HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

CODE OF PRACTICE

FOURTH EDITION

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INTRODUCTION

Medical intervention or research which aims to alleviate infertility or reduce the risk of inherited abnormality intrudes upon the most private and sensitive aspects of our existence and relationships. The Human Fertilisation and Embryology Authority was established in response to deep public concern about the implications which the new techniques might have for the perception and valuing of human life and family relationships.

The HFEA's principal task is to regulate, by means of a licensing system, any research or treatment which involves the creation, keeping and using of human embryos outside the body, or the storage or donation of human eggs and sperm. It must also maintain a Code of Practice giving guidance about the proper conduct of the licensed activities.

The object of the Code is 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 it, we have been guided both by the requirements of the Human Fertilisation and Embryology Act and by:

* the respect which is due to human life at all stages in its development;

* the right of people who are or may be infertile to the proper consideration of their request for treatment;

* a concern for the welfare of children, which cannot always be adequately protected by concern for the interests of the adults involved; and

* a recognition of the benefits, both to individuals and to society which can flow from the responsible pursuit of medical and scientific knowledge.

We recognise that these considerations may sometimes conflict and have sought to reconcile them in a way which is both practicable and in accordance with the spirit and intentions of the Act. Our 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.

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. It also adopts the guidance given by other authorities or