken into account in deciding whether or not to accept gametes or embryos for treatment.
- 4.7 Where consent to approach the GP is refused, treatment centres are expected to consider asking for proof of identification in the form of a birth certificate, passport or similar documentation. Failure to provide satisfactory evidence of identification is expected to be taken into account in deciding whether or not to accept gametes or embryos for treatment.

Suitability As Donors

- 4.8 Before accepting gametes for the treatment of others, treatment centres are expected to consider the suitability of the intending donor. All potential donors must be given suitable opportunities to receive counselling. Where this involves embryos the counselling is expected to be offered to both partners of the donating couple. The views of all treatment centre personnel involved with the prospective donor are expected to be taken into account. In particular, treatment centres are expected to consider:

- (i) Personal or family history of heritable disorders
and
- (ii) Personal history of transmissible infection
and
- (iii) The level of potential fertility indicated by semen analysis (where appropriate)
and
- (iv) If the prospective donor has children, the implications for the prospective donor in respect of the donation for themselves and their existing families and any offspring born of their donation both in the short and longer term
and
- (v) If the prospective donor does not have children, the implications for themselves and any future family

Potential Donors Undergoing Treatment

- 4.9 It is expected that the possibility of donating gametes should be raised before and not during a potential donor's treatment cycle. It is expected to be raised by the counsellor rather than by anyone directly involved in that person's treatment. There must be no pressure or undue influence on a patient to donate supernumerary gametes or embryos. It is expected that counselling should be offered in all cases.

Scientific Tests

- 4.10 It is expected that all reasonable steps should be taken to prevent the transmission of serious genetic disorders. This will usually be served by taking a thorough history from the prospective donor.
- 4.11 It is expected that genetic testing should be limited to the determination of carrier status for inherited recessive disorders in which abnormal test results carry no significant direct health implications for the prospective donor.
- 4.12 Centres are expected to ensure that where prospective donors are genetically tested, they have the same level of support and counselling as recipients. They are expected to be informed of the test results and offered post test counselling as applicable.
- 4.13 **Cystic Fibrosis.** Normally, treatment centres are expected to screen prospective donors especially if they emanate from a population group which contains a high frequency of cystic fibrosis carriers. Where a treatment centre uses unscreened donors it is expected to inform the patient concerned and offer screening and counselling. Where a treatment centre uses screened donors, it is expected to caution the patient about the limits of the test and the likelihood that a screened donor could be a cystic fibrosis carrier. In exceptional circumstances (e.g. difficulty in replacing a donor) treatment centres may use a cystic fibrosis positive donor. In such

circumstances, the patient is expected to be made aware of the risks associated with this practice and offered relevant screening and counselling.

- 4.14 **Tay-Sachs, Thalassaemia and Sickle Cell anaemia.** It is expected that screening should be carried out in appropriate population groups.
- 4.15 **HIV testing.** The minimum procedure to be adopted is expected to be that set out in the HFEA and Department of Health's HIV Screening For People Providing Gametes And/Or Embryos For Donation guide (see Appendix C).
- 4.16 **Cytomegalovirus (CMV) antibodies.** Treatment centres are expected to screen all those considering such donation for cytomegalovirus antibodies. Wherever possible, treatment centres are expected to use CMV seronegative donors, and are expected to ensure that gametes from those who are CMV seropositive are used only for CMV seropositive recipients. Only those seropositive prospective donors who are unlikely to have an active infection (IgG positive and IgM negative) are expected to be used. Gametes from a seronegative potential donor who seroconverts during the course of donation must not be used for treatment services.
- 4.17 Testing of potential donors for other infections is expected to (for sperm) follow the British Andrology Society guidelines and (for eggs and embryos) the British Fertility Society guidelines (see Appendix F).
- 4.18 It is essential that all recipients of gamete donations receive information explaining the limitations of testing procedures and the risks associated with treatment. If any concerns are raised appropriate counselling is expected to be made available.
- 4.19 Centres are expected to re-screen people considering donation where appropriate, and adopt any other test which may come to be regarded as a matter of good practice by the standards of professional colleagues in relevant specialities or may be indicated in a particular case while this *Code* is in force.
- 4.20 Where an embryo is donated for clinical treatment, each donating party is expected to undergo full screening as recommended for potential gamete donors (see paragraphs 4.10 – 4.19 above).
- 4.21 Gamete providers in surrogacy arrangements are expected to be screened in accordance with the usual requirements for potential donors. The screening is expected to comply with the advice given in paragraphs 4.10 – 4.20 above and that are set out in Appendix C of this *Code of Practice*.

Age Of People Considering Donation

- 4.22 Unless there are exceptional reasons for doing so, it is expected that sperm should not be taken for the treatment of others from donors over the age of 45. Such exceptional reasons are expected to be explained in the treatment records.
- 4.23 Unless there are exceptional reasons for doing so, it is expected that eggs should not be taken for the treatment of others from donors over the age of 35. Such exceptional reasons are expected to be explained in the treatment records.
- 4.24 It is expected that gametes for the treatment of others shall not be taken from anyone under the age of 18.
- 4.25 Where gametes are used to produce embryos specifically for donation, or embryos are donated following licensed fertility treatment, treatment centres are expected to follow the age limits that exist for gamete donors – 35 for egg donors and 45 for sperm donors – unless there are exceptional reasons for not doing so. If there are exceptional reasons, these are expected to be explained in the treatment records.

Payment And Expenses For People Providing Gametes For Donation

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 12

The following shall be conditions of every licence granted under this Act –

- (i) that no money or other benefit shall be given or received in respect of any supply of gametes or embryos unless authorised by directions.

- 4.26 Gamete donors must be paid no more than £15 for each donation plus reasonable expenses in accordance with HFEA Directions (see guidance in Appendix G).

People Unsuitable As Donors

- 4.27 Where a treatment centre decides that a potential donor is unsuitable for donation, it is expected to record the reasons and also explain these to the individual concerned. The reasoning behind the treatment centre's decision should be presented to the relevant individual sensitively and any questions answered in a straightforward and comprehensive manner.

- 4.28 It is expected that counselling should be offered to all potential donors who are deemed to be unsuitable for any reason. Where a treatment centre refuses to accept a potential gamete donor because of physical or psychological problems that require separate treatment or specialist counselling, the treatment centre is expected to provide reasonable assistance to the individual in obtaining relevant treatment or counselling.
- 4.29 Where information affecting the suitability of a potential donor becomes known after the selection process is complete, the treatment centre is expected to review the potential donor's suitability and take appropriate action.
- 4.30 Where a treatment centre learns that a gamete donor has a previously unsuspected genetic disease or is the carrier of a deleterious recessively inherited condition (e.g. through the birth of a baby with cystic fibrosis), the treatment centre is expected to:
- (i) Notify the supplying centre and the HFEA immediately. (The supplying centre is expected to notify other centres of the carrier status of the gamete donor) and
 - (ii) Consider notifying the gamete donor of their condition, and where the gamete donor has been informed of their condition, offer counselling and testing and
 - (iii) Inform patients who have received treatment using those donor gametes where the treatment has resulted in a live birth, and offer these patients counselling and
 - (iv) Where a woman is pregnant as a result of treatment with those donor gametes, carefully consider when and how the woman should be given this information
- 4.31 Centres are expected to advise gamete donors that where, subsequent to a donation being made, the donor discovers they are affected by a previously unsuspected genetic disease or finds they are a carrier of a deleterious recessively inherited condition (e.g. through the birth of a baby with cystic fibrosis), they are expected to inform the centre which accepted the donation as soon as possible. The centre is expected to then proceed as in paragraph 4.28 above.

People Involved In An Egg Sharing Arrangement

- 4.32 It is expected that egg providers shall be treated in the same way as other potential gamete donors (see paragraphs 4.10 – 4.18 above and Appendix C).
- 4.33 It is expected that egg providers and recipients shall be made aware, prior to consent, of the screening that will be undertaken before treatment is commenced.

Part 5 – Information

General Obligations

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 13

(6) A woman shall not be provided with any treatment services involving –

- (a) the use of any gametes of any person, if that person's consent is required under paragraph 5 of Schedule 3 to this Act for the use in question,
- (b) the use of any embryo the creation of which was brought about *in vitro*, or
- (c) the use of any embryo taken from a woman, if the consent of the woman from whom it was taken is required under paragraph 7 of that Schedule for the use in question,

unless the woman being treated and, where she is being treated together with a man, the man have been given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and have been provided with such relevant information as is proper.

Schedule 3, Paragraph 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.

5.1 Before anyone is given licensed treatment (i.e. *in vitro* fertilisation or treatment using donated gametes) or consents to the use or storage of embryos or to the donation or storage of gametes, they must be given “such relevant information as is proper”. This is expected to be distinguished from the requirement to offer counselling, which people who are seeking treatment, providing gametes/embryos for donation or wishing to store their gametes/embryos need not accept.

5.2 Where individuals are providing gametes or embryos for donation, or wish to store their gametes or embryos, it is expected that they will be given oral explanations about the **medical**,

scientific, legal, and psychosocial implications of their decision. It is expected that relevant written materials will be given to ensure that they know about all the implications of their decisions and therefore make an informed choice. In addition, they are expected to be informed of the procedures adopted in the relevant treatment centre for handling, storing, managing and using the gametes and embryos. It is expected that these individuals will be encouraged to seek any further information that they may need, and all their questions should be answered in as straightforward and comprehensive a way as possible.

- 5.3 Treatment centres are expected to be able to provide all relevant and correct information to these individuals, and have a clearly identified point of contact for this information. It is expected that this information provider will have been given appropriate guidance and training. It is expected that a written record of all information provided to patients will be kept by treatment centres.
- 5.4 It is expected that information will be given to every individual consenting to treatment and/or storage about the following:
- (i) The availability of counselling
and
 - (ii) The option to vary or withdraw the terms of consent at any time up to the point where the gametes or embryos have been used in treatment or in research projects including, in the case of embryos, the consequences of variation or withdrawal of consent by either gamete provider where the wishes of gamete providers, or where she is not one of these people, those of either gamete provider and the woman to be treated, do not coincide
and
 - (iii) The actual procedure used to collect gametes including description of possible discomfort, pain and risk to the individual in this procedure, including, for example, use of superovulatory drugs
and
 - (iv) The possible deterioration or loss of viability of gametes or embryos as a consequence of storage
and
 - (v) Costs, fees or reimbursements relevant to treatment, counselling, donation or storage or gametes or embryos
and
 - (vi) Regulations relating to statutory storage periods for gametes and embryos, and regulations relating to extension of storage times including, in the case of embryos, the requirement for the consent of both gamete providers to any extension of storage periods
and
 - (vii) Options available in the event of death or mental incapacity of them and/or of a donor and the consent required to fulfil individual's wishes

Additional Information

- 5.5 It is expected that information will also be given to individuals seeking treatment about the following:
- (i) The centre's policy on selecting patients
and
 - (ii) The waiting time for treatment and the possible disruption of the individual's domestic/personal/professional life which may be caused by treatment
and
 - (iii) Other available infertility treatments including those for which a licence is unnecessary
and
 - (iv) Possible variations, outcomes and limitations of the proposed treatment (data provided in all relevant patient resources are expected to be the centre's own most recent live birth rate per treatment cycle as verified by the HFEA, and the national live birth rate per treatment cycle)
and
 - (v) The possible side effects and risks in treatment to the woman and any resulting child, including ovarian stimulation, ovarian hyperstimulation syndrome (OHSS) and the putative risk of cancer
and
 - (vi) The risks to the woman and fetus associated with multiple pregnancy, including:
 - (a) the level of increased risk of miscarriage and complications such as raised blood pressure
and
 - (b) the higher incidence of premature birth that is associated with multiple pregnancies, including reference to the problems of low birth weight, increased still birth and perinatal mortality
and
 - (c) the increased incidence of disability and other health problems associated with multiple pregnancy, as well as the potential need for extended stays in hospital both before and after birth
and
 - (d) the possible practical, financial and emotional impact of a multiple birth on the family unit and the individual children
and
 - (vii) The treatment centre's statutory duty to take account of the welfare of any resulting or affected child
and
 - (viii) The advantages and disadvantages of continued treatment after failed attempts
and

- (ix) The availability of embryo freezing facilities and:
 - (a) the likelihood of success with embryo freezing, thawing and transfer
 - (b) the implications of storage (including the possible deterioration or loss of viability of gametes or embryos as a consequence of storage and the potential risk of cross contamination between samples)and
- (x) The importance of informing the treatment centre about any resulting birth

Information Relating To The Donation Of Gametes

Information for those receiving treatment with donor gametes/embryos.

- 5.6 If the treatment involves the donation of gametes, individuals seeking treatment are expected to receive information about genetic and other screening which people providing gametes undergo at that treatment centre. This information is expected to include details about:
- (i) The sensitivity of the tests to be carried out
and
 - (ii) The possibility that a screened provider of gametes may be a carrier of a genetic disease or infection
and
 - (iii) The availability of genetic screening (especially if the people providing gametes at the centre are not screened for cystic fibrosis)
and
 - (iv) Who will be the child's legal parent(s) under the HFE Act and other relevant legislation (see also paragraph 3.14 & 6.33). Nationals or residents of other countries, or individuals treated with gametes obtained from foreign donors, are expected to be informed that the law in other countries may be different from that in the United Kingdom
and
 - (v) Information which centres must collect and register with the HFEA in respect of the donors and the extent to which that information may be disclosed to people born as a result of donation
and
 - (vi) A child's potential need to know about its origins
and
 - (vii) A child's right to seek information about its origins upon reaching the age of 18 years or, if contemplating earlier marriage, 16 years

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 31

- (1) The Authority shall keep a register which shall contain any information obtained by the Authority which falls within subsection (2) below.
- (2) Information falls within this subsection if it relates to –
 - (a) the provision of treatment services for any identifiable individual, or
 - (b) the keeping or use of the gametes of any identifiable individual or of an embryo taken from any identifiable woman,

or if it shows that any identifiable individual was, or may have been, born in consequence of treatment services.
- (3) A person who has attained the age of eighteen (“the applicant”) may by notice to the Authority require the Authority to comply with a request under subsection (4) below, and the Authority shall do so if –
 - (i) the information contained in the register shows that the applicant was, or may have been, born in consequence of treatment services, and
 - (ii) the applicant has been given suitable opportunity to receive proper counselling about the implications of compliance with the request.
- (4) 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 other than a parent of the applicant would or might, but for sections 27 to 29 of this Act, be a parent of the applicant and, if it does show that –
 - (i) giving the applicant so much of that information as relates to the person concerned as the Authority is required by regulations to give (but no other information), or
 - (ii) stating whether or not that information shows that, but for sections 27 to 29 of this Act, the applicant, and a person specified in the request as a person whom the applicant proposes to marry, would or might be related.
- (5) Regulations cannot require the Authority to give any information as to the identity of a person whose gametes have been used or from whom an embryo has been taken if a person to whom a licence applied was provided with the information at a time when the Authority could not have been required to give information of the kind in question.
- (6) A person who has not attained the age of eighteen (“the minor”) may by notice to the Authority specifying another person (“the intended spouse”) as a person whom the minor

proposes to marry require the Authority to comply with a request under subsection (7) below, and the Authority shall do so if –

- (i) the information contained in the register shows that the minor was, or may have been, born in consequence of treatment services, and
 - (ii) the minor has been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.
- (7) The minor may request the Authority to give the minor notice stating whether or not the information contained in the register shows that, but for sections 27 to 29 of this Act, the minor and the intended spouse would or might be related.

5.7 Centres are expected to give additional information to individuals who consent to the donation or storage of embryos or to the donation or storage of gametes on the following points:

- (i) The screening to be undertaken including the practical implications of an HIV antibody test
and
- (ii) The scope and limitations of genetic testing which will be carried out together with the implications for the potential donor and his or her family
and
- (iii) Whether or not they will be regarded under the HFE Act as parents of any child born as a result of their donation (see also paragraph 6.35)
and
- (iv) That gametes and embryos so donated will not normally be used for treatment when the number of live birth events which have occurred as a result thereof has reached 10 (or such lower figure as is specified by the donor)
and
- (v) That the HFE Act generally permits donors to preserve their anonymity
and
- (vi) The information which centres must collect in respect of donors and register with the HFEA and the extent to which this information may be disclosed to people born as a result of the donation (see also Section 31 of the HFE Act above)
and
- (vii) The possibility that a child born disabled as a result of a donor's failure to disclose defects, about which the donor knew or ought reasonably to have known, may be able to sue the donor for damages
and
- (viii) Where the woman is not undergoing infertility treatment herself, and where she makes an altruistic egg donation, that the woman will not incur any financial or other penalty if she withdraws her consent after preparation for egg recovery has begun

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 35

- (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 sections 27 to 29 of this Act, 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 sections 27 to 29 of this Act, 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.
- (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 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.”

Human Fertilisation and Embryology Act 1990, Schedule 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 below.

Schedule 3, Paragraph 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 or embryo to which the consent is relevant.

- (2) 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, or
 - (b) for the purposes of any project of research.

Information For Research Donors

5.8 People consenting to the use of gametes or embryos for the purposes of a research project may specify conditions subject to which the gametes or embryos may be so used and are expected to be given the following information:

- (i) Research is experimental and any gametes and embryos used and created for the purposes of any project of research will not be transferred for treatment
and
- (ii) Only those fresh or frozen gametes and embryos that are surplus to treatment will be used for research
and
- (iii) Research will not affect the treatment cycle
and
- (iv) The donation of gametes or embryos for research will not compromise treatment
and
- (v) They are under no obligation to donate gametes and embryos for research
and
- (vi) They have the right to vary or withdraw their consent from any project of research at any time up until the gametes and embryos are used for the purposes of such research project
and
- (vii) They are expected to have an opportunity to ask questions and discuss the research project
and
- (viii) After the research has been completed, all donated gametes and embryos will be allowed to perish

5.9 If donated gametes and embryos could be used in secondary research, those consenting are expected to be so informed and given the following further information:

- (i) The possibility that gametes and embryos, or embryo cell samples, may be fixed for future studies and that such research is called secondary research

- and
 - (ii) Secondary research could include genetic research (and the resulting implications)
and
 - (iii) As a means of protecting confidentiality, gametes and embryos for secondary research may be anonymised but that this may be reversible
and
 - (iv) If gametes and embryos are to be reversibly anonymised and if genetic research were to be proposed, those considering donation are expected to be offered counselling about the implications
and
 - (v) If gametes and embryos were to be irreversibly anonymised, those considering donation are expected to be fully informed of the implications, that is to say, the inability to feed results back
and
 - (vi) If embryos are to be used for stem cell research, it is expected that those considering donation are given thorough and appropriate information, including that any stem cells lines created may continue indefinitely and may be used in different research projects
- 5.10 Where any genetic research is to be carried out on identifiable samples, or those capable of being identified, it is expected that explicit consent will be obtained. This should be preceded by information about the research project and what, if any, information may be fed back to the donor.

People Seeking Long Term Storage Of Gametes And Embryos

- 5.11 Treatment centres are expected to produce specific information tailored to the needs and circumstances of oncology patients and other patients requiring long-term storage, including specific information appropriate to minors, and, as a minimum, the requirements listed in paragraphs 5.1 – 5.6 above.

People Involved In An Egg Sharing Arrangement

- 5.12 As well as fulfilling requirements contained in paragraphs 5.1-5.4 above, it is expected that egg providers and egg recipients will be provided with separate written information which is expected to include:
- (i) Criteria used for the selection of women donating and receiving eggs in egg sharing arrangements
and
 - (ii) The centre's procedures for determining how eggs will be shared between provider and recipient(s)

and

(iii) The screening that women donating eggs will be required to undergo

and

(iv) The terms of the agreement to be entered into

and

(v) The law relating to consent and the rights of the women donating to vary or withdraw her consent. Implications which may result from the withdrawal of consent is expected to be made clear to the parties before treatment is commenced

and

(vi) Available alternative treatment options

5.13 It is expected that women receiving eggs will receive the same information as other people seeking treatment with donated gametes outlined in paragraphs 5.5 and 5.6 above.

5.14 It is expected that women donating eggs will be given the information outlined in paragraph 5.7 above.

Part 6 – Consent

Consent To Examination And Treatment

- 6.1 All people generally have the right to withhold or give consent to examination and treatment³. General guidance on this matter is given in the Department of Health's:
- (i) Good Practice in Consent implementation Guide: consent to examination or treatment
 - (ii) Reference Guide to Consent for Examination or Treatment
 - (iii) The RCOG's "Gynaecological examinations: Guidelines for Specialist Practice" (July 2002)
and
 - (iv) The GMC's "Seeking patient's consent: the ethical considerations" (1998).
- 6.2 Unless there are exceptional circumstances, treatment centres may not examine or treat people without first obtaining their consent. The only exceptional circumstances which are likely to arise in the course of infertility treatment services are:
- (i) Where the procedure is necessary to save the patient's life
and
 - (ii) The treatment cannot be postponed
and
 - (iii) The patient is unconscious or mentally incapacitated and cannot indicate their wishes
- 6.3 For consent to be valid it must be:
- (i) Given voluntarily (without pressure or undue influence being exerted to accept treatment)
 - (ii) By a person who has capacity to consent to such treatment
and

³ It is a general principle of our common law that every person's body is inviolate (Per Lord Goff in *Re F (a mental patient: sterilisation)* [1990] 2 AC 1. See also *Sidaway v Governors of Bethlem Royal Hospital* [1985] AC 871 and *Airedale NHS Trust v Bland* [1993] 1 AllER 821.

- (iii) Upon receipt of sufficient information to enable them to understand the nature, purpose and implications of the treatment

Treatment centres are expected to give patients sufficient time to consider this information before giving consent.

Consent To The Presence Of Observers

- 6.4 If a member of the treatment centre's team wishes an observer to be present when an individual is being examined, treated or counselled, they are expected to explain, preferably beforehand, who the observer is and why this is desirable. The centre is expected to provide appropriate information and ask the individual whether or not there is an objection. If the individual objects, the observer is expected not to attend.

General Obligations

- 6.5 Treatment centres have an obligation to take all reasonable steps to ensure the valid identity of all persons accepted for treatment, including male partners who might not often be seen in the centre during treatment. Where there is doubt about a patient's identity, this is expected to include the examination of photographic identification evidence such as photo card driving licences and passports. Centres are expected to document this evidence in the patient records.
- 6.6 To avoid the possibility of misrepresentation or mistake (e.g. where patients present for treatment with new partners) centres are expected to check the identities of patients against identifying information held in the patient's file.
- 6.7 Treatment centres are expected to allow individuals seeking treatment, considering donation or storage sufficient time to reflect upon their decisions before obtaining their written consent. It is expected that a copy of the signed consent form will be provided for those who have given consent.
- 6.8 Individuals may specify additional conditions subject to which their gametes or embryos may be stored or used. Consent may be varied or withdrawn at any time providing that the gametes and embryos have not already been used in treatment services or research.
- 6.9 Gametes must not be taken from anyone who is incapable of giving a valid consent, or has not given a valid consent to examination and treatment and effective consent to the use or storage of those gametes.

Consent By Children And Young People

- 6.10 Parents cannot consent on behalf of their children to any licensed procedures, including the storage of mature gametes.
- 6.11 The General Medical Council describes ‘Gillick Competence’ in its Seeking Patients’ Consent: The Ethical Considerations guidelines (otherwise referred to as the Fraser Guidelines). These guidelines state:
- “You must assess a child’s capacity to decide whether to consent or refuse proposed investigation or treatment before you provide it. In general, a competent child will be able to understand the nature, purpose and possible consequences of the proposed investigation or treatment, as well as the consequences of non-treatment.”
- 6.12 Treatment centres are expected to have written information which is accessible to children and young people, given by a member of staff with competence in communicating with children.

Mental Capacity

- 6.13 Treatment centres are also directed to Assessment of Mental Capacity (BMA, 1995). When in any doubt, treatment centres are expected to seek their own legal advice.

Consent To Storage

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Schedule 3

Paragraph 2(2):

A consent to the storage of any gametes or any embryo must –

- (a) specify the maximum period of storage (if less than the statutory storage period), and
- (b) state what is to be done with the gametes or embryo if the person who gave the consent dies or is unable because of incapacity to vary the terms of the consent or to revoke it,

and may specify conditions subject to which the gametes or embryo may remain in storage.

- 6.14 Individuals consenting to the storage of gametes or embryos must:
- (i) Specify the maximum period of storage (if less than the statutory storage period)

- (ii) State what is to be done with the stored gametes or embryos upon their own death or incapacity which renders them incapable of varying or revoking consent

Statutory Storage Period

- 6.15 The normal storage period for gametes is 10 years (see paragraphs 6.43 and 6.44 below for extension of the normal storage period).
- 6.16 Where sperm was in storage on 1 August 1991, storage may legally continue without the written consent of the individual who provided the sperm. However, there is no obligation upon a centre to continue to store sperm in the absence of a written agreement to do so.
- 6.17 The normal storage period for embryos is five years (see paragraphs 6.45 – 6.47 below for extension of the normal storage period).

Consent To Use

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Schedule 3

Paragraph 2(1)

A consent to the use of an 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, or
- (c) use for the purposes of any project of research,

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

- 6.18 Where there is an intention to create an embryo outside the body, each individual consenting to the use of the embryo produced from their gametes must specify one or more of the following purposes for which it/they may be used:
- (i) The provision of treatment for that individual or that individual and a named partner
 - (ii) The provision of treatment for others
 - (iii) Research
- 6.19 Where consent to the use of sperm was given before 1 August 1991, that consent must have been in writing and not subsequently withdrawn.

- 6.20 If consent has not been obtained either before or after 1 August 1991, the sperm must not be used unless and until such consent is obtained.
- 6.21 Where a gamete provider dies, the gametes and the embryos created by these gametes must not be used unless the gamete provider has given written consent to use after his or her death, and then the gametes or embryos can only be used for the purposes specified.

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Schedule 3

Paragraph 6(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 person whose gametes were used to bring about the creation of the embryo to the use for that purpose of the embryo and the embryo is used in accordance with those consents.

- 6.22 Where embryos which have been stored are to be used, the terms of the consent of the woman who produced the eggs must be compatible with the consent of the man who provided the sperm.

Consent To Export

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 24(4)

Directions may authorise any person to whom a licence applies to receive gametes or embryos from outside the United Kingdom or to send gametes or embryos outside the United Kingdom in such circumstances and subject to such conditions as may be specified in the directions, and directions made by virtue of this subsection may provide for sections 12 to 14 of this Act to have effect with such modifications as may be specified in the directions.

Direction 1991/8 Export Of Gametes

- 6.23 The specific consent of people providing gametes must be obtained for the export of those gametes or of embryos produced using them (see also paragraph 8.33).

Posthumous Use

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Schedule 3

Paragraph 2(2)

A consent to the storage of any gametes or any embryo must –

- (a) specify the maximum period of storage (if less than the statutory storage period), and
- (b) state what is to be done with the gametes or embryo if the person who gave the consent dies or is unable because of incapacity to vary the terms of the consent or to revoke it

and may specify conditions subject to which the gametes or embryo may remain in storage.

Paragraph 5(1)

A person's gametes must not be used for the purposes of treatment 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.

6.24 In order for a woman to use her deceased husband or partner's sperm for treatment, the man must have given consent to the posthumous use of his sperm for that purpose/treatment.

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 28(6)

Where –

- (a) the sperm of a man who had given such consent as is required by paragraph 5 of Schedule 3 to this Act was used for a purpose for which such consent was required, or
- (b) 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 to be treated as the father of the child.

6.25 Centres are expected to inform people seeking treatment that the HFE Act provides that where the sperm of a man is used for insemination, *in vitro* fertilisation or embryo transfer after his

death, he is not to be treated as the father of any child that results from the use of that sperm, except for the purpose of being recorded on the register of births as the father of the child subject to the requirements of the Human Fertilisation and Embryology (Deceased Fathers) Act 2003 being fulfilled and for no other purpose. The Human Fertilisation and Embryology (Deceased Fathers) Act 2003 also provides for a man in certain circumstances to be recorded as the father of a child resulting from treatment services provided to his wife or partner after his death, using embryos created before his death using donated sperm, provided he has consented in writing to being so recorded.

- 6.26 Where an embryo which has been produced using the egg of a woman who has since died is used in treatment, the egg provider is not to be regarded in law as the mother of any child that results from the use of that egg.
- 6.27 Where embryo donation is considered in circumstances of mental incapacity or death, each partner is expected to undergo – or have undergone – screening as outlined in paragraphs 4.10 – 4.21 and all valid consents are expected to be in place.

People Seeking Treatment

- 6.28 As well as considering the requirements of paragraphs 6.1 – 6.27 above, no licensed treatment is expected to be given to any woman without her written consent to that specific treatment. The written consent is expected to explain the nature of the treatment, the steps to be taken and indicate that the woman has been given the information referred to in Part 5 of this *Code of Practice*. The woman is expected to be given the opportunity to decide if she wishes to consent to all stages of her treatment before it begins, or whether she would prefer to consider the number of eggs or embryos to be replaced after retrieval (see also 8.18).
- 6.29 If the woman is to receive frozen embryo transfer, she is expected to be asked at that stage to consider the number of embryos to be transferred.
- 6.30 It is expected that a copy of the signed consent form will be given to the consenting woman. Examples of consent forms appear in Appendix E.
- 6.31 If it is possible that the question of treatment with donated gametes or embryos derived from them may arise, the centre is expected to raise the matter with the person(s) seeking treatment beforehand. The centre is expected to allow people sufficient time to reflect before asking for consent to treatment with donated material and counselling if they so wish.

Consent Of The Husband Or Male Partner And Legal Fatherhood

- 6.32 Treatment centres are expected to explain that there is a difference in law between the legal status of ‘father’ and having ‘parental responsibility’ for a child. Treatment centres are expected to also adopt the procedures set out below to assist the prevention or resolution of later disputes about legal fatherhood. In all cases of any doubt, couples are expected to be advised to seek their own legal guidance on this matter.

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 28

- (1) This section applies in the case of a child who is being or has been carried by a woman as the result of the placing in her of an embryo or of sperm and eggs or her artificial insemination.
- (2) If –
 - (a) at the time of the placing in her of the embryo or the sperm and the eggs or of her insemination, the woman was a party to a marriage, and
 - (b) the creation of the embryo carried by her was not brought about with the sperm of the other party to the marriage,then, subject to subsection (5) below, the other party to the marriage shall 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 insemination (as the case may be).
- (3) If no man is treated, by virtue of subsection (2) above, as the father of the child but –
 - (a) the embryo or the sperm and eggs were placed in the woman, or she was artificially inseminated, in the course of treatment services provided for her and a man together by a person to whom a licence applies, and
 - (b) the creation of the embryo carried by her was not brought about with the sperm of that man,then, subject to subsection (5) below, that man shall be treated as the father of the child.
- (4) Where a person is treated as the father of the child by virtue of subsection (2) or (3) above, no other person is to be treated as the father of the child.
- (5) Subsections (2) and (3) above do not apply –
 - (a) in relation to England and Wales and Northern Ireland, to any child who, by virtue of the rules of common law, is treated as the legitimate child of the parties to a marriage,
 - (b) in relation to Scotland, 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, or
- (c) to any child to the extent that the child is treated by virtue of adoption as not being the child of any person other than the adopter or adopters.

(6) Where –

- (a) the sperm of a man who had given such consent as is required by paragraph 5 of Schedule 3 to this Act was used for a purpose for which such consent was required, or
- (b) the sperm of a man, or any embryo the creation of which was brought about with his sperm, was used after his death,

he is not to be treated as the father of the child.

(7) The references in subsection (2) above to the parties to a marriage at the 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 this subsection it shall be presumed, unless the contrary is shown, that one of them reasonably believed at that time that the marriage was valid.

(8) This section 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.

(9) In subsection (7)(a) above, “judicial separation” includes a legal separation obtained in a country outside the British Islands and recognised in the United Kingdom.

6.33 Where the man and woman are married. Where treatment occurs with donated sperm, the woman’s husband will be the father unless, at the time of placing the embryo or sperm and eggs in the woman, or her insemination:

- (i) The man and the woman were judicially separated
or
- (ii) It is shown that the husband did not consent to the placing in her of the donated sperm and he was not receiving treatment services with the woman

6.34 If a married woman is being treated with donated sperm, treatment centres are expected to explain the legal position and ask her whether her husband consents to the treatment. If he does, the centre is expected to take all practicable steps to obtain his written consent. If the

woman does not know, or he does not consent, centres are expected to, if he agrees, take all practicable steps to ascertain the position and (if this is the case) obtain written evidence that he does not consent.

- 6.35 **Where the man and the woman are not married** or there is a judicial separation. Where treatment occurs with donated sperm, the woman's male partner will be the father if the embryo or sperm and eggs were placed in the woman, or she was artificially inseminated, in the course of treatment services provided for her and the man together (but see also paragraph 6.33).
- 6.36 Treatment centres are expected to explain the legal position and implications to the man and woman and record at each appointment whether or not the man was present. Centres are expected to try to obtain the written acknowledgment of the man both that they are being treated together and that donated sperm is to be used and, if the man does not attend at the time of embryo replacement, that the written acknowledgement is updated immediately before that embryo replacement.

Relevant Legislation

CHILDRENS ACT 1989

Section 2(2)

Where a child's father and mother were not married to each other at the time of his birth –

- (a) the mother shall have parental responsibility for the child;
- (b) the father shall not have parental responsibility for the child, unless he acquires it in accordance with the provisions of this Act.

Section 3(1)

In this Act 'parental responsibility' means all the rights, duties, powers, responsibilities and authority which by law a parent of a child has in relation to the child and his property.

Section 4(1)

Where a child's father and mother were not married to each other at the time of his birth –

- (a) the court may, on the application of the father, order that he shall have parental responsibility for the child; or
- (b) the father and mother may by agreement ('a parental responsibility agreement') provide for the father to have parental responsibility for the child.

NB: For equivalent statutory provisions outside of England see (as appropriate) Children (Scotland) Act 1995 and Children (Northern Ireland) Order 1995.

- 6.37 Treatment centres are expected to also explain that when a child is born to an unmarried couple, the male partner will not automatically have parental responsibility for that child.
- 6.38 Unmarried couples with concerns about parental responsibility and their legal rights are expected to seek their own legal advice.

People Providing Gametes And Embryos For Donation

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Schedule 3

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

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

Paragraph 5(1)

A person's gametes must not be used for the purposes of treatment 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.

Paragraph 6(1)

A person's gametes 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 being used for one or more of the purposes mentioned in paragraph 2(1) above.

Paragraph 6(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 person whose gametes were used to bring about the creation of the embryo to the use for that purpose of the embryo and the embryo is used in accordance with those consents.

- 6.39 Additionally, if there is an intention to donate gametes for the treatment of others (including the creation of an embryo for that purpose), the written consent of the potential donor(s) must be obtained.

- 6.40 Treatment centres are not required to obtain the consent of the donor's partner before the donor may donate gametes. Where the donor is married or in a long-term relationship, treatment centres are expected to nonetheless encourage the donor to seek the partner's consent in writing to the use of the gametes for donation.
- 6.41 Where a woman withdraws her consent for egg donation after preparation has commenced, the treatment centre is expected to accept any financial loss which it sustains as a result of the withdrawal of either the woman providing or receiving the eggs.

People Seeking Long Term Storage Of Gametes And Embryos

- 6.42 Those seeking and consenting to long term storage of gametes may consent to storage separately from consent to use.

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990 The Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991.

1.
These Regulations may be cited as the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 and shall come into force on 1st August 1991.
- Extension of statutory storage period for gametes
2.
 - (1) In the circumstances specified in paragraph (2) below, section 14(3) of the Human Fertilisation and Embryology Act 1990 (statutory storage period in respect of gametes) shall have effect in respect of any gametes as if for ten years there were substituted the appropriate period specified in the Schedule to these Regulations.
 - (2) The circumstances referred to in paragraph (1) are that the gametes were provided by a person
 - (a) whose fertility since providing them has or is likely to become, in the written opinion of a registered medical practitioner, significantly impaired.
 - (b) who was aged under 45 on the date on which the gametes were provided, and
 - (c) who does not consent to the gametes being used for the purpose of providing treatment services to persons other than that person, or that person and another together, and never has so consented while the gametes were ones to which this regulation applied.

6.43 In addition to the requirements outlined above, treatment centres are expected to be aware of the following:

- (i) The normal maximum storage period for gametes is 10 years
- (ii) Gametes may be stored for more than 10 years where the person seeking storage was under the age of 45 when the gametes were placed into storage providing that the other conditions relating to extended storage have been satisfied

6.44 Before consent is obtained from any individual wishing to store gametes for more than 10 years, treatment centres must ensure that the intended donor satisfies the conditions for extended storage.

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

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

Extension of statutory storage period in respect of embryos

2.

- (1) In the circumstances specified in paragraph (2) below, section 14(4) of the Act (statutory storage period in respect of embryos) shall have effect as if for five years there were substituted the appropriate period specified in the Schedule to these Regulations.
- (2) Those circumstances are that
 - (a) each of the relevant persons has confirmed in writing that that person has no objection to any embryo which is created using gametes provided by that person being stored for a period in excess of five years for use in the provision of treatment services;
 - (b) the woman being treated is aged under 50 on the relevant date and the treatment in question would not result in her being a surrogate mother within the meaning of section 1(2) of the Surrogacy Arrangements Act 1985(b); and
 - (c) in the written opinion of two registered medical practitioners, one of the relevant persons, on where she is not one of those persons, the woman being treated, has or is likely to become prematurely and completely infertile.
- (3) In the circumstances mentioned in paragraph (4) below, section 14(4) of the Act shall have effect as if for five years there were substituted
 - (a) if the woman being treated is aged 45 or under on the relevant date, ten years; or
 - (b) if she is aged 46 or over, the appropriate period specified in the Schedule to these Regulations,

(4) Those circumstances are

- (a) the circumstances specified in paragraph (2)(a) and (b) above: and
- (b) that in the written opinion of a registered medical practitioner one of the relevant persons or, where she is not one of those persons, the woman being treated
 - (i) has, or is likely to develop, significantly impaired fertility, or
 - (ii) has a gene or genes such that a child born with that gene or those genes may suffer from such physical or mental abnormalities as to be seriously disabled.

6.45 As well as the requirements of paragraph 6.18 above, centres are expected to be aware that the normal storage period for embryos is usually five years, although embryos may be stored for more than five years where the woman who would be treated by the embryos was under 50 years when the embryos were placed in storage and providing the other conditions for an extended storage period have been satisfied.

6.46 Centres must ensure that anyone wanting to store an embryo for more than five years satisfies all conditions for an extended storage period before their consent is obtained.

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Schedule 3

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

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

6.47 Those seeking storage of embryos created from their gametes must specify the purpose for which they are to be used, namely:

- (i) In providing treatment for the person giving consent
or
- (ii) In providing treatment for the person giving consent and a specified partner
or
- (iii) In a project of research

People Involved In An Egg Sharing Arrangement

6.48 As well as considering the requirements of paragraphs 6.1 – 6.12, 6.15 and 6.18 – 6.40, where people are involved in an egg sharing arrangement, HFEA consent forms are expected to be completed and signed as follows:

- (i) The egg provider is expected to complete Form HFEA(00)7 in respect of use of eggs and storage of embryos created for her own use. In accordance with HFEA guidance, it is expected that Form HFEA(00)7 will be completed as if the egg provider was an IVF patient
- (ii) It is expected that a second Form HFEA(00)7 will be completed in accordance with HFEA guidance by the egg provider as if she were an egg donor

In this way, different conditions may be placed on the storage of spare embryos created and cryopreserved. Using only one Form HFEA(00)7 would not permit consent to be varied in this way.

- 6.49 It must be emphasised that the HFE Act allows a gamete donor to withdraw or vary consent up to the time that the embryo thus created (cryopreserved or otherwise) is used in treatment services or research.
- 6.50 The consequences of withdrawal of consent are expected to be made clear to affected parties before commencing treatment. Those consequences are expected to be contained in patient information for providers and recipients and included in any relevant written agreement.
- 6.51 In accordance with HFEA guidance, the male partners of the egg provider and the egg recipient are expected to complete Form HFEA(00)6.
- 6.52 Where it is proposed that embryos are to be used, the terms of the woman's consent to the storage of those embryos using her eggs must be compatible with the consent of the man whose sperm fertilised those eggs, both for the egg provider and the egg recipient.

Part 7 – Counselling

General Obligations

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 13

- (1) The following shall be conditions of every licence under paragraph 1 of Schedule 2 to this Act.
- (6) A woman shall not be provided with any treatment services involving –
- (a) the use of any gametes of any person, if that person's consent is required under paragraph 5 of Schedule 3 to this Act for the use in question,
 - (b) the use of any embryo the creation of which was brought about *in vitro*, or
 - (c) the use of any embryo taken from a woman, if the consent of the woman from whom it was taken is required under paragraph 7 of that Schedule for the use in question,

unless the woman being treated and, where she is being treated together with a man, the man have been given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and have been provided with such relevant information as is proper.

Schedule 3

Paragraph 3(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, ...

It is expected that counselling will only be provided by qualified counsellors i.e. counsellors who meet the criteria for counselling staff as set out in paragraph 1.9 of this *Code of Practice*.

7.1 Counselling is expected to be clearly distinguished from:

- (i) Information which is to be provided to all relevant parties in accordance with guidance in Part 5 of this *Code of Practice*

- (ii) The normal relationship between clinical staff and the potential donor or seeker of storage or treatment (including the giving of professional advice) and
- (iii) The process of assessing individuals and deciding whether to accept them for treatment as donors, or to accept gametes and embryos for storage in accordance with guidance given in Parts 3 and 4 of this *Code of Practice*

7.2 Those:

- (i) Seeking licensed treatment in the form of *in vitro* fertilisation or
- (ii) Whose treatment involves donated gametes/embryos or
- (iii) Donating gametes for the treatment of others or
- (iv) Consenting to the storage of gametes or
- (v) Consenting to the use of or storage of embryos or
- (vi) Consenting to the use of gametes or embryos posthumously

must be given “a suitable opportunity to receive proper counselling about the implications of taking the proposed steps” before they consent. This is expected to include the provision of both verbal and written information on the counselling service provided (see paragraph 7.5).

7.3 Counselling is recognised as beneficial in relation to all licensed treatments. No-one is obliged to accept it but centres are expected to take into account refusal of the offer of counselling prior to either donation or treatment with donated gametes or embryos in the centre’s decision to proceed with that donation or treatment.

7.4 In appropriate cases the following distinct types of counselling are expected to be made available:

- (i) **Implications Counselling.** The purpose of implications counselling is to enable the individual being counselled to reflect upon and understand the proposed course of action for that individual, their family and children born as a result and anyone else affected by the donation or treatment. It should be distinguished from implications advice or guidance provided by other members of the multidisciplinary team.
- (ii) **Support Counselling.** The purpose of support counselling is to give emotional support at times of particular stress. This may occur at any stage before, during and after donation or treatment e.g. when there is a failure to achieve pregnancy

- (iii) **Therapeutic Counselling.** The purpose of therapeutic counselling is to assist people in developing successful coping strategies for dealing with both the short and long term consequences of infertility and treatment. It includes helping people to try to adjust to their expectations and to come to terms with their particular situation. Therapeutic counselling may be an ongoing process and can be continued, or take place for the first time, after the course of treatment has been completed. The duration of therapeutic counselling will be determined by the individual's needs

- 7.5 Treatment centres must ensure that all individuals referred to in paragraph 7.2 above receive an offer of counselling. Centres are expected to ensure that patients are made aware that the offer of counselling is routine. The offer of counselling is expected to include written information giving the name(s) of the qualified counsellor, explaining the counsellor's role, when the counsellor is available and how to access the service. There is expected to be no pressure to accept the offer of counselling but sufficient time is expected to be allowed by the centre for consideration of the offer and the information supplied.
- 7.6 Treatment centres are expected to create an atmosphere that is conducive to discussion and allows sufficient time for counselling to be conducted sensitively. In providing counselling, centres are expected to be aware of the individual needs of patients, including disability and language.
- 7.7 Counselling is expected to be provided only by a qualified counsellor who meets the criteria in paragraph 1.9 and is expected to be independent of the clinical decision making process.
- 7.8 Treatment centres are expected to offer people the opportunity to be counselled with a partner if they have one and or individually. It is not acceptable for a treatment centre to offer group-only sessions. However group session may be offered in addition to individual/couple sessions.
- 7.9 Individuals are expected to be able to seek counselling at any stage of their investigation or treatment i.e. before, during and after treatment. Counselling is expected to normally be made available after the person seeking treatment or potential donor has received oral and written explanations as described in Part 4 of this *Code of Practice*. Discussion may then focus on the meaning and consequences of the decision rather than just practical aspects of any given treatment. However, timing and frequency of counselling is primarily a matter to be agreed between the counsellor and the individual concerned.
- 7.10 Treatment centres are expected to invite those seeking treatment to consider:
 - (i) Their attitude to their own or partner's infertility and
 - (ii) The possibility that treatment will fail

Implications Counselling

[See Human Fertilisation and Embryology Act 1990 section 13(6) and Schedule 3 paragraph 3(3)(1)(a) on page 69.]

- 7.11 Implications counselling must be made available prior to any proposed treatment, donation or storage decision, including the posthumous use of stored gametes/embryos.
- 7.12 Treatment centres must make implications counselling available to everyone. It is expected that this will be provided by the counsellor. Centres are also expected to provide access to therapeutic counselling in appropriate cases or refer people to sources of more specialist counselling outside the centre.
- 7.13 The counsellor providing implications counselling is expected to discuss with all individuals involved the following issues:
- (i) The social responsibilities of centres, those seeking treatment and gamete/embryo providers to ensure the best possible outcome for the potential child and anyone who might be affected by the treatment/donation
and
 - (ii) The implications of the procedure for:
 - (a) themselves
 - (b) their families, including any existing or future children and social circle
 - (c) any resulting child or childrenand
 - (iii) Their feelings about the use of embryos derived from their gametes and possible disposal
and
 - (iv) Their children's feelings about donation or disposal of embryos
 - (v) How the envisaged procedures may be explained to relatives, friends and potential children together with the advantages and disadvantages of openness
and
 - (vi) The significance of non identifying information provided by the donor for any resulting child

Treatment With Donated Gametes Or Embryos

- 7.14 Where a woman is in the process of undergoing fertility treatment and the question of treatment with donated gametes or embryos derived from them arises, it is expected that donation implication counselling will be offered separately from treatment implications

counselling. Treatment involving the use of donated material is expected not to proceed unless the woman, and where appropriate her partner, have been given a suitable opportunity and time to receive donation implications counselling.

7.15 Additionally, it is expected that where treatment using donated gametes or embryos is an option, those seeking treatment will be invited to consider:

- (i) Their feelings regarding the fact that they are not the child's genetic parents
- (ii) Their perceptions of the child's needs throughout childhood and adolescence
- (iii) The child's need for information about his/her origins

People Providing Gametes And Embryos For Donation

7.16 Where a couple is undergoing infertility treatment and the possibility of donation arises, donor implications counselling is expected to be undertaken separately from treatment implications counselling (see 7.11). Where the possibility of donation arises later in treatment, it is expected that treatment will not proceed unless the couple or woman, if being treated singly, have been given a suitable opportunity and time to receive counselling.

7.17 As well as considering the requirements of paragraphs 7.1 – 7.24 of this *Code of Practice*, counsellors are expected to invite people considering donation of gametes and embryos to consider in particular:

- (i) The reasons for wanting to provide donated gametes
and
- (ii) Their attitudes to resulting children and their willingness to forego future knowledge
and responsibility in respect of such children
and
- (iii) The possibility of their own childlessness
and
- (iv) Their perception of the needs of children born as a result of their donation
and
- (v) Their perception of the needs of any existing or future children of their own
and
- (vi) Possibility, with embryo donation, of the existence of full genetic siblings to their own
children, resulting from their donation
and
- (vii) Their attitudes to allowing embryos produced from their gametes to be used for
research

- 7.18 Where those seeking donation or storage of gametes or embryos are married or have long term partners, the treatment centre is expected to counsel the couple together. Where one partner wishes in addition to receiving separate counselling regarding implications in respect of donation or storage, treatment centres are expected to take all practicable steps to offer counselling at the centre concerned or facilitate external counselling.

Support Counselling

- 7.19 Treatment centres are expected to take all practicable steps to offer support to any individual requiring help. Examples may include the following:
- (a) Individuals who are unsuitable for treatment
 - (b) Individuals experiencing difficulty coping with a treatment cycle
 - (c) Individuals whose treatment has failed
 - (d) Potential but unsuitable donors

Those steps may include reasonable assistance in contacting a local or national support group or referral to a relevant outside agency or organisation.

- 7.20 Treatment centres are expected to ensure that all staff who are in contact with the patient as part of their training, are prepared to offer appropriate emotional support to all people suffering distress at any stage of their investigation, counselling and treatment. Training is expected to include an explanation of the role of counselling. Any member of staff is expected to know when to refer people to the qualified counsellor and be able to refer an individual for counselling.

Therapeutic Counselling

- 7.21 To assist individuals to come to terms with their situation, treatment centres are expected to have procedures in place to identify people who suffer particular distress and offer them therapeutic counselling, where appropriate and practical, from the centre's qualified counsellor. Where this is not practicable, centres are expected to refer people on to an identified independent counsellor who meets the criteria in paragraph 1.9. It is expected that procedures will be in place for both the centre referrals and self referrals and that these procedures will be clearly outlined in the written information on counselling supplied to everyone at their first point of contact with the centre.
- 7.22 Where individuals are suffering from mental ill-health or severe psychological problems (not necessarily related to fertility), treatment centres are expected to help them to obtain appropriate external help and advice.

Genetic Counselling

7.23 Centres are expected to:

- (i) Have arrangements in place for referral whenever appropriate to specialist genetic counselling services
and
- (ii) Ensure that whenever individuals are referred for genetic counselling the confidentiality provisions of the HFE Act are considered and complied with

Later Counselling

7.24 Centres are expected to take all practicable steps to provide further opportunities for counselling about the implications of treatment, donation or storage after consent has been given, and throughout the period in which the person is providing gametes, or receiving treatment, if this is requested. If someone who has previously been a donor or patient returns to the centre asking for further counselling, the centre is expected to take all practicable steps to help them obtain it.

Records

- 7.25 It is expected that the offer of counselling and the individual's decision to accept or reject such offers is recorded in the main medical notes.
- 7.26 Information obtained in the course of counselling is expected to be confidential. (But for an exception see Part 3 of this *Code of Practice* where a team member has cause for concern as a result of information received in confidence.) The written records of the professional counsellor are expected to be kept in a secure place.

People Seeking Long Term Storage Of Gametes And Embryos

- 7.27 While considering the requirements of paragraphs 7.1 – 7.26, treatment centres are expected to ensure that specialist external counselling – which may be more appropriate for oncology patients or others requiring long term storage of gametes or embryos – is made available.
- 7.28 Treatment centres are expected to be aware of the special needs of those seeking long term storage of gametes and embryos and ensure that counselling is available at any time during storage.

People Involved In An Egg Sharing Arrangement

- 7.29 The HFEA strongly recommends that couples contemplating participation in egg sharing arrangements receive implications counselling.

7.30 Independent counsellors are expected to be aware of the medical processes and the legal and social issues relevant to egg sharing arrangements.

7.31 It is expected that counselling will be provided to egg sharers, their partners, and to recipient women and their partners, equivalent to that described in paragraphs 7.25 – 7.26.

[See HFE Act Section 13(6) and Schedule 3(3)(1)(a) above.]

7.32 Implications counselling must be offered to egg sharers, their partners and to recipient women and their partners, and is expected to cover the following:

- (i) The implications of not knowing whether the recipient has succeeded
and
- (ii) The implications of knowing the outcome of the recipient's treatment
and
- (iii) The implications if the sharer remains childless
and
- (iv) The implications for the recipient of using the eggs of a woman who herself is facing
treatment
and
- (v) The implications of the possibility of half-siblings of similar age resulting from the
treatment

Part 8 – Use Of Gametes And Embryos

Obtaining Gametes And Embryos

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 24

- (4) Directions may authorise any person to whom a licence applies to receive gametes or embryos from outside the United Kingdom or to send gametes or embryos outside the United Kingdom in such circumstances and subject to such conditions as may be specified in the directions, and directions made by virtue of this subsection may provide for sections 12 to 14 of this Act to have effect (whether by expiry, suspension, revocation or otherwise)

Section 24

- (3) 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.

General Directions D 1991/3: Keeping gametes and embryos in the course of carriage between premises.

General Directions D 2001/1: Information to be provided to a person to whom another licence applies where gametes or embryos are supplied. Records to be kept of gametes or embryos supplied.

- 8.1 Treatment and research centres may only import and export gametes and embryos in accordance with Directions made by the HFEA.
- 8.2 Treatment and research centres may only transport gametes and embryos between licensed premises in accordance with Directions made by the HFEA.

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 12

The following shall be conditions of every licence granted under this Act –

- (f) that, where gametes or embryos are supplied to a person to whom another licence applies, that person shall also be provided with such information as the Authority may specify in directions, ...

Conditions of licences for treatment

Section 13

(1) The following shall be conditions of every licence under paragraph 1 of Schedule 2 to this Act.

(2) Such information shall be recorded as the Authority may specify in directions about the following –

- (e) any mixing of egg and sperm and any taking of an embryo from a woman or other acquisition of an embryo, and
- (f) such other matters as the Authority may specify in directions.

General Directions D2000/2: Recording information about consents for and circumstances of storage or use of gametes and embryos, and other matters about which information is to be recorded.

Conditions of Storage Licences

Section 14

(1) The following shall be conditions of every licence authorising the storage of gametes or embryos -

- (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.

General Directions D1991/7: Recording information about consents for and circumstances of storage or use of gametes and embryos, and other matters about which information is to be recorded

General Directions 1992/2: Directions of records

Conditions of Research Licences

Section 15

- (1) The following shall be conditions of every licence under paragraph 3 of Schedule 2 to this Act.
- (2) The records maintained in pursuance of the licence shall include such information as the Authority may specify in directions about such matters as the Authority may so specify.

General Directions 1991/6: Information under a research licence to be recorded and provided to the Human Fertilisation and Embryology Authority

General Directions D1991/7: Recording information about consents for and circumstances of storage or use of gametes and embryos, and other matters about which information is to be recorded

General Directions 1992/2: Directions of records

Directions as to particular matters

Section 24

- (3) 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.

- 8.3 Where any part of treatment takes place in a premises which is not the subject of a licence otherwise known as a satellite or transport centre, the licensed centre where the subsequent embryo transfer will take place must ensure that the requirements of the HFE Act, the HFEA *Code of Practice* and Directions made by the HFEA are complied with before treatment begins. These requirements cover information, counselling, the welfare of the child and confidentiality. The licensed centre is expected to supply the satellite or transport centre with copies of the HFE Act and the HFEA *Code of Practice*.

Clinical Use

- 8.4 It is expected that eggs, sperm or embryos created from the patient/s will not be used for treatment where there are reasonable grounds for believing that procedures to which the eggs or sperm have been subject carry an actual, or reasonable theoretical risk of harm to their developmental potential. Treatment centres are expected to satisfy the HFEA that sufficient scientific evidence is available to establish that procedures used do not prejudice the developmental potential of gametes or embryos.

- 8.5 Similarly, it is expected that embryos will not be used for treatment where there are reasonable grounds for believing that procedures to which the embryos themselves have been subject carry an actual or a reasonable theoretical risk of harm to their development, or a theoretical risk of harm to their developmental potential. Treatment centres are expected to satisfy the HFEA that sufficient scientific evidence is available to establish that procedures used do not prejudice the developmental potential of embryos.

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Schedule 3

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 below.

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 or embryos to which the consent is relevant.
- (2) 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, or
 - (b) for the purposes of any project or research

***In vitro* fertilisation and subsequent use of embryo**

6.

- (1) A person's gametes 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 being used for one or more of the purposes mentioned in paragraph 2(1) 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 person whose gametes were used to bring about the creation of the embryo to the use for one or more of the purposes mentioned in paragraph 2(1) 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 person whose gametes were used to bring about the creation of the embryo to the use for that purpose of the embryo and the embryo is used in accordance with those consents.
- (4) Any consent required by this paragraph is in addition to any consent that may be required by paragraph 5 above.

8.6 It is expected that attempts to produce embryos *in vitro* will not to be made unless there is an intention to store or use the resulting embryo(s) or unless there is a specific reason why it is necessary to do so in connection with the provision of treatment services for a particular woman. On each such occasion:

- (i) It is expected that the reason will be explained to the woman
- (ii) It is expected that counselling relating to the implications of the treatment is offered to her
- (iii) The written consent of each person providing the gametes must have been obtained

8.7 Frozen embryo transfer is a regulated activity. Where a woman has had an embryo stored and subsequently wishes to have treatment transferring the embryos to her, the treatment centre must:

- (i) Consider her for treatment in the usual manner
- (ii) Take into account the welfare of the child (see also Part 3)
and
- (iii) Check that the treatment is in accordance with the terms of the consent given by both parties

8.8 It is expected that gametes or embryos that have been exposed to a material risk of contamination and which might cause harm to recipients or to resulting children will not to be used for treatment. If in any doubt about these risks, treatment centres are expected to seek expert advice.

8.9 Treatment centres are expected not to:

- (i) Select the sex of embryos for social reasons
or
- (ii) Attempt to produce embryos *in vitro* by embryo splitting for treatment purposes

Termination And Disposal

8.10 The special status of the human embryo is fundamental to the provisions of the HFE Act. The termination of the development of a human embryo and the disposal of the remaining material are sensitive and delicate issues. Treatment and research centres are expected to take this into account when considering how the development of an embryo is to be brought to an end and what is to happen thereafter. The approach to be adopted will depend on whether the embryos are being stored for treatment or to be used for research.

8.11 Where consent to continued storage has been withdrawn by only one gamete provider, centres are expected to take steps to ensure that the other gamete provider (unless that person is a donor) is informed of the centre's obligation to dispose of the embryos. Where the woman/partner to be treated is not one of the gamete providers, the centre is expected to take similar steps to ensure that she is informed of the obligation to dispose of the embryos.

8.12 Where embryos are used for research, the research centre is expected to decide at the outset:

- (i) The duration of the culture period
and
- (ii) The method to be used to terminate development
and
- (iii) The procedure to be used to ensure that embryos do not develop after 14 days or (if earlier) the appearance of the primitive streak

People Seeking Treatment

Additional Information

8.13 Normally, it is expected that sperm will be produced in a licensed centre.

8.14 As well as considering the requirements of paragraphs 8.1 – 8.12 above, treatment centres may, in exceptional circumstances, permit a man to provide sperm produced at home. In these circumstances, the treatment centre is expected to:

- (i) Take all reasonable steps to satisfy itself that the sperm has been produced by that man and
- (ii) Take all reasonable steps to satisfy itself that the sperm has been produced not more than two hours previously and
- (iii) Take all reasonable steps to satisfy itself that the sperm has not been subject to subsequent interference and
- (iv) Formally record these matters in the patient records

8.15 Treatment centres are expected to ensure that back-up and emergency clinical facilities and the availability of appropriate staff (as outlined in Part 2 of this *Code of Practice*) are available to patients if required.

8.16 Where embryos have been created using partner sperm produced at home and donation is being considered, the fact that the sperm was not produced at a licensed treatment centre is expected to be taken into account.

Transfer Of Eggs And Embryos

8.17 It is expected that women will not be treated with gametes, or with embryos derived from gametes, of more than one man or woman during any treatment cycle.

8.18. The policy set out in paragraphs 8.19 to 8.22 below aims to maintain pregnancy rates and to minimise the risk of multiple pregnancy

8.19 In all cases it is expected that the appropriate number of eggs or embryos to be transferred, and the reasons for this (including the risks of multiple pregnancy) will be assessed and discussed with the woman and her partner and her consent placed in the medical records.

Use of patient's own egg or embryos (fresh or frozen)

8.20 In circumstances where women are using their own fresh or frozen eggs or embryos, centres are expected to ensure that:

- (i) Women aged under 40 at the time of transfer receive no more than either two eggs or embryos in any one cycle, regardless of the procedure used;

- (ii) Women aged 40 or over at the time of transfer receive no more than either three eggs or embryos in any one cycle, regardless of the procedure used.

Use of donated eggs or embryos

- 8.21 Where donated fresh or frozen eggs or embryos are used, centres are expected to ensure that no more than two eggs or embryos are placed in a woman regardless of her age at the time of transfer and regardless of the procedure used.

Use of aneuploidy screening

- 8.22 Where aneuploidy screening is employed, centres are expected to ensure that no more than two embryos are placed in a woman regardless of her age at the time of transfer.

Donor Insemination

- 8.23 Before commencing treatment by donor insemination, the treatment centre is expected to discuss with the patient the number of treatment cycles to be attempted in the event of failure to conceive, before further investigation takes place and thereafter, and review this situation at regular intervals.
- 8.24 Treatment centres may supply sperm for home insemination only in exceptional circumstances which make it impracticable or undesirable for the patient to be inseminated at the centre. When sperm is supplied for home insemination, the treatment centre is expected to record this detail in writing and explain the relevant exceptional circumstances in the treatment records.
- 8.25 As with other donor insemination treatment, the requirements of the HFE Act and guidance in the *Code of Practice*, including those relating to providing information, assessment of the patient, consideration of the welfare of the child and the offer of counselling, must be complied with, where it is decided to offer home insemination treatment.
- 8.26 Before agreeing to supply sperm for home insemination, the treatment centre is expected to obtain a written undertaking from the woman concerned to supply appropriate information to the treatment centre about the outcome of the treatment.

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 4

- (1) No person shall –
 - (a) store any gametes, ...
except in pursuance of a licence.

Section 2

- (2) References in this Act to keeping, in relation to embryos or gametes, include keeping while preserved, whether preserved by cryopreservation or in any other way; and embryos or gametes so kept are referred to in this Act as “stored” (and “store” and “storage” are to be interpreted accordingly). ...

Section 14

- (1) The following shall be conditions of every licence authorising the storage of gametes and embryos –
- (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,

- 8.27 Treatment centres must not supply frozen sperm to a person not covered by a licence. Treatment centres may only supply sperm, which is in the process of thawing for the purposes of home insemination. Provided that the woman has attended the treatment centre for assessment purposes, the sperm may be provided to her either by handing it to her in person or by sending it to her by courier. The use of a dry shipper or any other container which would preserve the sperm in a frozen or preserved state upon leaving the treatment centre is prohibited.
- 8.28 Treatment centres are expected to complete DI Treatment Form (96)2 in the normal way and are expected to enter the date of supply or posting as the date of insemination. It is expected to also be noted that the sperm was for home insemination.

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Schedule 3

Consent to use of gametes or embryos

Consent

1.

A consent under this Schedule must be given in writing and, 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 –

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

- (e) use in providing treatment services to persons not including the person giving consent, or
- (f) use for the purposes of any project of research,

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

People Providing Gametes And Embryos For Donation

- 8.29 If embryo donation is being considered where an embryo has been created using partner sperm produced at home, the treatment centre must take that fact into consideration.
- 8.30 Where a donor of gametes or embryos has, as a result of such donations, achieved 10 live birth events, it is expected that the donor's gametes or embryos will not to be used on a subsequent occasion. Where such a donor has specified a limit which is less than 10 live birth events, this limit must never be exceeded. It is the joint responsibility of supplier and user of donated gametes or embryos to agree an appropriate procedure for ensuring that the limit of 10 live birth events is not exceeded.
- 8.31 The limit of 10 live birth events may be exceeded only in exceptional cases and never when a lesser limit has been prescribed by the donor. An example of an exceptional case would be where the recipient wished to have a subsequent child from the same donor. The HFEA expects to be notified whenever the limit of 10 live birth events is exceeded.
- 8.32 A 'live birth event' is the birth of a live child or children. This means that the birth of twins or triplets is expected to be considered a single 'live birth event'.

Export Of Gametes

- 8.33 Gametes from donors who have produced 10 live birth events in the United Kingdom must not be exported. (General Direction 1991/8 Export of Gametes).

Posthumous Use

- 8.34 Insemination of a woman at a licensed treatment centre using her late husband or partner's sperm is regulated under the HFE Act (see paragraphs 8.1-8.12 and Part 6 of this *Code of Practice*).

Part 9 – Storage And Handling Of Gametes And Embryos

General Obligations

- 9.1 Treatment centres are expected to ensure that the highest possible standards are maintained in the storage and handling of gametes and embryos.

Screening

- 9.2 All patients placing gametes, embryos and ovarian or testicular tissue in storage which falls under an HFEA licence are expected to be screened for Hepatitis B, Hepatitis C and HIV, as outlined in Section 9.4 of the Association for Clinical Embryologists' Guidelines.
- 9.3 Centres are expected to ensure that storage of tissue that does not require a licence from the HFEA fulfils the requirements of the *Code of Practice* for Tissue Banks (Department of Health, 2001) (see also Guidance on the Microbiological Safety of Human Organs, Tissues and Cells Used in Transplantation (Department of Health 2000)).
- 9.4 It is expected that screened samples will be kept in a separate cryostore from unscreened samples. Unscreened samples include:
- i) Any samples stored before comprehensive screening of all patients was introduced and
 - ii) Any samples in temporary storage while the results of screening tests are obtained

Security

- 9.5 It is expected that gametes and embryos will be stored in a designated security area with controlled access.
- 9.6 The Person Responsible is expected to permit access to the designated security area only to the treatment centre's named individuals for whom access is essential in the course of their work. No other people are expected to have access to gametes and embryos.

- 9.7 In order to minimise the amount of handling required in retrieving gametes and embryos, their storage location is expected to be recorded in detail. Each and every occasion when gametes or embryos are handled is expected to be recorded.
- 9.8 There is expected to be an effective monitoring system to ensure high standards of security wherever gametes and embryos are handled or stored.

Identification

- 9.9 The sources of gametes and embryos are expected to be accurately recorded and labelled in a way that is not susceptible to unauthorised or undetectable alteration.
- 9.10 Records are expected to enable authorised staff to trace what happens to an individual embryo, egg or sperm sample from the date of collection. This also applies to fresh embryos and frozen embryos once thawed.

Storage Review

- 9.11 Storage centres are expected to carry out reviews, at least annually, of the status of stored gametes and embryos. The purposes of these reviews are expected to be:
- (i) To reconcile the centre's records with the genetic material stored and
 - (ii) To review the purpose and duration of storage and
 - (iii) To identify action that needs to be taken
- 9.12 In order to give storage centres sufficient advance notice of the end of the statutory storage period specified in the storage centres' licences (or such shorter period as is specified by the gamete donor), storage centres are expected to operate a bring-forward system.
- 9.13 Storage centres are expected to endeavour to maintain contact with the providers of stored gametes and embryos to inform them when the terminal storage date for their gametes and embryos is approaching. The providers are expected to be given sufficient notice to enable them to consider the available options and have access to appropriate information and advice. Centres are expected to inform providers of the importance of keeping the centres informed of a change in contact details.

Contamination

- 9.14 It is expected that gametes and embryos intended for treatment will not be placed in close proximity to radioactive material or any known potential source of infection, chemical or atmospheric contamination (see also Part 2 of this *Code of Practice*).

Transfer Of Gametes And Embryos

- 9.15 It is the responsibility of the receiving centre to ensure that effective consents have been given to use and storage of gametes or embryos transferred to the centre. This will include consent to the creation of embryos *in vitro* where donor sperm is provided for use in IVF treatment.
- 9.16 Centres are responsible for ensuring that the standards of quality and security of gametes and embryos are maintained, wherever the material happens to be on the premises. This includes material being transferred from the laboratory for treatment or preparation for treatment.
- 9.17 Apart from the release of sperm for home insemination (in accordance with Paragraphs 8.24 – 8.28) gametes and embryos may not leave licensed premises except in accordance with HFEA Directions. Where gametes or embryos are transferred between sites, adequate arrangements are expected to be made to protect their quality and security. All storage, treatment and research centres are expected to operate a fail-safe mechanism to ensure that correct gametes and embryos are transferred.

Part 10 – Research

General Standards

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 3

- (1) No person shall –
- (a) bring about the creation of an embryo, or
 - (b) keep or use an embryo,
- except in pursuance of a licence.

Schedule 2 paragraph 4

- (1) A licence under this schedule can only authorise activities to be carried on premises specified in the licence and under the supervision of an individual designated in the licence.
- (2) A licence cannot –
- (a) authorise activities falling within both paragraph 1 and paragraph 3 above,
 - (b) apply to more than one project of research,
 - (c) authorise activities to be carried on under the supervision of more than one individual, or
 - (d) apply to premises in different places.

The Human Fertilisation and Embryology (Research Purpose) Regulations 2001 Further purposes for which research licences may be authorised

- 2(1) The Authority may issue a licence for research under paragraph 3 of Schedule 2 to the Act for any of the purposes specified in the following paragraph.
- 2(2) A licence may be issued for the purposes of –
- (a) increasing knowledge about the development of embryos;

- (b) increasing knowledge about serious disease, or
- (c) enabling any such knowledge to be applied in developing treatments for serious disease.

10.1 Research involving the creation, keeping or use of human embryos outside the body must be licensed by the HFEA. Research centres must apply to the HFEA for separate licences in respect of each separate research project.

10.2 The HFEA may only grant licences for research projects if it appears to the HFEA that the activity to be authorised by the licence is necessary or desirable for one or more of the following purposes:

- (i) To promote advances in the treatment of infertility
- (ii) To increase knowledge about the causes of congenital disease
- (iii) To increase knowledge about the causes of miscarriages
- (iv) To develop more effective techniques of contraception
- (v) To develop methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation
- (vi) To increase knowledge about the development of embryos
- (vii) To increase knowledge about serious disease
- or
- (viii) To enable such knowledge to be applied in the development of treatments to combat serious disease

10.3 The HFEA will not grant a research licence using human embryos unless it is fully satisfied that the use of human embryos is necessary for the purposes of the research.

Prohibitions

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 3

- (1) No person shall –
- (a) bring about the creation of an embryo, or
 - (b) keep or use an embryo
- except in pursuance of a licence.

- (2) No person shall place in a woman –
 - (a) a live embryo other than a human embryo, or
 - (b) any live gametes other than human gametes.
- (3) A licence cannot authorise –
 - (a) keeping or using an embryo after the appearance of the primitive streak
 - (b) placing an embryo in an animal
 - (c) keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use, or
 - (d) replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo.
- (4) For the purposes of subsection (3)(a) above, the primitive streak is to be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with the day when the gametes are mixed, not counting any time during which the embryo is stored.

10.4 The following activities are **prohibited** by the HFE Act:

- (i) Placing animal gametes or embryo(s) in a woman
- (ii) Keeping or using an embryo after the appearance of the primitive streak or after 14 days – whichever is the earlier
- (iii) Placing a human embryo in an animal
- (iv) Replacing a nucleus of a cell of an embryo with a nucleus taken from the cell of any person, another embryo or a subsequent development of an embryo
- (v) Altering the genetic structure of any cell while it forms part of an embryo

Human Fertilisation and Embryology Act 1990

Section 15(4)

No embryo appropriated for the purposes of any project of research shall be kept or used otherwise than for the purposes of such a project.

10.5 Embryos which have been appropriated for a research project must not be used for any other purposes.

10.6 Before the HFEA approves a research license, it is expected that each research project will be referred to a properly constituted ethics committee for approval.

- 10.7 Research centres within the NHS are expected to refer research projects to the relevant Multiple Centre Research Ethic Committees and/or Local Research Ethics Committee (LREC).
- 10.8 Research centres outside the NHS may also refer research projects to the LREC by prior arrangement or may set up their own committees which are expected to be independent and consist of no fewer than five members. The chairman of this committee is expected to be independent of the centre concerned. No more than one third of the membership of such a committee is expected to be employed by or have a financial interest in the research centre.
- 10.9 Membership of the Ethics Committee is expected to be approved by the HFEA. For further information concerning the creation and operation of a research ethics committee, research centres are expected to contact the Department of Health.
- 10.10 Proposals for research projects involving the use of embryos will be submitted to appropriate academic referees chosen by the HFEA for peer review.
- 10.11 Medical practitioners are bound to follow the General Medical Council's guidance set out in *Research: the Role and Responsibilities of Doctors* published in 2002. In particular in relation to funding and payments:
- (i) All financial interests and sums of money known or estimated to be paid for the research must be disclosed to a research ethics committee
 - (ii) Payments are expected not to be offered at a level which could induce research participants to take risks that they would otherwise not take, or to volunteer more frequently than is advisable or against their better interests or judgement
 - (iii) Participants must be given information on how the research is funded, including any benefits which would accrue to researchers and/or their departments
 - (iv) There must be honest and full responses to participants' questions, including enquiries about direct payments made and any financial interests in the research project or its sponsoring organisations
 - (v) Ensure that everyone in the research team, including nurses and non-medical staff, is informed about the way in which the research is being financed and managed
- 10.12 The attention of research centres is also drawn to those paragraphs of this *Code of Practice* dealing with:
- (i) 6.5 – 6.24 consent to storage and use of gametes and embryos
and
 - (ii) 8.4 – 8.9 the use of gametes and embryos which have been subject to procedures that might prejudice their developmental potential
and
 - (iii) 8.10 – 8.12 the termination and disposal of embryos which have been used for research

Part 11 – Records

Accuracy

- 11.1 All information that centres are required to keep by HFEA Directions is expected to be accurately recorded with proper cross references where this is required.
- 11.2 Centres' attention is drawn to paragraphs 3.9, 4.22, 4.23, 4.25, 4.27, 5.3, 6.23, 6.33, 6.35, 7.25, 7.26, 8.14, 5.24, 9.7, 9.9, 9.10, 9.11, 9.12 and 13.1(ii) of this *Code*, which set out additional matters about which records are expected to be kept.

Confidentiality

- 11.3 Centres must ensure that information provided in confidence is kept confidential and only disclosed in the circumstances permitted by law⁴. It is expected that patients will not have access to any other person's records (including those of a patient's spouse or partner) without that other person's prior consent.

Access To Health Records And The Data Protection Act 1998 (Annex A)

- 11.4 Centres are expected to establish written procedures for considering applications for access to confidential records. There is expected to be a clearly identified individual in each centre whose responsibility it is to receive, check and arrange authorised access to confidential records.
- 11.5 Centres must ensure that they notify the Data Protection Commissioner in accordance with the Data Protection Act 1998⁵.
- 11.6 Centres are expected to allow all donors and clients who provide information about themselves to the centre access to the record of that information and an opportunity to correct it.
- 11.7 Centres are expected to be aware that under the Data Protection Act 1998, the individual whose health records are being held (known as the "data subject") is normally entitled to their

⁴ This is an obligation under the general law.

⁵ Data Protection Act 1998 section 18.

own health records, provided their request is made in writing (which includes a request by electronic means) and the required fee is paid. The maximum fee is currently £50⁶. The source of the information and an explanation of unintelligible terms is expected to be given.

- 11.8 Centres are expected to comply with a request promptly and in any event within 40 days of receipt of the request (providing the relevant fee has been paid) or if later, within 40 days of receipt of any additional information required, to satisfy themselves as to the identity of the person making the request and locate the information which the individual seeks.

Access Exemptions To The Data Protection Act 1998 (Annex B) Human Fertilisation And Embryology Act 1990

Information about the provision of treatment services, the keeping or use of gametes or embryos and whether identifiable individuals were born in consequence of treatment services are exempt from Section 7 of the Data Protection Act 1998⁷. This information may only be disclosed if such disclosure falls within the exemptions set out in Sections 31 and 33 of the HFE Act.

Human Fertilisation and Embryology Act 1990

Section 31 Information

31.

- (1) The Authority shall keep a register which shall contain any information obtained by the Authority which falls within subsection (2) below.
- (2) Information falls within this subsection if it relates to –
 - (a) the provision of treatment services for any identifiable individual, or
 - (b) the keeping or use of the gametes of any identifiable individual or of an embryo taken from any identifiable woman,or if it shows that any identifiable individual was, or may have been, born in consequence of treatment services.
- (3) A person who has attained the age of eighteen (“the applicant”) may by notice to the Authority require the Authority to comply with a request under subsection (4) below, and the Authority

⁶ Health records that are not exclusively electronic, where the request is made before 24 October 2001 and is for a permanent copy of the records. In these circumstances, a maximum fee of £50 is set unless some of the record was made in a period of 40 days immediately preceding the request when no fee may be charged.

⁷ Data Protection (Miscellaneous Subject Access Exemptions) Order 2000.

shall do so if –

- (a) the information contained in the register shows that the applicant was, or may have been, born in consequence of treatment services, and
 - (b) the applicant has been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.
- (4) 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 other than a parent of the applicant would or might, but for sections 27 to 29 of this Act, be a parent of the applicant and, if it does show that –
 - (a) giving the applicant so much of that information as relates to the person concerned as the Authority is required to give (but no other information), or
 - (b) stating whether or not that information shows that, but for sections 27 to 29 of this Act, the applicant, and a person specified in the request as a person whom the applicant proposes to marry, would or might be related.
- (5) Regulations cannot require the Authority to give any information as to the identity of a person whose gametes have been used or from whom an embryo has been taken if a person to whom a licence applied was provided with the information at a time when the Authority could not have been required to give information of the kind in question.
- (6) A person who has not yet attained the age of eighteen (“the minor”) may by notice to the Authority specifying another person (“the intended spouse”) as a person whom the minor proposes to marry require the Authority to comply with a request under subsection (7) below, and the Authority shall do so if –
 - (a) the information contained in the register shows that the minor was, or may have been, born in consequence of treatment services, and
 - (b) the minor has been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.
- (7) The minor may request the Authority to give the minor notice stating whether or not the information contained in the register shows that, but for sections 27 to 29 of this Act, the minor and the intended spouse would or might be related.

Section 33

(as amended by the Human Fertilisation and Embryology (Disclosure of Information) Act 1992)

- (1) No person who is or has been a member or employee of the Authority shall disclose any information mentioned in subsection (2) below which he holds or has held as such a member or employee.

- (2) The information referred to in subsection (1) above is –
 - (a) any information contained or required to be contained in the register kept in pursuance of section 31 of this Act, and
 - (b) any other information obtained by any member or employee of the Authority on terms or in circumstances requiring it to be held in confidence.
- (3) Subsection (1) above does not apply to any disclosure of information mentioned in subsection (2)(a) above made –
 - (a) to a person as a member or employee of the Authority,
 - (b) to a person to whom a licence applies for the purposes of his functions as such,
 - (c) so that no individual to whom the information relates can be identified,
 - (d) in pursuance of an order of a court under section 34 or 35 of this Act,
 - (e) to the Registrar General in pursuance of a request under section 32 of this Act, or
 - (f) in accordance with section 31 of this Act.
- (4) Subsection (1) above does not apply to any disclosure of information mentioned in subsection (2)(b) above –
 - (a) made to a person as a member or employee of the Authority,
 - (b) made with the consent of the person or persons whose confidence would otherwise be protected, or
 - (c) which has been lawfully made available to the public before the disclosure is made.
- (5) No person who is or has been a person to whom a licence applies and no person to whom directions have been given shall disclose any information falling within section 31(2) of this Act which he holds or has held as such a person.
- (6) Subsection (5) above does not apply to any disclosure of information made –
 - (a) to a person as a member or employee of the Authority,
 - (b) to a person to whom a licence applies for the purposes of his functions as such,
 - (c) so far as it identifies a person who, but for sections 27 to 29 of this Act, would or might be a parent of a person who instituted proceedings under section 1A of the Congenital Disabilities (Civil Liability) Act 1976, but only for the purpose of defending such proceedings or instituting connected proceedings for compensation against that parent,
 - (d) so that no individual to whom the information relates can be identified,
 - (e) in pursuance of directions given by virtue of section 24(5) or (6) of this Act,
 - (f) necessarily –

- (i) for any purpose preliminary to proceedings, or
 - (ii) for the purposes of, or in connection with, any proceedings,
 - (g) for the purpose of establishing, in any proceedings relating to an application for an order under subsection (1) of section 30 of this Act, whether the condition specified in paragraph (a) or (b) of that subsection is met, or
 - (h) under section 3 of the Access to Health Records Act 1990 (right of access to health records)
- (6A) Paragraph (f) of subsection (6) above, so far as relating to disclosure for the purposes of, or in connection with, any proceedings, does not apply –
- (a) to disclosure of 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 to this Act, for the purposes of treatment services in consequence of which an identifiable individual was, or may have been, born, 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.
- (6B) In the case of information relating to the provision of treatment services for any identifiable individual –
- (a) where one individual is identifiable, subsection (5) above does not apply to disclosure with the consent of that individual;
 - (b) where both a woman and a man treated together with her are identifiable, subsection (5) above does not apply –
 - (i) to disclosure with the consent of them both, or
 - (ii) if disclosure is made for the purpose of disclosing information about the provision of treatment services for one of them, to disclosure with the consent of that individual.
- (6C) For the purposes of subsection (6B) above, consent must be to disclosure to a specific person, except where disclosure is to a person who needs to know –
- (a) in connection with the provision of treatment services, or any other description of medical, surgical or obstetric services, for the individual giving the consent,
 - (b) in connection with the carrying out of an audit of clinical practice, or
 - (c) in connection with the auditing of accounts.

- (6D) For the purposes of subsection (6B) above, consent to disclosure given at the request of another shall be disregarded unless, before it is given, the person requesting it takes reasonable steps to explain to the individual from whom it is requested the implications of compliance with the request.
- (6E) In the case of information which relates to the provision of treatment services for any identifiable individual, subsection (5) above does not apply to disclosure in an emergency, that is to say, to disclosure made –
- (a) 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 with whose consent the information could be disclosed under subsection (6B) above, and
 - (b) in circumstances where it is not reasonably practicable to obtain that individual's consent.
- (6F) In the case of information which shows that any identifiable individual as, or may have been, born in consequence of treatment services, subsection (5) above does not apply to any disclosure which is necessarily incidental to disclosure under subsection (6B) or (6E) above.
- (6G) Regulations may provide for additional exceptions from subsection (5) above, but no exception may be made under this subsection –
- (a) for disclosure of a kind mentioned in paragraph (a) or B) of subsection (6A) above, or
 - (b) for disclosure in circumstances in which section 32 of this Act applies, of information having the tendency mentioned in subsection 92) of that section.”
- (7) This section does not apply to the disclosure to any individual of information which –
- (a) falls within section 31(2) of this Act by virtue of paragraph (a) or (b) of that subsection, and
 - (b) relates only to that individual or, in the case of an individual treated together with another, only to that individual and that other.
- (8) At the end of Part IV of the Data Protection Act 1984 (Exemptions) there is inserted –

35A.

Personal data consisting of information showing that an identifiable individual was, or may have been, born in consequence of treatment services (within the meaning of the Human Fertilisation and Embryology Act 1990) are except from the subject access provisions except so far as their disclosure under those provisions is made in accordance with section 31 of that Act (the Authority's register of information).

- (9) In subsection (6)(f) above, references to proceedings include any formal procedure for dealing with a complaint.

11.9 If the information referred to in paragraph 11.8 of this *Code of Practice* falls within the exceptions in Section 33 of the HFE Act, it will be subject to the procedure for providing access set out in the Data Protection Act 1998 summarised in paragraph 12.6 below. Additional exceptions⁸ and modifications⁹ to the Data Protection Act 1998 are expected to also have been taken into account before access is given.

The Human Fertilisation And Embryology Act 1990

11.10 The HFE Act Section 33(5) sets out the general rule on the disclosure of certain information by centres. Information about any identifiable person who receives treatment services, provides gametes or is born as a result of treatment services can generally only be disclosed to members and staff of the HFEA or to someone else who is covered by a licence for the purpose of licensed activities. This general rule is subject to the following exceptions as set out in the HFE Act Section 33(6)-(7):

- (i) Information about an identifiable person who receives treatment services or provides gametes can be disclosed to that person
- (ii) Information about an identifiable person who receives treatment services can also be disclosed
- (iii) With that person's consent to specified people, or to unspecified people who need to know in connection with treatment or carrying out a clinical or financial audit. The procedure for obtaining consent is set out in paragraphs 6.5 – 6.9. The consent is expected to be in writing and thoroughly discussed beforehand with the person to whom the information relates. In the case of consent to disclosure to unspecified people, centres are expected to always satisfy themselves that the information is disclosed only to someone who really needs to know the identity of the person seeking treatment
- (iv) In an emergency, i.e. where it is necessary to avert imminent danger to the health of the person to whom the information relates, and where it is not reasonably practicable to obtain that person's consent. If it is reasonably practicable to obtain consent in an emergency, and that consent is refused or not requested, then the information must not be disclosed
- (v) Information about an identifiable person may be disclosed if it is necessary for any purpose preliminary to, or in connection with, proceedings including any formal procedure for dealing with complaints. This is subject to the following exceptions:

⁸ *The provisions of the Access to Health Records Act 1990 still apply to the right of access by the personal representatives of deceased persons to his/her health records relevant to a claim arising out of a patient's death.*

⁹ *Account must be taken of the Data Protection (Subject Access Modification) (Health) Order 2000.*

- (a) no information may be disclosed which enables a donor to be identified where an identifiable individual was or may have been, born as a result of treatment with that donor's gametes
 - (b) where the proceedings involve an application for determination of legal parentage and the information may be disclosed is relevant to that determination. In these circumstances, a court may order information to be disclosed by the Authority, provided that the information is relevant to those proceedings, it is in the interests of justice to order disclosure and account has been taken of the welfare of any children who may be affected by the disclosure
- (vi) A court may order information to be disclosed for the purpose of establishing whether the conditions for making a parental order in a surrogacy case are fulfilled. Identifying information may be disclosed in connection with formal court proceedings for the purpose of establishing the genetic parentage of a child who is subject to an application for a parental order in a surrogacy case
- (vii) Under the Access to Health Records Act 1990 information held on health records about a patient that has died may be disclosed subject to certain safeguards to the patient's Personal Representative or to any person who may have a claim arising from the death. Access may not be given to any part of the patient's record if it contains a note made at the patient's request that he/she did not wish access to be given on such an application¹⁰

11.11 Information can also be disclosed if it cannot lead to the identification of anyone to whom the information relates.

11.12 Centres are expected to ensure that people to whom they disclose identifying information are aware that the information remains protected by the existing common law on confidentiality. Those receiving information are expected to also be advised that if it is not kept confidential, a child might learn in an inappropriate way that they were born as a result of treatment services (see paragraphs 5.6 – 5.8).

11.13 Centres are expected to have clear security procedures which will prevent unauthorised access to records, and particular care is expected to be taken where records are kept outside the licensed premises, e.g. when counselling takes place outside the centre. If confidentiality is breached, the centre is expected to investigate and deal with the breach and submit a full explanation to the HFEA. If it appears that a criminal offence has been committed the centre is expected to inform the police but where the centre is in any doubt it is expected to consult the HFEA.

¹⁰ For Northern Ireland see *Access to Health Records (Northern Ireland) Order 1993 SI 1993/1250 as amended by the Data Protection Act 1998 Schedules 15 and 16.*

11.14 Centres are expected to have appropriate security measures in place for all record keeping systems. These are expected to include data held on paper, electronically or any other type of system.

People Involved In An Egg Sharing Arrangement

11.15 In addition to paragraphs 11.1-11.14 above, the records of the egg provider and the egg recipient(s) are expected to be kept separate to maintain anonymity.

Annex A

Data Protection (Miscellaneous Subject Access Exemptions) Order 2000

2.
 - (1) The Data Protection (Miscellaneous Subject Access Exemptions) Order 2000 shall be amended as follows.
 - (2) In Part II of the Schedule to that Order, under “(a) Adoption records and reports”, after “Regulations 6 and 14 of the Adoption Agencies Regulations 1983[3]” omit “, so far as they relate to records and other information in the possession of local authorities”.
 - (3) In Part III of the Schedule to that Order, under “(a) Adoption records and reports”, after “Regulation 23 of the Adoption Agencies (Scotland) Regulations 1996[4]” omit “, so far as it relates to records and other information in the possession of local authorities”.

Annex B

Data Protection Act 1998

Section 18

18.

- (1) Any data controller who wishes to be included in the register maintained under section 19 shall give a notification to the Commissioner under this section.
- (2) A notification under this section must specify in accordance with notification regulations-
 - (a) The registrable particulars,
and
 - (b) A general description of measures to be taken for the purpose of complying with the seventh data protection principle
- (3) Notification regulations made by virtue of subsection (2) may provide for the determination by the Commissioner, in accordance with any requirements of the regulations, of the form in which the registrable particulars and the description mentioned in subsection (2)(b) are to be specified, including in particular the detail required for the purposes of section 16(1)(c), (d), (e) and (f) and subsection (2)(b).
- (4) Notification regulations may make provision as to the giving of notification-
 - (a) By partnerships
or
 - (b) In other cases where two or more persons are the data controllers in respect of any personal data
- (5) The notification must be accompanied by such fee as may be prescribed by fees regulations.
- (6) Notification regulations may provide for any fee paid under subsection (5) or section 19(4) to be refunded in prescribed circumstances.

Part 12 – Confidentiality

General Obligations

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 33

- (5) No person who is or has been a person to whom a licence applies and no person to whom directions have been given shall disclose any information falling within section 31(2) of this Act which he holds or has held as such a person.

- 12.1 Information obtained by treatment centres from people seeking treatment or considering donation must be kept confidential, unless disclosure of any information is authorised by law. Certain information may be disclosed in circumstances authorised by the HFE Act (see also Part 11 of this *Code of Practice*). Where a treatment centre is in doubt about disclosing information, it is expected to consult the HFEA.

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

(As amended by the Human Fertilisation and Embryology (Disclosure Of Information) Act 1992)

Section 33

- (6) Subsection (5) above does not apply to any disclosure of information made:
- (a) to a person as a member or employee of the Authority,
 - (b) to a person to whom a licence applies for the purposes of his functions as such,
 - (c) so far as it identifies a person who, but for sections 27 to 29 of this Act, would or might be a parent of a person who instituted proceedings under section 1A of the Congenital Disabilities (Civil Liability) Act 1976, but only for the purpose of defending such proceedings, or instituting connected proceedings for compensation against that parent,
 - (d) so that no individual to whom the information relates can be identified,
 - (e) in pursuance of directions given by virtue of section 24(5) or (6) of this Act,
 - (f) necessarily –

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

- (g) for the purpose of establishing, in any proceedings relating to an application for an order under subsection (1) of section 30 of this Act, whether the condition specified in paragraph (a) or (b) of that subsection is met, or
- (h) under section 3 of the Access To Health Records Act 1990 (right of access to health records).

6(A) Paragraph (f) of subsection (6) above, so far as relating to disclosure for the purposes of, or in connection with, any proceedings, does not apply –

- (a) to disclosure of 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 to this Act, for the purposes of treatment services in consequence of which an identifiable individual was, or may have been, born, 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.

6(B) In the case of information relating to the provision of treatment services for any identifiable individual –

- (a) where one individual is identifiable, subsection (5) above does not apply to disclosure with the consent of that individual;
- (b) where both a woman and a man treated together with her are identifiable, subsection (5) above does not apply –
 - (i) to disclosure with the consent of them both, or
 - (ii) if disclosure is made for the purpose of disclosing information about the provision of treatment services for one of them, to disclosure with the consent of that individual.

6(C) For the purposes of subsection (6B) above, consent must be to disclosure to a specific person, except where disclosure is to a person who needs to know –

- (a) in connection with the provision of treatment services, or any other description of medical, surgical or obstetric services, for the individual giving the consent,
- (b) in connection with the carrying out of an audit of clinical practice, or
- (c) in connection with the auditing of accounts.

- 6(D) For the purposes of subsection (6B) above, consent to disclosure given at the request of another shall be disregarded unless, before it is given, the person requesting it takes reasonable steps to explain to the individual from whom it is requested the implications of compliance with the request.
- 6(E) In the case of information which relates to the provision of treatment services of any identifiable individual, subsection (5) above does not apply to disclosure in an emergency, that is to say, to disclosure made –
- (a) 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 with whose consent the information could be disclosed under subsection (6B) above, and
 - (b) in circumstances where it is not reasonably practicable to obtain that individual's consent.
- 6(F) In the case of information which shows that any identifiable individual was, or may have been, born in consequence of treatment services, subsection (5) above does not apply to any disclosure which is necessarily incidental to disclosure under subsection (6B) or (6E) above.
- 6(G) Regulations may provide for additional exceptions from subsection (5) above, but no exception may be made under this subsection –
- (a) for disclosure of a kind mentioned in paragraph (a) or (b) of subsection (6A) above, or
 - (b) for disclosure, in circumstances in which section 32 of this Act applies, of information having the tendency mentioned in subsection (2) of that section.
- (7) This section does not apply to the disclosure to any individual of information which –
- (a) falls within section 32(2) of this Act by virtue of paragraph (a) or (b) of that subsection, and
 - (b) relates only to that individual or, in the case of an individual treated together with another, only to that individual and that other.
- (8) At the end of Part IV of the Data Protection Act 1984 (Exemptions) there is inserted –
- “Information about human embryos, etc.
- 35A. Personal data consisting of information showing that an identifiable individual was, or may have been, born in consequence of treatment services (within the meaning of the Human Fertilisation and Embryology Act 1990) are exempt from the subject access provisions except so far as their disclosure under those provisions is made in accordance with section 31 of that Act (the Authority's register of information).”

- (9) In subsection (6)(f) above, references to proceedings include any formal procedure for dealing with a complaint.

Disclosure Without Consent

- 12.2 The HFE Act states that information about the provision of treatment services for any identifiable individual or the keeping or use of an embryo taken from any identifiable woman may – in general – only be disclosed to the HFEA, a person named on a centre’s licence for the purpose of their functions, or to the particular patient concerned. However, information about the provision of treatment services for an identifiable individual may also be disclosed either:
- (i) With the consent of every person to whom the information relates
or
 - (ii) In an emergency, where disclosure is necessary to avert imminent danger to the health of the individual to whom the information relates and it is not reasonably practicable to obtain the consent of that individual

If it is practicable to obtain consent in an emergency and there is a failure to request that consent, or such consent is refused, the information must not be disclosed.

- 12.3 Also, if disclosing the identity of any resulting child cannot be avoided as a result of disclosing the treated person’s name with consent or in an emergency, this is not against the law.

Disclosure With Consent

- 12.4 Where consent has been given, information relating to the provision of treatment services for an identifiable individual may only be disclosed where both of the following conditions are also met:
- (i) Reasonable steps have been taken to explain the implications of disclosure of any information to the individual before their consent is given
and
 - (ii) The person(s) to whom the information is to be disclosed is specified in the consent form (e.g. a solicitor or interpreter), or is someone who needs information in connection with either providing treatment services or other medical, surgical or obstetric services to the individual, carrying out an audit of clinical practice or in connection with the auditing of accounts

(For other circumstances where information may be disclosed see Part 11 of this *Code of Practice*.)

12.5 The provision of relevant information to clinicians and others involved in treatment or diagnosis is usually in the interests of the individual concerned. However, patients do have the right to decide if any information is to be disclosed and to whom (except in emergency situations). Therefore treatment centres are expected to seek each patient's written consent for disclosure of information which relates to the provision of treatment services to them (see also the model consent form in Appendix B).

Centres must:

- (i) Tell the individual whose consent is sought precisely what information is to be disclosed
- (ii) Explain fully:
 - (a) the reasons for disclosure (e.g. so that a GP can be kept informed about the fertility treatment)
 - (b) the implications of disclosure so that a fully-informed decision can be made. This will include the fact that once disclosed the information will no longer be covered by the special provisions of the HFE Act but only by the general law of confidentiality (see Part 11)
- (iii) Either specify the individual to whom the information is to be disclosed or, specify the organisation to whom the information is to be disclosed where the disclosure is required in connection with either:
 - (a) the provision of treatment services, or any other medical, surgical obstetric services for the individual giving consent
 - or
 - (b) the audit of clinical practice
 - or
 - (c) the audit of accounts
- (iv) Renew the consent of the individual(s) if treatment which has not initially involved consent subsequently does so

12.6 Treatment centres must take particular care where consent is provided for information to be disclosed to an unspecified individual. Centres are expected to take care to ensure that any person to whom the information is disclosed *does* need to know the information in connection with the provision of treatment or other medical, surgical or obstetric services (see also Part 11 on disclosure of information in connection with medical and financial audits).

12.7 Treatment centres are expected to:

- (i) Make clear to the recipients of such information the precise terms upon which it is disclosed and for which consent has been given

- (ii) As far as possible, ensure that those recipients only record details of treatment services on the patient's record and not on those of a resulting child or children

12.8 Where a treatment centre refers a patient seeking treatment to another licensed treatment centre, it is expected that relevant information should be provided in accordance with the requirements of good clinical practice. Information relevant to the welfare of the child is always expected to be supplied.

People Involved In Gamete Donation Or Egg Sharing Arrangements

Additional Safeguards

- 12.9 In addition to the above, centres are expected to take extra care in respect of the separation of provider and recipient notes, facilities and procedures in treatment involving egg sharing and gamete and embryo donation.
- 12.10 It is expected that particular care should be taken to ensure that confidentiality is not compromised, for example where the woman donating/sharing eggs and the woman receiving them are treated at the same centre at similar times.

Part 13 – Complaints

General Obligations

13.1 The treatment centre is expected to ensure that written procedures are in place for acknowledging and investigating complaints, as well as collecting suggestions and compliments. The centre's procedure for dealing with complaints is expected to include:

- (i) The nomination of a member of the centre's staff as a complaints officer who is expected to be:
 - (a) as the first point of contact when a patient complains and
 - (b) responsible for the effective operation of the complaints procedure together with the investigation of complaints
- (ii) The maintenance of an accurate complaints register including, for each complaint:
 - (a) an explanation of the steps taken
 - (b) records of oral or written communications with the complainant
 - (c) a record of the outcome and action taken

It is expected that the complaints log is kept by, or under the supervision of, the complaints officer who, together with any other staff involved in the complaints procedure, is expected to receive appropriate training.

13.2 The centre is expected to inform the HFEA annually on the form provided of the number of written complaints received, their outcome (and those unresolved) during the previous 12 months.

13.3 The centre is expected to ensure that centre staff are fully conversant with the right of a patient to complain and the appropriate procedure to be followed. An independent element is expected to be included in the investigation where appropriate. Staff are expected to understand that whilst complaints may appear to be trivial to them, they may nonetheless be of great concern to the complainant. Staff are expected not to deter patients from making formal complaints if they so wish.

- 13.4 The centre is expected to display notices prominently in reception areas explaining the complaints procedure, including the name and location of the complaints officer. It is expected that this information will also be given to patients (see paragraph 5.5 above). If someone feels unable to raise their complaint with the nominated complaints officer there is expected to be someone else available of at least the equivalent seniority.
- 13.5 It may often be appropriate to deal with minor complaints as they arise without invoking a formal complaints procedure. Staff are expected to deal promptly and conscientiously with such issues as they arise. If a patient remains dissatisfied as a result of the investigation of their complaint, they are expected to be made aware of whatever wider procedure might be available to them e.g. the Health Commissioner in the NHS.
- 13.6 In NHS treatment centres/clinics, these procedures are expected to be in accordance with standards required of NHS services and as set out in this *Code of Practice* (see Annex B). In private treatment centres/clinics, the procedures are expected to be in accordance with the standards required by the National Care Standards Commission in England or the Care Commission in Scotland or the Care Standards Inspectorate Wales in Wales or the relevant successor body and as set out in this *Code of Practice* (see Annex A as an example of the provisions applicable in England).

Annex A

Independent centres providing licensed and unlicensed fertility treatment

The Private and Voluntary Health Care (England) Regulations 2001

Relevant Legislation

CONDUCT OF HEALTH CARE ESTABLISHMENTS AND AGENCIES

CHAPTER 1

QUALITY OF SERVICE PROVISION

Complaints

23.

- (1) The registered person shall establish a procedure (in these Regulations referred to as “the complaints procedure”) for considering complaints made to the registered person by a patient or a person acting on behalf of a patient.
- (2) The registered person shall ensure that any complaint made under the complaints procedure is fully investigated.
- (3) The registered person shall supply a written copy of the complaints procedure to every patient and, upon request, to .
 - (a) any person acting on behalf of a patient; and
 - (b) any person who is considering whether to become a patient.
- (4) The written copy of the complaints procedure shall include.
 - (a) the name, address and telephone number of the Commission; and
 - (b) the procedure (if any) which has been notified by the Commission to the registered person for making complaints to the Commission relating to the establishment or agency.

- (5) The registered person shall maintain a record of each complaint, including details of the investigations made, the outcome and any action taken in consequence and the requirements of regulation 21(3)(b) and (c) shall apply to that record.
- (6) The registered person shall supply to the Commission annually a statement containing a summary of the complaints made during the preceding twelve months and the action taken in response.

Independent centres are expected to follow the core standards set by the Department of Health in *Independent Health Care: National Minimum Standards* as follows:

Complaints Process

STANDARD C14

C14.1

The registered person ensures that there is a written policy and procedures for handling and investigating complaints about all aspects of service, care and treatment provided in, or on behalf of, the establishment/agency and that such a policy includes the stages and time-scales for the process.

C14.2

All complainants receive a written acknowledgement within two working days of receipt of their complaint (unless a full reply can be sent within five working days).

C14.3

A full response is made within 20 working days of receipt of the complaint, or where the investigation is still in progress, a letter explaining the reason for the delay is sent to the complainant and a full response made within five days of a conclusion being reached.

C14.3

The complaints procedure ensures that the complainant receives written confirmation of the stages of investigation and action taken.

C14.4

The complaints procedure is brought to the attention of all personnel (i.e. all staff, agency staff and practitioners with practising privileges), and they receive training on: what constitutes a complaint; the procedures for receiving and dealing with a complaint.

C14.5

Those staff involved in the provision and procedural elements of the complaints procedure are trained in its operation.

C14.6

A register of complaints, including information on whether or not the complaint was upheld, the results of investigation, the action taken and the resolution of complaints is maintained.

C14.7

Procedures are in place that enable issues raised in complaints to be learnt from in order to improve practice.

Information For Patients About Complaints

STANDARD C15

C15.1

The complaints procedure or information based upon it is accessible to patients and their family members/carers.

C15.2

Where requested the patient and/or family members or carers are given support in using the complaints procedure.

C15.3

Where care and treatment are provided to children, staff are aware of the difficulties a child faces in expressing concerns or complaints and how the child is expected to be helped to overcome these.

Annex B

NHS Centres Providing Licensed And Non Licensed Treatment

NHS centres providing licensed and non licensed treatment are expected to follow the general standards (above) set out by the HFEA and the NHS guidelines for dealing with patient complaints as outlined below:

- (i) Centres are expected to send a full written reply from the relevant chief executive or complaints manager within four weeks of receiving a complaint. If this cannot be achieved the patient is expected to be kept informed of any progress.
- (ii) If a patient is not satisfied with the outcome of this, the patient can within 28 days of receiving the written reply, ask for an independent review. This will be considered by a convener who will decide within four weeks, whether to refer the matter back for further investigation or to set up an independent review panel or take no further action as a result of an independent review panel's recommendation.
- (iii) The independent review panel will re-examine the concerns put to it, and will produce a report which sets out the results of the investigation, along with the conclusions of any appropriate comments or suggestions. The patient is expected to be sent a copy of the report. A chief executive is expected to write to the patient and tell them of any action being taken as a result of the panel's recommendation.
- (iv) If the patient is still not satisfied once the NHS complaints procedure has been completed, the patient can ask the Health Service Commissioner (sometimes known as the Ombudsman) to investigate their case. The Ombudsman is independent of both Government and the NHS. They do not have to investigate every complaint, but will usually do so if there is clear evidence of hardship or injustice.

Part 14 – Preimplantation Testing

Definitions

- 14.1 Preimplantation genetic diagnosis (PGD) is a technique which involves the genetic testing of embryos created *in vitro* for deleterious, heritable genetic conditions which are known to be present in the family of those seeking treatment and from which the embryos are known to be at risk. The technique typically involves several stages: the creation of an embryo *in vitro*, the removal of one or more blastomeres, the genetic testing of those blastomeres for certain genetic conditions and the transfer of suitable embryos to a woman. The purpose of PGD is to provide information that allows unaffected embryos to be selected for transfer. People seeking PGD may have different requirements from those requiring IVF to overcome fertility problems since they are not necessarily infertile.
- 14.2 Preimplantation screening is to be distinguished from preimplantation genetic diagnosis in which a pre-existing diagnosis indicates that an embryo is at significant risk of being affected by a serious inherited genetic condition. Preimplantation screening refers to techniques whereby certain categories of patient thought to be at a higher than average risk of conceiving abnormal embryos have their embryos tested to determine whether certain abnormalities are present.
- 14.3 The purpose of preimplantation genetic screening for aneuploidy (abnormal number of chromosomes) is to help those seeking fertility treatment to achieve a successful pregnancy and to reduce the risk of miscarriage. Whilst it helps to identify chromosomally abnormal embryos, aneuploidy screening does not necessarily identify normal embryos. In some cases, information discovered through preimplantation testing may help those who have been unable to conceive or carry children identify the underlying basis of their infertility.

Polar Body/Blastomere Biopsy

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 17

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

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

14.4 A polar body/blastomere biopsy practitioner is defined as the person who removes polar bodies or cells from the egg or embryo for the purpose of PGD or preimplantation genetic screening (PGS).

14.5 Polar body/blastomere biopsy may only be carried out by trained, competent staff recognised as such by the HFEA.

Licensing Of Preimplantation Testing

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 3

(1) No person shall –

- (a) bring about the creation of an embryo, or
- (b) keep or use an embryo,
except in pursuance of a licence.

Schedule 2, Paragraph 1

(1) A licence under this paragraph may authorise any of the following in the course of providing treatment services –

[...]

- (d) practices designed to secure that embryos are in a suitable condition to be placed in a woman or to determine whether embryos are suitable for that purpose,
- (e) placing any embryo in a woman,

[...]

(2) Subject to the provisions of this Act, a licence under this paragraph may be granted subject to such conditions as may be specified in the licence and may authorise the performance of any of the activities referred to in sub-paragraph (1) above in such manner as may be so specified.

14.6 Centres may only carry out preimplantation tests for those genetic conditions, chromosomes or traits (or combinations of these), and using those specific tests (or combinations of tests),

listed in the preimplantation testing Annex to their licence or approved by a licence committee in any particular case.

- 14.7 Centres must submit an application to the HFEA for each new condition for which they wish to test and for each new test that they wish to use¹¹.
- 14.8 Centres wishing to test a single embryo for more than one genetic condition or trait must apply to the HFEA for each specific combination of tests that they propose to use, irrespective of whether the centre is already licensed to use each of the tests individually.
- 14.9 Embryos from which biopsies have been taken, or resulting from gametes from which biopsies have been taken, may not be transferred with any other (non-biopsied) embryos in the same treatment cycle.
- 14.10 Centres may not use any information derived from tests on an embryo, or any material removed from it or from the gametes that produced it, to select embryos of a particular sex for social reasons.

Accreditation Of Genetics Laboratories

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 17

- (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
[...]
 - (d) that suitable practices are used in the course of the activities

- 14.11 All genetics laboratories used for preimplantation testing are expected to be Clinical Pathology Accreditation (CPA) accredited (or equivalent) or at least be working towards CPA, with accreditation to be completed within five years.

¹¹ The HFEA produces separate detailed guidance on submitting new preimplantation testing applications.

PREIMPLANTATION GENETIC DIAGNOSIS

Staff Involved

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 17

- (1) It shall be the duty of the individual under whose supervision the activities authorised by a licence are carried on (referred to in this Act as the “person responsible”) to secure –
- (a) that the other persons to whom the licence applies are of such character, and are so qualified by training and experience, as to be suitable persons to participate in the activities authorised by the licence

14.12 It is expected that a multidisciplinary team will be involved in the provision of the PGD service, including reproductive specialists, embryologists, clinical geneticists, infertility counsellors, genetic counsellors, cytogeneticists and molecular geneticists. This team is expected to maintain close contact with the primary care physician or the referring clinician, and treatment is expected to also encompass continued support of patients following PGD.

Genetic Consultation

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 13

- (6) A woman shall not be provided with any treatment services [...] unless the woman being treated and, where she is being treated together with a man, the man have been given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and have been provided with such relevant information as is proper.

14.13 People seeking treatment are expected to have access to both clinical geneticists and genetic counsellors.

14.14 Ideally, people seeking treatment are expected to be referred to the treating centre by a Regional Genetics Centre. However, all those seeking treatment are expected to at least be known to an accredited clinical geneticist.

14.15 Centres are expected to work closely with the local genetics team of those seeking treatment.

Patient Information

14.16 The patient information for PGD is expected to include reference to the process, procedures and risks involved in undertaking IVF and biopsy procedures in the context of the provision of a sophisticated genetic test. References are expected to be made to the experience of the clinic in carrying out the procedure.

14.17 Information provided to those seeking treatment to be taken into account is expected to include:

- (i) Genetic and clinical information about the specific condition
- (ii) Its likely impact on those affected and their families
- (iii) Information about treatment and social support available
and
- (iv) Where the family has no direct experience of the condition, the testimony of families and individuals about the full range of their experiences of living with the condition

14.18 Where information about the particular genetic disorder has already been provided, for example by a regional genetics centre, it will not be necessary to provide this information again. If this is the case, the treatment centre is expected to satisfy itself that this information has already been provided to a satisfactory standard.

14.19 The possible outcomes of genetic testing and their implications are expected to have been fully explored with those seeking treatment prior to PGD being undertaken.

Clinical Decision Making

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 13

- (5) A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for a father), and of any other child who might be affected by the birth

14.20 The decision to use PGD is expected to be made in consideration of the unique circumstances of those seeking treatment, rather than the fact that they carry a particular genetic condition.

14.21 Indications for the use of PGD are expected to be consistent with current practice in the use of (post-implantation) prenatal diagnosis (PND).

14.22 It is expected that PGD will be available only where there is a significant risk of a serious genetic condition being present in the embryo. The perception of the level of risk by those seeking treatment is an important factor in the decision making process. The seriousness of the condition is expected to be a matter for discussion between the people seeking treatment and the clinical team.

14.23 In any particular situation the following factors are expected to be considered when deciding the appropriateness of PGD:

- (i) The view of the people seeking treatment of the condition to be avoided
- (ii) Their previous reproductive experience
- (iii) The likely degree of suffering associated with the condition
- (iv) The availability of effective therapy, now and in the future
- (v) The speed of degeneration in progressive disorders
- (vi) The extent of any intellectual impairment
- (vii) The extent of social support available
- and
- (viii) The family circumstances of the people seeking treatment

PREIMPLANTATION GENETIC SCREENING FOR ANEUPLOIDY

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Schedule 2, Paragraph 1

- (1) A licence under this paragraph may authorise any of the following in the course of providing treatment services –
- [...]
- (d) practices designed to secure that embryos are in a suitable condition to be placed in a woman or to determine whether embryos are suitable for that purpose

14.24 Preimplantation genetic screening (PGS) for abnormal number of chromosomes (aneuploidy screening) may be performed either on blastomeres removed from cleavage stage embryos or on first and second polar bodies removed from eggs/embryos during *in vitro* fertilisation.

14.25 It is expected that PGS for aneuploidy will only to be used in the treatment of the following categories of patient:

- (i) Women over 35 years of age
- (ii) Women with a history of recurrent miscarriage not caused by translocations or other chromosomal rearrangements
- (iii) Women with several previous failed IVF attempts where embryos have been transferred
or
- (iv) Women with a family history of aneuploidy not caused by translocations or other chromosomal rearrangements

Patient Information

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 13

- (6) A woman shall not be provided with any treatment services [...] unless the woman being treated and, where she is being treated together with a man, the man have been given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and have been provided with such relevant information as is proper.

14.26 Patient information for PGS for aneuploidy is expected to include reference to the process, procedures and risks involved in undertaking IVF and biopsy procedures. Reference is expected to be made to the experience of the clinic in carrying out the procedure. Patients are expected to be also informed in writing:

- (i) That embryos that have been biopsied may not be suitable for cryopreservation and use in subsequent treatment cycles
- (ii) That the more tests that are used to examine the chromosomes, the greater the likelihood of finding chromosome abnormalities (whether they are biologically significant or not), and thus the lower the chance of finding suitable embryos for transfer
- (iii) Of the procedure to be followed in the case of a diagnostic failure
- (iv) That there is no guarantee against a miscarriage occurring despite preimplantation aneuploidy screening being performed
- (v) That patients are recommended to undergo prenatal screening
- (vi) Of the financial costs of treatment
and
- (vii) Of the possible emotional burden should a successful pregnancy not result following PGS for aneuploidy

14.27 Centres are expected to inform patients that genetic counselling is available and are expected to make arrangements to provide such counselling if required.

Recording And Reporting Of Information

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Section 12

The following shall be conditions of every licence granted under this Act—

[...]

(d) that proper records shall be maintained in such a form as the Authority may specify in directions,
[...]

(g) that the Authority shall be provided, in such form and at such intervals as it may specify in directions, with such copies of or extracts from the records, or such other information, as the directions may specify.

Section 13

(1) The following shall be conditions of every licence under paragraph 1 of Schedule 2 to this Act.

(2) Such information shall be recorded as the Authority may specify in directions about the following—
[...]

(f) such other matters as the Authority may specify in directions.

14.28 The Person Responsible at a centre must notify the Authority in writing before clinical polar body/blastomere biopsy procedures are first carried out by a particular practitioner at that centre (see General Direction D.2003/1).

14.29 Twelve months after a polar body/blastomere biopsy practitioner has been recognised as competent, the Person Responsible must provide the Authority with the information set out in the appropriate Schedule to General Direction D. 2003/1.

14.30 Where information submitted to the HFEA indicates a significant break in the proposed practitioner's practice of polar body/blastomere biopsy, the Authority may require re-examination of the person's competence in the relevant technique.

14.31 For each treatment cycle involving preimplantation testing, the Person Responsible must record the information set out in the appropriate Schedule to General Direction D. 2003/1.

Part 15 – Witnessing Clinical And Laboratory Procedures

General

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

13.

- (1) The following shall be conditions of every licence under paragraph 1 of Schedule 2 to this Act.
- (2) Such information shall be recorded as the Authority may specify in Directions about the following –
 - (e) any mixing of egg and sperm and any taking of an embryo from a woman or other acquisition of an embryo, and
 - (f) such other matters as the Authority may specify in directions.

12.

The following shall be conditions of every licence granted under this Act –

- (d) that proper records shall be maintained in such form as the Authority may specify in directions,

Directions on records of witnessing clinical and laboratory procedures Ref: D 2002/1

All licensed centres are expected to have procedures in place to double-check the identification of:

- (i) The individuals undergoing treatment
- (ii) The sperm and eggs at the time of insemination
- (iii) The embryos and the patient at the time of embryo transfer
- (iv) The gametes and embryos at the time of cryopreservation and thawing

The core standards required for witnessing clinical and laboratory practices are found in Annex A Chairman's Letter CH (02) 01. All licensed centres were expected to introduce these standards into their work practice from 1st October 2002. In addition centres are expected to document all witnessing procedures in the patient's medical records.

Protocol For Witnessing Clinical And Laboratory Procedures

In accordance with the Chair's letter, centres are expected to adopt the following witnessing procedures for:

Egg Collection

15.1 Centres are expected to:

- (i) Ask the patient her name and date of birth in the presence of at least two members of staff. This information must be cross-checked against the patient's medical records and laboratory data sheet
- (ii) Ask the patient to give their name etc i.e. the response must not be a passive *yes / no* to a name read out, the response must be active
- (iii) Cross-reference identifying information marked on all culture dishes/tubes (lids and dishes) to the patient and the patient's documentation by the embryologist and another appropriate person

Sperm Sample

15.2 Centres are expected to:

- (i) Ask the male partner to identify himself (name and date of birth)
- (ii) Ensure an appropriate person witness that the patient's details correspond with the details written on the sample container and all corresponding paperwork

Sperm Preparation

15.3 Centres are expected to:

- (i) Ensure that identifying information marked on all tubes is cross-referenced to the male partner and all corresponding documentation by the embryologist/andrologist and another appropriate person
- (ii) Not have more than one unprocessed sample in the processing area at any one time

Insemination/ICSI

15.4 Centres are expected to:

- (i) Ensure that the patient's identifying information on the tube containing the sperm preparation and on all dishes containing eggs is confirmed by an appropriate person
- (ii) Ensure that the mixing of sperm and eggs must be witnessed by an appropriate person

Fertilisation Check

15.5 Centres are expected to:

- (i) Ensure that identifying information marked on all culture dishes is cross-referenced to the patient and the patient's documentation by the embryologist and another appropriate person

Embryo Transfer

15.6 Centres are expected to:

- (i) Ask the patient to identify herself (name and date of birth) in the presence of the doctor or nurse who will carry out the embryo transfer and an embryologist
- (ii) Ask patients to give their name etc i.e. the response must not be a passive *yes / no* to a name read out, the response must be active
- (iii) Ensure that this information is cross-checked against the patient's medical records and laboratory data sheet
- (iv) Ensure that two appropriate persons verify that the identifying information on the dish containing the embryos corresponds to the patient and the patient's documentation

Gamete/Embryo Freezing

15.7 Centres are expected to:

- (i) Ensure that all ampoules/straws are clearly labelled with no less than two methods of identification
- (ii) Ensure that two appropriate persons verify that the name on the tubes/dishes containing the gametes/embryos matches the name on the ampoules/straws
- (iii) Ensure that the storage of all material is witnessed by two appropriate persons

Removal Of Cryopreserved Material

15.8 Centres are expected to:

- (i) Ensure that two appropriate persons verify that the name on the ampoules/straws matches the information in the patient's medical records
- (ii) Ensure that two appropriate persons must witness the removal of all material from storage

Donor Insemination

15.9 Centres are expected to:

- (i) Ask the patient to identify herself (name and date of birth) in the presence of the doctor or nurse who will carry out the insemination and a second appropriate person
- (ii) Ensure that a witness confirms the matched donor and observes all labelling of tubes/ampoules before the semen sample is used

15.10 All witnessing procedures must be fully documented in the patient's medical records in accordance with Directions on records of witnessing clinical and laboratory procedures (Ref: D 2002/1).

Part 16 – Intra-Cytoplasmic Sperm Injection (ICSI)

General

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Schedule 2

Activities For Which Licences May Be Granted

Licences for treatment

- 1(1) A licence under this paragraph may authorise any of the following in the course of providing treatment services –
- (a) bringing about the creation of embryos *in vitro*,
- (2) Subject to the provisions of this Act, a licence under this paragraph may be granted subject to such conditions as may be specified in the licence and may authorise the performance of any of the activities referred to in sub-paragraph (1) above in such manner as may be so specified.

Intra-Cytoplasmic Sperm Injection (ICSI) is a specialised and novel area of clinical biology which is seen to require specific standards with respect to the facilities and competence of practitioners. At present it is only two areas of clinical biology which require a licence within the overall context of the treatments offered by clinics licensed by the HFEA.

Under the HFE Act treatments involving *in vitro* fertilisation must be carried out in licensed centres, therefore, clinical ICSI is expected to be carried out within a standard IVF setting against a background of existing clinical protocols within a licensed centre.

Definitions

ICSI is the type of IVF (*in vitro* fertilisation) treatment that involves the injection of a single sperm straight into an egg.

The ICSI practitioner is defined as the person who injects the spermatozoon into the egg.

ICSI Practitioners

16.1 Centres must ensure that:

- i) Clinical ICSI is carried out only by trained competent staff recognised as such by the Authority
- ii) The Person Responsible at a centre notifies the Authority before clinical ICSI procedures are first carried out by a particular practitioner at that centre
- iii) Three months after a new ICSI practitioner has been recognised as competent, the Person Responsible provides the Authority with the information set out in the proforma attached to Annex B of the Chief Executive's Letter CE(97)[4]

Conditions i, ii and iii reinforce that clinical ICSI is to be carried out by suitably trained competent staff only. The Authority recognises that there are various ways in which centres can train their embryologists to perform ICSI.

- iv) When applying for an ICSI licence the Person Responsible provides the Authority with the information set out in Annex B of the Chief Executive's Letter CE (97) [4]. (An ICSI practitioner is defined as the person who injects the spermatozoon into the egg)

16.2 Centres are expected to ensure that:

- i) A complete log book proforma for the newly qualified ICSI practitioner is signed off by the Person Responsible and made available to the HFEA for inspection. See guidance for centres Annex B (CE (97) [4])
- ii) An application is not made for an ICSI licence unless the potential practitioner has achieved a damage rate of less than 25% in respect of 50 consecutive human eggs
- iii) Candidates can demonstrate that they are aware of the HFEA's requirements about ICSI
- iv) All newly licensed ICSI practitioners are expected to submit a three month progress report (proforma). See guidance for centres Annex B (CE (97)[4])

Recognised ICSI Practitioners

16.3 Centres must ensure that:

- i) The Person Responsible at a centre notifies the Authority before clinical ICSI procedures are first carried out by a particular practitioner at that centre

The Authority will continue to require details regarding patient selection criteria, the information about ICSI provided for patients, consent forms, protocols, procedures and results as set out in Annex B (reference CE (97)[4]). In recognition of the important role played by the ICSI practitioner, the Authority will also require detailed information regarding the performance of each ICSI practitioner at the centre.

Where an embryologist/ICSI practitioner has had significant time away from practice e.g. maternity leave, the embryologist/ICSI practitioner and the Person Responsible are expected to make the decision as to when the individual is fit to perform clinical ICSI. Once satisfied, the Person Responsible is expected to sign the logbook and notify the HFEA accordingly.

Licensing Obligations

16.4 Centres must ensure that:

- i) ICSI is expected to only be carried out by recognised ICSI practitioners who have demonstrated technical competence
- ii) ICSI and other embryos are expected to only be transferred during the same treatment cycle in exceptional circumstances, with an upper limit of 2% of all ICSI embryo transfers
- iii) The circumstances justifying such a transfer is expected to be specified in the patient's notes and such cycles are expected to be notified to the Authority on a monthly basis¹²
- iv) Oocytes which have failed after 24 hours to fertilise by normal IVF procedure are not to be used in ICSI treatment

The Authority takes the view that there is insufficient evidence supporting the safety of ICSI using ageing eggs since the chromosomal status of the oocyte is uncertain.

Factors To Be Considered

16.5 Centres are expected to produce protocols describing the reasons for the use of ICSI and these reasons are expected to be documented in the patient files. The circumstances in which ICSI may be appropriate include:

- i) When the sperm count is low
- ii) When the sperm cannot move properly or are in other ways abnormal
- iii) When sperm has been retrieved directly from the epididymis (PESA)¹³ or the testicles (TESA/TESE)¹⁴, from the urine, or by electro-ejaculation

¹² An upper limit per centre of 2% of mixed ICSI/IVF embryo transfers per annum is allowed. See Chairman's Letters CH (99) 5 28 October 1999.

¹³ PESA – Percutaneous epididymal sperm aspiration.

¹⁴ TESA / TESE – Testicular sperm aspiration / extraction.

- iv) When there are high levels of antibodies in the semen
- v) When there have been previous fertilisation failures
- vi) Men who have very few sperm (oligospermia) or no sperm (azoospermia) in their semen, or who have high numbers of abnormal sperm that are unable to fertilise an egg, or who previously have had little or no chance of fathering their own genetic offspring

16.6 Centres are expected to ensure that their patient information at the very minimum includes the information contained in the current HFEA's patient leaflet on ICSI.

16.7 The patient information is expected to include the following information about the risks of ICSI:

- i) Risks involved with ICSI
- ii) Possible inheritance of genetic and chromosomal abnormalities including the following:
 - (a) inheritance of cystic fibrosis gene mutations
 - (b) sex chromosome defects and the inheritance of sub-fertility
- iii) Abnormal numbers or structures of chromosomes
- iv) Novel chromosomal abnormalities
- v) Possible developmental and birth defects
- vi) Possible risks during pregnancy such as miscarriage

Centres are expected to refer to the current HFEA leaflet on ICSI for further guidance.

Appendix A

GUIDANCE FOR EGG SHARING ARRANGEMENTS

Background

The HFEA has drawn up guidance for HFEA licensed treatment centres offering or intending to offer licensed treatments involving an egg sharing arrangement. Egg sharing must be documented on a centre's licence.

Throughout this guidance the term 'egg provider' is used to describe the woman sharing her eggs. The term 'egg recipient' is used for the woman receiving some or any these eggs.

Any egg sharing arrangement where the egg provider is herself undergoing licensed treatment is expected to be subject to this guidance. Treatment centres are reminded that this is a unique situation in which the egg provider is both an IVF patient and an egg donor. The HFEA recognises there may be a potential conflict of interest in egg sharing arrangements but this is expected not to interfere with the clinical care that is provided at any given treatment centre.

Consent And Agreements

In addition to the required statutory consent, two additional and separate agreements are expected to be drawn up for egg sharing arrangements. One is expected to be between the egg provider and the treatment centre, and the other between the egg recipient(s) and the treatment centre (see below). Where there are few eggs available, the arrangement for egg sharing is expected not to compromise the egg provider's treatment (see below).

Treatment centres are expected to draw up agreements between themselves and the egg providers and themselves and the egg recipients. Treatment centres are expected to ensure that the information contained in the agreement for the egg provider is consistent with that in the agreements of the egg recipient(s). Treatment centres are expected to obtain their own legal advice on the content and possible legal consequences of their agreements. The following is a guide to the kind of information that is expected to be included in these agreements.

Agreement Between A Licensed Treatment Centre And The Egg Provider

The agreement between the treatment centre and the egg provider is expected to set out the terms of the arrangement in full. It is expected to clearly identify the egg provider and the treatment centre, and be signed by both parties. The agreement is expected to include narrative including:

i) General

A statement confirming that:

- a) Any patient consenting to the donation of eggs under the HFE Act will not be the legal parent of any child/children resulting from the donation
- b) In any anonymous egg sharing arrangement, the treatment centre can release non identifying information to the donor only where:
 - ¹ the egg recipient and her partner/husband have consented in writing to this information being released
 - ¹ the donor has consented in writing to the treatment centre for this information to be released to her
 - ¹ and appropriate counselling has been offered to all parties involved in the egg sharing arrangement

ii) Treatment

A statement from the patient confirming that they have:

- (a) Had an opportunity to discuss the treatment procedures involved in providing her eggs as part of an egg sharing arrangement with a qualified member of the treatment centre's staff
- (b) Received both verbal and written information about the treatment provided
- (c) Received all the required information listed in the relevant Parts of the HFEA's *Code of Practice* (this information could be attached to the agreement) and
- (d) Been offered counselling about the implications of the treatment

The nature of the treatment is expected to be set out in full. This is expected to include:

- (a) The number of cycles of treatment involved
- (b) The date upon which treatment will commence and
- (c) Full details of the egg sharing arrangement (more guidance on this is given below)

The nature and duration of the treatment covered by the agreement is expected to be clear. The patient and treatment centre are encouraged to confirm that the treatment and payment for that treatment will be carried out in accordance with the agreement and that both parties are bound by this agreement.

iii) Consent

A statement confirming:

- (a) That consent of the patient for the treatment has been obtained
- (b) That two HFEA statutory consent forms 00(7) have been completed (see additional note on consent)
- (c) That this agreement does not override the terms of Paragraph Four of Schedule 3 of the HFE Act. (This means that the egg provider may withdraw or vary her consent in respect of any embryo created using her egg at any time until that embryo is used for treatment or research) and
- (d) The consequences of any withdrawal of consent and the liability of the parties involved and any additional costs that may occur

iv) Cost

A statement describing:

- (a) What costs (if any) are expected to be paid by the egg provider to the treatment centre and
- (b) The circumstances that would result in the egg provider being liable for the total cost and the total sums they would have to pay (see also below)

v) Egg Sharing Arrangements

The agreement relating to egg sharing is expected to make it clear that where there are fewer eggs collected than the minimum needed for sharing, the egg provider is expected to be given the option of using all the eggs at no additional cost to her.

The agreement is expected to also cover full details of the egg sharing arrangements, including:

- (a) The minimum number of eggs required for sharing
- (b) How these eggs will be allocated
- (c) Whether or not the egg provider will be liable to pay for any of the costs of the treatment (If the treatment is free, an appropriate caveat could be included if the egg provider becomes liable for payment if she varies her consent at any time before the embryos are used for treatment/or research)

Agreement Between A Licensed Treatment Centre And The Egg Recipient

The agreement between the treatment centre and the egg recipient is expected to set out the terms of the arrangement in full. It is expected to clearly identify the egg recipient and the treatment centre, and be signed by both parties. The agreement is expected to also include narrative including:

i) General

A statement confirming that:

- (a) Any patient that has given effective consent to donate eggs under the HFE Act will not be the legal parent of any child(ren) resulting from the donation
- (b) In an anonymous egg sharing arrangement, the centre can release non identifying outcome information to the donor only where:
 - ¹ egg recipient and her partner/husband treated together have consented in writing to this information being released and
 - ¹ the donor has consented in writing to this information to be released to her and
 - ¹ appropriate counselling has been given to all parties involved in the egg sharing arrangement

ii) Treatment

A statement from the patient confirming that they have:

- (a) Had an opportunity to discuss with a qualified member of the treatment centre's staff the treatment procedures involved in receiving eggs as part of an egg sharing arrangement
- (b) Received verbal and written information about the treatment provided
- (c) Received all the required information listed in the relevant sections of the HFEA's *Code of Practice* (this information could be attached to the agreement) and
- (d) Been offered counselling about the implications of the treatment

The nature of the treatment of the egg recipient is expected to be set out in full. This is expected to include:

- (a) The number of cycles of treatment involved
- (b) The date upon which treatment will commence
- (c) Details of the egg sharing arrangement

and

- (d) As part of the treatment of the egg recipient she will be provided with eggs from an egg provider donor

The egg provider will also have undergone treatment procedures to obtain the eggs to be donated to the egg recipient. The nature and duration of the recipient's treatment and the egg-provider's treatment covered by the agreement is expected to be clearly specified.

The patient and treatment centre are expected to confirm that the treatment and payment for it will be carried out in accordance with the agreement and that both parties are bound by this agreement.

iii) Consent

A statement that this agreement does not override the terms of Paragraph Four of Schedule 3 of the HFE Act. (This means that the egg provider may withdraw or vary her consent in respect of any embryo created using her egg at any time until that embryo is used for treatment or research.)

iv) Cost

A statement describing:

- (a) What costs the egg recipient is liable for and
- (b) What treatment services these costs will cover. (This may include all or part of the egg provider's treatment and is expected to be stated clearly in the agreement)

Appendix B

CONSENT TO DISCLOSURE OF IDENTIFYING INFORMATION ABOUT MY/OUR FERTILITY TREATMENT TO ANOTHER PERSON WHO IS NOT COVERED BY A LICENCE

Introduction

This form documents your consent to disclosure of your identifying information to individuals who are not covered by a Treatment Licence. Your consent to disclosure allows individuals that are not covered by the centre's Treatment Licence to access your information. The law requires that any information that centres obtain from people considering treatment or gamete/embryo donation must be kept confidential. Your consent to disclosure is a legal requirement by the Human Fertilisation and Embryology Act 1990. You may withdraw your consent to disclosure at any time up to the point a treatment event has occurred.

Information about you, your medical treatment, and family background may be recorded, either on paper or in computer files, as part of providing you with fertility treatment. This information is very important in providing you with the best possible treatment.

You have choices on how a centre uses your personal information, however, some information is vital to the provision of your treatment.

Patient name (wife/partner):

Patient name (husband/partner):

- 1) **I/we understand** the implication of consenting to the disclosure of identifying information about my/our treatment and this has been explained to me/us.

I/we understand that I/we do not have to consent to all or any of the following:

- 2) **I/we consent** to disclosure of identifying information about my/our fertility treatment:

To my/our General Practitioner/s (specify name(s))

for the purpose of providing information about my/our fertility treatment.

but

I/we **do not consent** to the following information being disclosed:

- 3) I/we **consent to disclosure of identifying information** about my/our fertility treatment to other people (unspecified) who need to know for the purposes of (tick as applicable):

- ☐ my/our fertility treatment or other medical, surgical or obstetric treatment;
☐ a medical audit (monitoring the unit's performance)
☐ auditing the unit's accounts.
☐ inspection by the National Care Standards Commission, or the Care Commission in Scotland or the Care Standards Inspectorate Wales, or the relevant successor body.

but

I/we **do not consent** to disclosure to the following people for the following purposes:

and, I/we **do not consent** to the following information being disclosed:

Signed (wife/female partner)

_____ Date _____

Signed (husband/male partner)

_____ Date _____

Confirmation of Consent

On behalf of the team treating the patient, I have confirmed with the patient/s they have no further questions.

Signed (Health Care professional)

_____ Date _____

Important notes: (tick if applicable)

Patient has withdrawn consent: ☐

Interpreter required: ☐

Appendix C

GUIDANCE ON SCREENING FOR HIV INFECTION FOR LICENSED CENTRE PRODUCED BY THE HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY IN CO-OPERATION WITH THE DEPARTMENT OF HEALTH.

As with all organs and tissue for transplantation donors of gametes (semen and eggs) must be shown to be free of infection with HIV. This entails testing the blood of donors for HIV antibody at the time donations are made. Antibodies may not appear in the blood for up to three or possibly six months after infection. In order to avoid transplanting gametes collected during this “window” period of infection, donors of gametes which are stored before use (semen) are expected to be tested a second time for HIV antibody at least 180 days after the first test. When the donation must be used immediately (eggs) there is a slight risk that donor infection will not be identified.

Centres are expected to assess the suitability of individual donors including any possible history of transmissible infection. The informed consent of the person concerned is expected to be obtained before any HIV test is carried out. Donors are expected to be advised of the practical implications of having an HIV test, even if it proves negative. Where an individual is at risk or is shown to be HIV positive, the treatment centre is expected to offer counselling from the treatment centre’s own qualified counsellor and also arrange specialist HIV counselling.

It is expected that semen will be used only for others when immediate and 180 day tests for HIV antibody are negative. In no circumstances is it expected that donated semen be used which has been collected less than 180 days before the most recent negative HIV antibody test.

At the beginning of the treatment and collection cycle of a woman whose eggs are to be taken for the treatment of others, her blood is expected to be tested for the presence of HIV antibodies. If treatment and collection are to take place some time after the initial assessment, a preliminary sample is expected to also be tested at the time of the initial assessment. The eggs are expected only to be used if the HIV antibody test is negative. The small risk of HIV infection is expected to be explained to the recipient of donated eggs.

It is expected that the blood of both people whose gametes were used to produce an embryo will be tested for HIV antibodies if and when they decide to make the embryo available for the treatment of others. It is expected that stored embryos will not be used if they have been created less than 180 days before the most recent negative antibody tests on both donors.

Centres are expected to adopt any additional guidance on HIV testing which is given by the Department of Health.

Appendix D

PARENTAL ORDERS IN SURROGACY CASES

Condition which must be fulfilled before a parental order can be granted

- ¹ The child must be genetically related to at least one of the commissioning couple
- ¹ The surrogate parents must have consented to the making of the order (unless incapable of giving consent or are untraceable) no earlier than six weeks after the birth of the child
- ¹ The commissioning couple must be married to each other, and both must have reached the age of 18
- ¹ The commissioning couple must have applied for an order within six months of the child's birth
- ¹ No money, other than expenses, must have been paid in respect for the surrogacy arrangement, unless authorised by a court
- ¹ The child must be living with the commissioning couple
- ¹ The commissioning couple must be domiciled in the United Kingdom, the Channel Islands or the Isle of Man

Application forms for parental orders will be available from Family Proceedings Courts (Magistrate Courts) in the commissioning couple's home area. Legal Services Commission funding may be available to cover parental order proceedings.

In any proposed surrogacy situations where the above requirements would not be met would need to take account of the requirements of the Adoption Act 1972. This requires the involvement of an approved adoption agency and other requirements.

Situations that may arise that would mean a parental order could not be applied for include:

- (i) The commissioning parents are not married
- (ii) There is no genetic link between the commissioning parents and the baby the surrogate is carrying. This would be, for example, where donor sperm had been used in a partial surrogacy arrangement (i.e. using the surrogate's egg) or donated embryos had been used to initiate the pregnancy
- (iii) Payment beyond reasonable expenses had been given to the surrogate mother
- (iv) The commissioning parents are not domiciled in the United Kingdom, the Channel Islands or the Isle of Man

Centres must not offer surrogacy in these situations unless they have taken account of the legal requirements of the Adoption Act 1972ⁱ. This would include the need to involve a registered adoption agency prior to the birth of the baby and the full adoption procedure would need to be gone through. Where a child is born to a surrogate mother, the placement of that child with the commissioning couple for them to adopt may involve a breach of the Adoption Act 1972. Centres are in danger of breaching the Adoption Act 1972 if they set up or offer to set up a surrogacy arrangement that could not result in an application for a parental order being applied for.

Registration of birth in surrogacy cases

Surrogate parents (birth mother and her partner/husband) are the legal parents of a child born through a surrogacy arrangement until legal parentage is transferred to the commissioning couple. The surrogate mother must therefore register the baby to which she has given birth in the normal way. Her husband or partner is expected to normally be registered as the father.

When a parental order has been granted by a court, the Registrar General will make an entry in a separate Parental Order Register re-registering the child. This will be cross-referenced with the entry in the Register of Births. It will not be possible for the public to make a link between entries in the Register of Births and the Parental Order Register. It will be possible for adults who are the subject of parental orders to gain access, after being offered counselling, to their original birth certificates.

ⁱ Section 11 of the Adoption Act 1972, provides that an adoption shall not make arrangements of the adoption of a child or place a child for adoption, unless (a) the proposed adopter is a relative of the child and he is acting in pursuance of an order of the High Court.

Appendix E

CONSENT TO TREATMENT INVOLVING EGG RETRIEVAL AND/OR EGG OR EMBRYO REPLACEMENT

Name of Centre: _____

Address: _____

Name of woman: _____

Address: _____

This consent form is in two parts. These may be signed separately. When frozen embryos are being replaced they are expected to be signed separately.

Part I

1. I consent to [delete/complete as applicable]:

i. be prepared for egg retrieval

ii. the removal of eggs from my ovaries with the aid of:

a) laparoscopy

b) ultrasound

iii. the administration of any drugs and anaesthetics which may be found necessary in the course of the procedure(s)

iv. the mixing of the following [tick each column as required]:

☐ my egg(s)

☐ with the sperm of my husband/partner

☐ eggs donated by

☐ with sperm donated by

☐ an anonymous donor's egg(s)

☐ with an anonymous donor's sperm

2. I understand that if the anonymous donor has given effective consent under the Human Fertilisation and Embryology Act 1990, the donor will not be the legal parent of any resulting child.
3. I have discussed with _____ the procedures outlined above.
I have been given information orally and in writing about them.
4. I have been given a suitable opportunity to take part in counselling about the implications of the proposed treatment. (For GIFT using donated sperm or eggs, or any IVF treatment.)

Patients's Signature:

_____ **Date** _____

Part II

1. I consent to:
 - i. the placing in my uterus or fallopian tube[s], as may be appropriate, of not more than (tick as applicable):
 - a) 1 ☐ egg(s) mixed with sperm in accordance with the consent given in
Part 1 (iv) above
 - 2 ☐_____
 - b) 1 ☐ embryo(s) created in accordance with the consent given in
Part 1 (iv) above
 - 2 ☐_____
 - ii. the administration of any drugs and anaesthetics which may be found necessary in the course of the procedure(s);
2. I understand that only the egg[s] from one woman and sperm from one man will be used in any one treatment cycle.
3. I have discussed with _____ the procedures outlined above.
I have been given information orally and in writing about them.
4. Other remarks (if required):

 Patients's Signature:

 Date _____

5. All the information listed in paragraph 6.5 of the Human Fertilisation and Embryology Authority's *Code of Practice* has been given to the patient. The patient has been offered a suitable opportunity to take part in counselling about the implications of the proposed treatment.

 Doctor's Signature:

 Date _____

HUSBAND'S CONSENT

I am the husband of _____ and I consent to the course of treatment outlined above. I understand that I will become the legal father of any resulting child.

Any other remarks:

Signature of husband:

 Date _____

Full name in block capitals: _____

Address:

NOTE: the centre is not required to obtain a husband's consent in order to make the treatment lawful, but where donated sperm is used it is advisable in the interests of establishing the legal parenthood of the child. See paragraphs 6.35 – 6.36 of the HFEA Code of Practice.

MALE PARTNER'S ACKNOWLEDGEMENT

I am not married to, but I acknowledge that she and I are being treated together, and that I will become the legal father of any resulting child.

Any other remarks:

Signature of male partner:

_____ Date _____

Full name in block capitals: _____

Address:

NOTE: the centre is not required to obtain a partner's consent in order to make the treatment lawful, but where donated sperm is used it is advisable in the interests of establishing the legal parenthood of the child. See paragraphs 6.35 – 6.36 of the HFEA Code of Practice.

Appendix F

GUIDELINES FROM PROFESSIONAL ORGANISATIONS

The purpose of the HFEA *Code of Practice* is to give guidance about the proper conduct of licensed activities. In this respect, the *Code of Practice* covers those areas that are specific to the carrying out of embryo research, IVF, donor insemination and related treatments. Most treatment centres also provide other services, and this *Code of Practice* assumes that everybody working in HFEA licensed centres will at all times observe the general standards and requirements of good professional practice. For each professional group these standards will be set out in relevant guidance and need not be repeated in this *Code of Practice*.

There are a number of professional guidelines from other organisations that are particularly relevant to the provision of licensable activities in HFEA licensed centres. In some respects these are more far reaching than the HFEA *Code of Practice*, covering, for example, areas of professional standards and training. These include:

- ¹ *Accreditation Standards And Guidelines For IVF Laboratories*, Association of Clinical Embryologists , March 1999
- ¹ *Guidelines For The Screening Of Semen Donors For Donor Insemination*, British Andrology Society 1999, Human Reproduction 14 (7)1823-1826
- ¹ *Embryo Transfer: Recommendations For Good Practice*, British Fertility Society, Human Reproduction 12 Natl. Suppl. JBFS 2(2) 88-92 1997
- ¹ *The Management Of Infertility In Tertiary Care*, Royal College of Obstetricians and Gynaecologists, January 2000
- ¹ *Guidance On The Inspection And Provision Of Counselling In Assisted Conception Centres*, British Infertility Counselling Association, October 1999
- ¹ *Guidelines For Nurses Carrying Out Embryo Transfers And Intrauterine Insemination*, Royal College of Nursing, 2000
- ¹ *Guidelines for Nurses Carrying out Egg Retrieval*, Royal College of Nursing, 2000
- ¹ *Recommendations For Good Practice On The Screening Of Egg And Embryo Donors*, British Fertility Society, 2000 Human Fertility (2000) 3, 62-165

OTHER RELEVANT GUIDELINES

General standards

- ¹ *National Minimum Standards And Regulations For Independent Health Care*, Department of Health, 2002
- ¹ *Code Of Professional Conduct*, Nurses and Midwifery Council, 2002
- ¹ *Good Medical Practice*, General Medical Council, 2001
- ¹ *The Initial Investigation And Management Of The Infertile Couple*, Royal College of Obstetricians and Gynaecologists, 1998

- ¹ *The Management Of Infertility in Secondary Care*, Royal College of Obstetricians and Gynaecologists, 1998
- ¹ *Gynaecological Examinations Guidelines For Specialist Practice*, Royal College Of Obstetricians and Gynaecologists, 2002
- ¹ *Ethical Framework For Good Practice In Counselling And Psychotherapy*, British Association For Counselling And Pyschotherapy, 2002
- ¹ *Codes of Practice For Social Care Workers And Employers*, General Social Care Council, 2002

Consent

- ¹ *Reference Guide To Consent For Examination Or Treatment*, Department of Health, 2001
- ¹ *Seeking Patients' Consent: The Ethical Considerations*, General Medical Council, 1998

Safe sedation

- ¹ *Implementing And Ensuring Safe Sedation Practice For Healthcare Procedures In Adults*, Academy of Medical Royal Colleges, 2002

Good manufacturing practice

- ¹ *Guide To Good Manufacturing Practice For Medicinal Products*, 91/356/EEC, 1991
- ¹ *Rules And Guidance For Pharmaceutical Manufacturers And Distributors*, HMSO, 1997

Laboratory practice

- ¹ *The Control Of Substances Hazardous To Health Regulationsⁱ*, Statutory Instrument No 437, 1999
- ¹ *Safety In Health Service Laboratories: Safe Working And Prevention Of Infection In Clinical Laboratories*, Health Service Advisory Committee, 1991

Tissue storage and donation

- ¹ *Use Of Human Organs and Tissue: A Draft Interim Statement For Consultation By The Department of Health*, Department of Health, 2002
- ¹ *A Code Of Practice For Tissue Banks Providing Tissues Of Human Origin For Therapeutic Purposes*, Department of Health, 2001
- ¹ *Guidance On The Microbiological Safety of Human Organs, Tissues And Cells Used In Transplantation*, Department of Health, 2000

Communicable diseases

- ¹ *Protection Against Blood-borne Viruses In The Workplace: HIV And Hepatitis*, Advisory Committee On Dangerous Pathogens, 1995
- ¹ *Guidance For Clinical Health Care Workers: Protection Against Blood-borne Viruses*, Department of Health, 1998

ⁱ These guidelines contain specific guidance on containment levels for handling of samples where infection with various biological agents is suspected.

- 1 *Revised Advice On Laboratory Containment Measures For Work With Tissue Samples In Clinical Cytogenetics Laboratories*ⁱⁱ, Advisory Committee On Dangerous Pathogens, 2001
- 1 *HIV Infected Health Care Workers: A Consultation Paper On Management And Patient Notification*, Department of Health, 2002
- 1 *Note For Guidance On Minimising The Risk Of Transmitting Animal Spongiform Encephalopathy Agents Via Human And Veterinary Medicinal Products*, Medicines Central Agency, 2001
- 1 *Transmissible Spongiform Encephalopathy Agents: Safe Working And The Prevention Of Infection*, Advisory Committee On Dangerous Pathogens, 1998
- 1 *Protecting Health Care Workers And Patients From Hepatitis B*, Department Of Health, 1993 And Scottish Office, 2003
- 1 *Hepatitis B Infected Health Care Workers*, National Health Service Scotland, 2000
- 1 *Hepatitis C Infected Health Care Workers*, Scotland Health Department, 2002
- 1 *Guidance On The Management Of AIDS/HIV Infected Health Care Workers And Patient Notification*, National Health Service Scotland, 1999

Research (clinical and embryological)

- 1 *Research: The Role And Responsibilities Of Doctors*, General Medical Council, 2002
- 1 *Human Tissue And Biological Samples For Use In Research: Operational And Ethical Guidelines*, Medical Research Council, 2001
- 1 *Governance Arrangements For NHS Research Ethics Committees*, Department of Health, 2001
- 1 *Research Governance Framework For Health And Social Care*, Department of Health, 2001

Statutory instruments

- 1 Care Standards Act 2000
- 1 Children Act 1979
- 1 Data Protection Act 1998
- 1 Human Rights Act 1998
- 1 Health and Safety at Work Act 1974
- 1 Health and Social Care Act 2001
- 1 Medicines Act 1968
- 1 Medical Act 1983
- 1 The Control of Substances Hazardous to Health Regulations 1999
- 1 The Private and Voluntary Care (England) Regulations 2001

Every effort has been made for these guidelines and the HFEA *Code of Practice* to be complementary. Where differences are apparent, treatment centres are expected to be aware of these differences and of the measures of best practice generally given in professional guidelines. Treatment centres are expected to ensure that they remain up to date with revisions/updates to these guidelines and the HFEA *Code of Practice*.

ⁱⁱ *This guide contains guidance on the containment levels that are expected to be used for handling known, suspected or unknown contaminated samples.*

Appendix G

GUIDANCE ON REASONABLE EXPENSES FOR DONORS

The following gives an indication of the types of expenses that treatment centres are expected to reimburse to people providing gametes for donation. (Receipts are not required for any expense incurred that is less than £15, however treatment centres are expected to be provided with receipted evidence for expenses that exceed this amount).

- Travel** – All travel costs are expected to be reimbursed to people providing gametes for donation provided that a reasonable route and standard class travel has been used to get to the treatment centre. Taxis are expected to normally only be used where public transport facilities are unavailable, but this is a discretionary rule that centres may apply flexibly if they so wish.

Travel Rates

| | |
|-------------------------|------------------------------------|
| <i>Public Transport</i> | <i>Fully receipted if over £15</i> |
| <i>Taxi</i> | <i>Fully receipted if over £15</i> |
| <i>Car</i> | <i>£0.300 per mile</i> |
| <i>Motorcycle</i> | <i>£0.153 per mile</i> |
| <i>Bicycle</i> | <i>£0.053 per mile</i> |

The travel expenses of an accompanying person can also be reimbursed on this same basis.

- Accommodation** – Where a treatment centre judges that accommodation is needed, this is expected to be arranged and paid for by the treatment centre.

- Subsistence Rates**

| | |
|--|-----------------------|
| <i>Absence from home or a place of business (not exceeding five hours)</i> | <i>£2.50 per day</i> |
| <i>Exceeding five hours but not exceeding ten hours</i> | <i>£5.00 per day</i> |
| <i>Over ten hours</i> | <i>£10.00 per day</i> |

- Miscellaneous expenses** – Depending on the circumstances, treatment centres are at liberty to decide whether to reimburse a person providing gametes for donation for miscellaneous expenses – telephone calls/car parking/ postal costs etc.
- Financial loss allowance** – The maximum financial loss allowance is £50.00 per day. A treatment centre is expected to be provided with detailed evidence of the specific, financial loss incurred as a result of donating gametes

- 6. Childminding expenses** – People providing gametes for donation are expected to claim for childminding expenses if these were directly incurred as a result of donating gametes. A receipt or a letter signed by the childminder is expected to be submitted to the treatment centre.

The total daily amount that can be claimed for financial loss and childminding expenses cannot exceed the maximum daily limit of £50.00.

Appendix H

LICENCE CONDITIONS

The HFE Act 1990 imposes certain conditions into all licences issued by the Authority. Some conditions are imposed into all licences (Section 12), all treatment licences (Section 13), all storage licences (Section 14) and all research licences (Section 15). These statutory licence conditions cannot be varied, but a Licence Committee can grant a licence subject to such further conditions as may be specified in the licence. A number of Standard licence conditions have been developed that can be applied at the discretion of Licence Committees to particular licences. Examples of these Standard conditions are provided below. This is not an exhaustive list. Additional conditions can be applied to any licence at the discretion of a Licence Committee.

STATUTORY CONDITIONS

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990 SECTION 12 GENERAL CONDITIONS

- (1) The following shall be conditions of every licence granted under this Act-
- a) that the activities authorised by this licence shall be carried out only on the premises to which this licence relates and under the supervision of the person responsible,
 - b) that any member or employee of the Authority, on production, if so required, of a document identifying the person as such, shall at all reasonable times be permitted to enter those premises and inspect them (which includes inspecting any equipment or records and observing any activity),
 - c) that the provisions of Schedule 3 to the Act relating to consent to the use of gametes or embryos shall be complied with,
 - d) that proper records shall be maintained in such form as the Authority may specify in directions,
 - e) that no money or other benefit shall be given or received in respect of any supply of gametes or embryos unless authorised by directions,
 - f) that, where gametes or embryos are supplied to a person to whom another licence applies, that person shall also be provided with such information as the Authority may specify in directions,
 - g) that the Authority shall be provided, in such form and at such intervals as it may specify in directions, with such copies of or extracts from the records, or such other information, as the directions may specify,

SECTION 13 CONDITIONS OF TREATMENT LICENCES

- (1) The following shall be conditions of every licence under paragraph 1 of Schedule 2 to this Act.
- (2) Such information shall be recorded as the Authority may specify in directions about the following –
 - a) the persons for whom services are provided in pursuance of this licence,
 - b) the services provided for them,
 - c) the persons whose gametes are kept or used for the purpose of services provided in pursuance of this licence or whose gametes have been used in bringing about the creation of embryos so kept or used,
 - d) any child appearing to the person responsible to have been born as a result of treatment in pursuance of this licence,
 - e) any mixing of egg and sperm and any taking of an embryo from a woman or the acquisition of an embryo, and
 - f) such other matters as the Authority may specify in directions.
- (3) The records maintained in pursuance of this licence shall include any information recorded in pursuance of clause (6) above and any consent of a person whose consent is required under Schedule 3 to the Act.
- (4) No information shall be removed from any records maintained in pursuance of this licence before the expiry of such period as may be specified in directions for records of the class in question.
- (5) A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for a father), and of any other child who may be affected by the birth.
- (6) A woman shall not be provided with any treatment services involving-
 - a) the use of any gametes of any person, if that person's consent is required under paragraph 5 of Schedule 3 to the Act for the use in question,
 - b) the use of any embryo the creation of which was brought about in vitro, or
 - c) the use of any embryo taken from a woman, if the consent of the woman from whom it was taken is required under paragraph 7 of Schedule 3 for the use in question,

unless the woman being treated and, where she is being treated together with a man, the man have been given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and have been provided with such relevant information as is proper.

(7) Suitable procedures shall be maintained-

- a) for determining the persons providing gametes or from whom embryos are taken for use in pursuance of this licence, and
- b) for the purpose of securing that consideration is given to the use of practices not requiring the authority of a licence as well as those requiring such authority.

SECTION 14 CONDITIONS OF STORAGE LICENCES

(1) The following shall be conditions of every licence authorising the storage of gametes or embryos –

- a) that gametes of a person or an embryo taken from a woman shall be placed in storage only if received from that person or woman or acquired from a person to whom a licence applies and that an embryo the creation of which has been brought about in vitro otherwise than in pursuance of this licence shall be placed in storage only if acquired from a person to whom a licence 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,
- c) that no gametes or 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,
- d) that such information as the Authority may specify in directions as to the persons whose consent is required under Schedule 3 to the 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 this 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 five years as the licence may specify.

(5) Regulations may provide that sub-section (3) or (4) above shall have effect as if for ten years or, as the case may be, five 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.

The storage period in respect of gametes under the licence may be extended if the circumstances set out in the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 are applicable. In such a case, the period set out in those regulations shall be substituted for ten years in the condition imposed by Section 14(3).

The storage period in respect of embryos under the licence may be extended if the circumstances set out in the Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996 are applicable. In such a case, the period set out in those regulations shall be substituted for the period of five years in the condition imposed by Section 14(4).

SECTION 15 CONDITIONS OF RESEARCH LICENCES

- (1) The following shall be conditions of every licence under paragraph 3 of Schedule 2 to this Act.
- (2) The records maintained in pursuance of the licence shall include such information as the Authority may specify in directions about such matters as the Authority may specify.
- (3) No information shall be removed from any records maintained in pursuance of the licence before the expiry of such period as may be specified in directions for records of the class in question.
- (4) No embryo appropriated for the purposes of any project of research shall be kept or used otherwise than for the purposes of such a project.

STANDARD LICENCE CONDITIONS APPLICABLE TO ALL LICENCES

- (1) Where the centre proposes to introduce new activities or treatment services not specified in the licence, these may not be commenced until notification has been given to the Authority and where the Authority considers it necessary an application has been made to the Authority for a licence relating to the new activities and such a licence has been granted.
- (2) In support of an inspection the Authority shall be provided, within 28 days of a request in writing being made, with such information as specified in the written request or in directions.

- (3) In consideration of the grant of the licence (or its variation to designate the individual named in this licence as person responsible), agrees to pay to the Authority any additional fee, as defined in Section 16(6) of the 1990 Act, within 28 days of the date of the notice of such additional fee.
- (4) A copy of the certificate of licence (first page of the licence) describing the activities authorised by the licence must be displayed at the licensed premises in a position or positions in which it can easily be read by persons who are receiving treatment services or providing gametes or embryos for use for the purposes of activities governed by this Act, or may wish to do so.

LICENCE CONDITIONS APPLICABLE TO INTRA-CYTOPLASMIC SPERM INJECTION

- (1) With respect to any ICSI treatment programme the following conditions apply:
 - a) ICSI and other embryos should only be transferred during the same treatment cycle in exceptional circumstances, with an upper limit of 2% of all ICSI embryo transfers, and should only be carried out by ICSI practitioners who have demonstrated technical competence. The circumstances justifying such a transfer should be specified in the patient's notes and such cycles should be notified to the Authority on a monthly basis
 - b) That when applying for an ICSI licence the person responsible provides the Authority with information as set out in Annex B to letter CE(97)4 of 9 July 1997 (An ICSI practitioner is defined as the person who injects the spermatozoon into the egg)
 - c) That oocytes which have failed after 24 hours to fertilise by normal IVF procedure are not to be used in ICSI treatment
 - d) That clinical ICSI is carried out only by trained, competent staff recognised as such by the Authority
 - e) That the person responsible notifies the Authority before clinical ICSI procedures are first carried out by a particular practitioner at that centre
 - f) That three months after a new ICSI practitioner has been recognised as competent, the person responsible provides the Authority with appropriate information set out in the pro forma attached to Annex B of the letter CE(97)4 of 9 July 1997 from the Authority

LICENCE CONDITIONS APPLICABLE TO BLASTOMERE/POLAR BODY BIOPSY

- (1) With respect to any programme involving blastomere/polar body biopsy:
 - a) That embryos from which biopsies have been taken, or resulting from gametes from which biopsies have been taken, may not be transferred with any other (non-biopsied) embryos in the same treatment cycle
 - b) That no embryo or material removed from it may be subjected to a test which supplies genetic information about the embryo that is not listed in an annex to this licence or

specifically approved by a licence committee in any particular case

- c) That no embryo may be transferred to a woman where that embryo, or any material removed from it or from the gametes that produced it, has been subject to a test, which supplies genetic information about the embryo, that is not specifically listed in an annex to this licence or not specifically approved by a licence committee in any particular case
- d) That centres should not use any information derived from tests on an embryo, or any material removed from it or from the gametes that produced it, to select embryos of a particular sex for social reasons
- e) That blastomere / polar body biopsy is carried out only by trained competent staff recognised as such by the Authority

LICENCE CONDITIONS APPLICABLE TO ANY PREIMPLANTATION TESTING PROGRAMME

- (1) That preimplantation testing may only be carried out for those genetic conditions, chromosomes or traits (or combinations of these), and using those specific tests (or combinations of tests), listed in the preimplantation testing Annex to their licence or approved by a licence committee in any particular case.

LICENCE CONDITIONS APPLICABLE TO ANY PROGRAMME OF PREIMPLANTATION SCREENING FOR ANEUPLOIDY

- (1) That preimplantation genetic screening (PGS) for aneuploidy may only be carried out for the chromosomes, or combinations of chromosomes, and using the specific tests, or combinations of tests, specifically listed in the preimplantation testing Annex to the licence.
- (2) That centres should not use any information derived from tests on an embryo, or any material removed from it or from the gametes that produced it, to select embryos of a particular sex for social reasons.
- (3) That PGS for aneuploidy may only be used in the treatment of the following categories of patient:
 - (a) Women over 35 years of age
 - (b) Women with a history of recurrent miscarriage not caused by translocations or other chromosomal rearrangements
 - (c) Women with several previous failed IVF attempts where embryos have been transferred
 - (d) Women with a family history of aneuploidy not caused by translocations or other chromosomal rearrangements

- (4) That before the people seeking treatment give consent to preimplantation screening of embryos for aneuploidy they must be given an oral explanation supported by relevant written material:
- (i) Of the risks associated with the preimplantation screening for aneuploidy
 - (ii) Of the experimental nature of this procedure
 - (iii) That embryos that have been biopsied may not be available for cryopreservation and for use in subsequent treatment cycles
 - (iv) Of the misdiagnosis rates associated with the preimplantation screening for aneuploidy, including that the misdiagnoses rates can be positive and negative
 - (v) That the more chromosome tests that are used, the higher the technical failure rate, and the lower the chance of finding suitable embryos for transfer
 - (vi) That there is no guarantee against a miscarriage occurring, despite PGS for aneuploidy being performed
 - (vii) That it is recommended that patients are offered the option of prenatal screening
 - (viii) Of the centre's protocols for managing diagnostic or technical failure
 - (ix) Of the costs of treatment both financially and emotionally in the context of the chance of not taking home a baby following preimplantation screening for aneuploidy
 - (x) That counselling is available

LICENCE CONDITIONS APPLICABLE TO TREATMENT INVOLVING CRYOPRESERVED OOCYTES

- (1) The use of cryopreserved oocytes in treatment services shall be restricted to oocytes frozen at the preovulatory stage.
- (2) Before a woman gives consent to the storage and/or use of cryopreserved oocytes in treatment services she must be given an oral explanation supported by relevant written material:
 - (a) Of all risks associated with the cryopreservation and thawing of oocytes and
 - (b) That counselling is available
- (3) Donors of cryopreserved oocytes shall be subject to the existing screening requirements as set out in the *Code of Practice*.

- (4) The centre shall not mix in the same treatment cycle:
- (a) Fresh oocytes with oocytes that have been cryopreserved
 - (b) Embryos that have been created using cryopreserved oocytes with embryos created using fresh oocytes
 - or
 - (c) Cryopreserved embryos that have been created using cryopreserved oocytes with cryopreserved embryos that have been created using fresh oocytes

LICENCE CONDITIONS APPLICABLE TO TREATMENT CONDITIONS INVOLVING STORAGE OF OOCYTES WITHIN OVARIAN TISSUE

- (1) With respect to treatment involving storage of oocytes within ovarian tissue the following conditions apply:
- a) That any oocytes obtained from cryopreserved ovarian tissue, shall not be used in any treatment services until such time as the Authority is satisfied that sufficient evidence on safety and efficacy is available to justify the introduction in to clinical practice of the replacement of embryos resulting from cryopreserved ovarian tissue
 - b) That before a woman gives consent to the storage of oocytes within cryopreserved ovarian tissue for their intended use in treatment services, she must be given an oral explanation supported by the relevant written material:
 - (i) Oocytes obtained from cryopreserved ovarian tissue cannot be used in treatment
 - (ii) Of the risks associated with the removal, cryopreservation and thawing of ovarian tissue
 - and
 - (iii) That counselling is available

Appendix I

THE HFEA REGISTER

The HFEA keeps a confidential Register of information about donors, patients and treatments provided by HFEA licensed treatment centres. This Register was set up on 1st August 1991 and contains information concerning children conceived from licensed treatments from that date onwards.

People below the age of 18 who propose to marry another person, may ask the HFEA to give them notice stating whether the Register shows that they are, or might be, related to their intended spouse.

As the law currently stands no information about patients, their children and donors will be given out by the HFEA under any circumstances other than those outlined in the legislation above. The names of the children are not collected. The current law does not allow people who apply for information from the Register to know the identity of current or past donors, or of patients and their children. It is a criminal offence to disclose that information.

The kind of information the HFEA now collects relates to a donor's appearance, interests and occupation. In the future, Parliament might decide that adults who contact the HFEA and learn that they were born as a result of treatment using a donor might be given some non-identifying details about that donor. Parliament is currently considering the possibility of non-identifying information being made available to adults born from treatment with donor gametes. However, the law as it presently stands and the HFE Act (1990) forbids identifying details of current and past donors from being disclosed. A change in the law would be required to alter this position.

Index

- abroad, see foreign countries
- Acts and regulations, App.F
- administration, 2.4
- adverse incidents, 2.23
- advertising, 2.29
- age of gamete providers
 - donors, 4.22-4.25
 - persons seeking treatment, 3.7-3.10
- ampoules, safety issues, 2.15
- andrologists, 1.15
- aneuploidy, preimplantation screening, 14.3, 14.24-14.26
 - licensing conditions, App.H
- assessment
 - donors, 4.1-4.33
 - persons seeking treatment, 3.1-3.31
- azoospermia, ICSI in, 16.5
- biopsy, polar body, see polar body/blastomere biopsy
- birth registration, surrogacy cases, App.D
- blastomere biopsy, see polar body/blastomere biopsy
- blood products tested for infection, 2.11
- child
 - competence, 6.11
 - information which may be disclosed to, 5.6
 - welfare of, 3.11-3.15
 - donor insemination, 8.25
 - written record in respect of, 3.25
- chromosome abnormalities
 - ICSI risk of inheriting, 16.7
 - numerical abnormalities, see aneuploidy
- clinical facilities, 2.5-8
- clinical procedures/practice
 - monitoring/assessing/improving, 2.27-2.25
 - witnessing, 15.1-15.10
- Code of Practice for Tissue Banks, 9.3
- competence, children, 6.11
- complaints, 13.1-13.6
- confidentiality, 12.1-12.10
 - records, 11.3
 - see also disclosure
- conscientious objection by staff, 1.18
- consent, 6.1-6.52
 - disclosure with, 12.2-12.3, App.B
 - disclosure without, 12.4-12.5
 - to donation of gametes/embryos, 5.1-2, 5.7, 6.39-6.41
 - research donors, 5.8-9, 8.12
 - withdrawn, 6.41, 6.49-6.5
 - to egg sharing, 6.48-6.50, App.A
 - to examination, 6.1-2, 6.9
 - to export of gametes/embryos, 6.23, 8.3
 - general obligations regarding, 6.5-6.9
 - to GP contacting and enquiry, see general practitioner
 - guidelines on, App.F
 - to observer presence, 6.4
 - of partner, see partner
 - to storage of gametes/embryos, 5.1-2, 5.4, 6.14, 6.8, 6.42, 6.14-6.16,
 - withdrawing consent, 8.11
 - to treatment, 6.1-2, 6.9, 6.28, 6.31, App.E
 - to use of gametes/embryos, 5.1, 5.7, 6.8, 6.18-6.22, 8.5
 - posthumous use, 6.21, 6.24-6.27
 - varying or withdrawing consent terms, 5.4, 8.5
- contamination, 9.14
- cost in egg sharing, App.A
- counselling, 7.1-7.32
 - with child to raised abroad, 3.11
 - donors/donation, 7.16-7.18
 - implications counselling, 4.8, 7.16, 7.18
 - unsuitability of donor, 4.26
 - egg sharing, 3.30, 7.29-7.32
 - facilities for, 2.18-21
 - general obligations, 7.1-7.10

genetic counselling, see genetic counselling
 later counselling, 7.24
 monitoring/assessing/improving standards of
 practice, 2.27-2.28
 staff involved, 1.9
 support counselling, 7.2, 7.19-7.20
 therapeutic counselling, 7.4, 7.21-22
 see also information

criminal convictions (staff), 1.19

cryopreservation, see freezing

cryopreserved material, see frozen embryo; oocyte

cystic fibrosis, donor screening, 4.13

cytomegalovirus antibodies, donor screening, 4.16

Data Protection Act (1998), 11.4-9, 11(Annex B)
 exemptions, 11.9, 11(Annex A)

Data Protection (Miscellaneous Subject Access
 Exemptions) Order (2000), 11(Annex A)

death of gamete provider and posthumous use, 6.21,
 6.24-6.27, 8.34

disclosure (of information)

to child about donor, 5.6

with consent, 12.4-8, App.B

without consent, 12.2-3

Data Protection Act and, 11.9**

Human Fertilisation and Embryology Act
 (1990) and, 11.10-14

see also confidentiality

doctors (medical practitioners)

family, see general practitioner

research and role/responsibilities of, 10.11

donation or provision of gametes and embryos, 4.1-
 4.33, 8.29-8.30

age of donors, 4.22-4.45

assessment with, 3.12

age of provider, 3.7-10

assessment/screening of donors, 4.1-4.33

consent, see consent

counselling of donors, see counselling

expenses for donors, 4.2-4.3, 4.24, App.G

information on

HFEA Register information on donor,

App.I

for patients, 5.6-5.10

for professionals, App.F

one donor used per treatment cycle, 9.17

for research purposes, see research

selection of donors/matching to recipient,
 3.18*

unsuitable donors, 4.27-4.29

witnessing donor insemination, 15.9-10, 6.41

see also egg sharing

egg

age of provider, 3.10

collection/retrieval

consent involving, App.E

location used, 2.12

risks associated with, 5.4

witnessing, 15.1

donation, withdrawal of consent, 6.41, 6.48-9

number transferred, 8.18-8.22

posthumous use, 6.26

replacement, consent involving, App.E

see also gametes; oocyte

egg sharing

confidentiality, 12.9-12.10

consent issues, 6.48-6.50

counselling, 3.30, 7.29-32

guidance, App.A

information for people involved, 3.28-3.31,
 4.32-4.33, 5.12, 11.15

embryos

consent issues (specific to embryos as opposed
 to gametes), 6.18, 6.22, 6.52

cryopreservation facilities, 2.13

disposal, 8.10, 10.12

donation (issues specific to embryos as
 opposed to gametes)

counselling, 4.8

screening of donors, 4.20, 6.27

selection of donors/matching to
 recipient, 3.18-3.19*

freezing, see freezing

- handling, 9.1-9.17
- obtaining, 8.1-8.3
- preimplantation testing, see preimplantation testing
- replacement, consent involving, App.E
- research, 10.1-10.3
 - guidelines, App.F
 - prohibited activities, 10.4-10.5
 - storage (specifically of), statutory period, 6.15
 - termination of development, 8.10, 10.12
 - transfer (to recipient)
 - frozen embryo, see frozen embryo
 - number transferred, 8.17, 8.19-8.21
 - witnessing, 15.6
 - transfer (=transport), 8.2, 9.16-9.17
 - use, 8.1-8.34
 - posthumous, 6.26
 - research centres, 10.12
- ethics committees and research, 10.6-7
- examination, consent to, 6.1-3, 7.6
- expenses, donors, 4.3, 4.24, App.G
 - see also cost; funding; payments
- export of gametes/embryos, 6.23, 8.3
- facilities, 2.1-2.30
 - clinical, 2.5-8
 - counselling, 2.18-21
 - laboratory, 2.9-17
 - standards, maintaining/improving, 2.27-8
- family doctor, see general practitioner
- family history, donors, 4.4-7
- fatherhood, legal issues, 3.13-4, 6.25, 6.32
- fertilisation check, witnessing, 15.5
- financial issues, see cost; expenses; funding; payments
- foreign countries
 - counselling with child to raised in, 3.11
 - donors from, 5.6
 - export of gametes/embryos, 6.23, (8.1), 8.3
 - import of gametes/embryos, 8.1
- freezing/cryopreservation (of gametes and embryos), 2.9-17
 - facilities, 2.13
 - person responsible for, 1.16
 - safety issues, 2.9-17
 - witnessing, 15.7
 - see also storage
- frozen embryos, transfer, 8.7
 - number transferred, 8.18-8.22
- frozen oocyte, see oocyte
- funding of research, guidance for medical practitioners, 10.11
- gametes
 - age of providers, see age
 - consent issues, see consent
 - cryopreservation facilities, 2.13
 - donors and donation, see donation
 - freezing, see freezing
 - handling, 9.1-9.17
 - obtaining, 8.1-8.3
 - storage, see storage
 - transport/transfer, 8.2, 9.16-9.17
 - use, 8.1-8.834
 - posthumous, 6.24-6.27, 6.26, 8.34
 - research centres, 10.12
 - see also egg; sperm
- general practitioner (GP; family doctor), consent to
 - contact
 - donor, 4.5-7
 - treated person, 3.20
- genetic consultation, 14.13-15
- genetic counselling, 7.23
 - donor with unsuspected disease, 4.30
- genetic diseases, ICSI risk of inheriting, 16.7
- genetic testing (incl. screening)
 - donors, 4.10-4.21
 - counselling, 4.28
 - information about, 5.6, 5.7
 - preimplantation, see preimplantation testing
 - staff roles/responsibilities, 1.14
- genetics laboratories, accreditation for
 - preimplantation testing, 14.11
- 'Gillick competence', 6.11

good manufacturing practice, guidelines on, App.F
GP, see general practitioner

handling of gametes/embryos, 9.1-9.17

hazards, see safety considerations

HFEA Register, App.I

history-taking

donors, 4.4-7

treated persons, 3.20

HIV testing

donor, 4.15, 5.7

guidance, App.C

home

insemination at, 8.13-8.16

sperm production at, 8.4, 8.16, 8.24

Human Fertilisation and Embryology Act (1990),
12.1-12.2

husband, consent issues, 6.32-6.37

disclosure of information, App.B

egg retrieval and/or egg or embryo

replacement, App.E

posthumous use of his gametes, 6.25

see also partner

ICSI, see intra-cytoplasmic sperm injection

implications counselling, 7.16-7.18

donor/donation, 4.8, 8.22, 8.24

egg sharers, 7.32

import of gametes/embryos, 8.1

in-service training, 1.17

infection

guidelines on, App.F

tests/screening for

blood products, 2.11

donors, 4.14-15

patients, 9.2

see also specific infections

information, 5.1-5.14

on complaints, 13(Annex A)

disclosure of, see disclosure

on donation, 5.6-5.10

on egg collection, 15.1

on egg sharing, 3.28-3.31, 4.32-4.33, 5.12,
11.15

on embryo transfer, 15.6

on fertilisation check, 15.5

HFEA Register of, App.I

on ICSI, 16.6-7

on insemination and ICSI, 15.4

on long-term storage of gametes/embryos,
3.27, 5.11

for people seeking treatment, 5.6-7, 6.28, 8.13-
8.16

on preimplantation genetic diagnosis, 14.16-
19, 14.26-14.31

on sperm samples, 15.2-15.3

on sperm use for insemination/ICSI, 15.4

see also counselling; records

insemination

at home, 8.13-8.16

witnessing, 15.4

donor insemination, 15.9-10

intra-cytoplasmic sperm injection (ICSI), 16.1-16.7

definitions, 16.1

factors to be considered, 16.5-7

licensing, 16.1, 16.2, 16.4, App.H

witnessing, 15.4

laboratory facilities, 2.9-17

laboratory procedures and practice

guidelines on, App.F

monitoring/assessing/improving, 2.27-8

witnessing, 15.1-15.10

licensing (and licence conditions), App.H

preimplantation testing, 14.5-10, App.H

research, 10.1-10.3, App.H

treatment, App.H

ICSI, 16.1, 16.2, 16.4, App.H

Local Research Ethics committee, 10.7

man, see fatherhood; husband; partner

marital status of treated person

married, 6.33

counselling considerations, 7.18

- unmarried, 6.35-6.36
 - see also husband; partner
- medical history (parents), 3.20
- medical practitioners, see doctors
- medical staff, 1.5-7
- men, see fatherhood; husband; partner
- mental capacity
 - assessment, 6.13
 - donor's mental incapacity, 6.27
- microbiological hazards, 2.10
 - see also infection
- mother
 - egg donor not regarded as, with posthumous use, 6.26
 - surrogate, see surrogate pregnancy
- multidisciplinary team
 - patient assessment, 3.21-3.24
 - preimplantation testing, 14.12
- multiple pregnancy
 - reducing risk, 8.18-19
 - risks associated with, 5.5
- NHS centres, dealing with complaints, 13(Annex B)
- nursing staff, 1.8
- oligospermia, ICSI in, 16.5
- oocyte (licensing involving treatment with)
 - in cryopreserved ovarian tissue, App.H
 - frozen oocyte, App.H
- organisations, professional, guidelines for, App.F
- ovarian tissue, cryopreserved, oocyte in, App.H
- ovum, see egg; oocyte
- parental orders, surrogacy cases, App.D
- parental responsibility
 - treatment centre determining, 3.11
 - treatment centre explaining legal aspects, 6.32
 - unmarried couples and, 6.37
- partner
 - consent issues, 6.32-6.38, 6.40, 6.51
 - disclosure of information, App.B
 - egg retrieval and/or egg or embryo replacement, App.E
 - posthumous use of gametes from, 6.24
 - counselling with or without,
 - marital status, see husband; marital status
- paternity, legal issues regarding, 3.14, 6.25, 8.23
- payments
 - donors, 4.2-4.3, 4.25
 - in research, guidance for medical practitioners, 10.11
 - see also cost; expenses; funding
- peer review, research proposal, 10.9-10.10
- Person Responsible, 1.2-4
 - criminal convictions reported to/dealt with by, 1.19
 - facilities/equipment and, 2.1-2
 - ICSI and, 16.1, 16.2, 16.3
 - preimplantation testing, 14.28, 14.29, 14.31
 - security, 9.6
- personnel, see staff
- ploidy abnormalities, see aneuploidy
- polar body/blastomere biopsy, 14.4
 - licensing conditions, App.H
 - recording and reporting of information, 14.28-31
- posthumous use, gametes/embryos, 6.24-27, 8.34
- pregnancy
 - multiple, see multiple pregnancy
 - surrogate, see surrogate pregnancy
- preimplantation testing, 14.1-14.31
 - aneuploidy, see aneuploidy
 - clinical decision making, 14.20-5
 - definitions, 14.1-3
 - genetics laboratory accreditation for, 14.11
 - licensing, 14.6-10, App.H
 - patient information, 14.16-19, 14.26-27
 - staff involved, 14.12
- Private and Voluntary Health Care (England) Regulations (2001), complaints in, 13(annex A)
- professional organisations, guidelines for, App.F
- professional standards, 2.30, App.F
- records, 11.1-11.15

- access to, 11.4-8
- accuracy, 11.1-2
- confidentiality, 11.3
- of counselling, 7.25-26
- of gamete/embryo source and handling, 9.10-11
- of gamete/embryo storage location, 9.7
- of preimplantation testing, 14.28-31
- welfare of child, 3.25
- see also information
- refusal to provide treatment, 3.23-4
- Register, HFEA, App.I
- registration of birth, surrogacy cases, App.D
- research, 10.1-10.12
 - donation for, 5.8-9
 - consent issues, 5.8-9, 8.12
 - information for donors, 5.8-9
 - sperm, age of donor, 3.9
 - general standards, 10.1-3
 - guidelines on, App.F
 - licensing, 11.1-3, App.H
 - prohibited activities, 10.4
- safety considerations (and hazards/risks), 2.9-17
 - in egg collection, 5.4
 - gamete/embryo harm caused by procedures, 8.4-5, 8.8
 - multiple pregnancy, 5.5
 - Person Responsible and adverse incidents, 1.4
- satellite centres, 2.3
- scientific staff, 1.10-16
- screening tests, see tests
- security, storage, 2.22, 9.6-8
- sedation, safe, information/guidance on, App.F
- semen, see sperm
- seminology laboratory, person responsible for, 1.14
- sickle cell anaemia, donor screening, 4.14
- social history (parents), 3.20
- sperm
 - consent issues regarding use, 6.19-20, 6.25
 - posthumous use, 6.24-5, 8.34
 - indications for ICSI related to, 16.5
 - insemination, see insemination
 - intra-cytoplasmic injection, see intra-cytoplasmic sperm injection
 - production
 - at home, 8.14, 8.16, 8.24
 - at licensed centre, 8.24
 - for research, age of donor, 8.13
 - samples, witnessing procedures with, 3.9
 - statutory storage period, 6.116
 - see also gametes
- spouse, male, see husband
- staff, 1.1-1.19
 - conscientious objection, 1.18
 - counselling staff, 1.9
 - criminal convictions, 1.19
 - in-service training, 1.17
 - medical staff, 1.5-7
 - nursing staff, 1.8
 - Person Responsible, see Person Responsible
 - scientific services, 1.11-16
 - standards of integrity, 1.1
 - see also multidisciplinary team
 - standards
 - donor assessment/screening, 4.1-3
 - facilities, maintaining/improving, 2.27-8
 - of integrity, 1.1
 - professional, 2.30, App.F
 - research, 10.1-3
- statutory instruments, App.F
- storage (of gametes and embryos), 9.1-9.17
 - consent issues, see consent
 - general obligations, 9.1
 - guidelines on, App.F
 - licensing conditions, App.H
 - long-term, people seeking, 6.42-47, 8.34
 - counselling, 7.27-8
 - information for, 3.26-7, 5.11
 - research centres, 10.12
 - reviews of status of stored material, 9.11-13
 - security, 2.22, 9.6-8
 - statutory period, 6.15-17
 - extension, 6.42, 6.45-6

- informing providers when approaching terminal date, 9.13
 - see also freezing
- straws, safety issues, 2.15
- support counselling, 7.2, 7.19-20
- surrogate pregnancy, 3.16-7*
 - parental orders, App.D
 - screening of gamete providers, 4.21
- Tay Sachs disease, donor screening, 4.14
- tests (incl. screening)
 - donors, 4.10-21, 4.33
 - information on, 5.6-7
 - genetic, see genetic testing
 - for infection, see infection
 - patients, 9.2-4
 - preimplantation, see preimplantation testing
- thalassaemia, donor screening, 4.14
- therapeutic counselling, 7.2, 7.21-22
- training, in-service, 1.17
- transport (and transfer), 8.2, 9.15-17
- transport centres, 2.3
- travel expenses, donors, App.G
- treatment
 - counselling on consequences of, 7.2, 7.15-16
 - licensing, see licensing
 - persons seeking
 - assessment, 3.1-3.31
 - consent, 6.1-3, 6.9, 6.28-30, App.E
 - information for, 5.6-7, 6.28-31, 8.13-8.23
 - verifying identity, 3.6
 - persons undergoing, as potential donors, 4.8
 - refusal to provide, 3.23-4
- witnessing of procedures, 15.1-15.10



The Human Fertilisation and Embryology Authority

One of the HFEA's statutory functions is to produce a *Code of Practice* which provides guidance to centres on the standards they are expected to establish in carrying out their licensed treatment.

This sixth edition of the *Code of Practice* has been designed for ease of use for those individuals working in licensed centres and other readers. Each Part of the *Code* includes the relevant legislation from the Human Fertilisation And Embryology Act 1990. Where legislation requires or empowers the HFEA to exercise its jurisdiction over certain matters through its licensing and regulatory system, the Authority's policy is explained and the relevant licence conditions or Directions which bring this into force are indicated. Guidance is provided on the proper conduct of activities in licensed centres and, where appropriate, agreed standards of best practice are given.

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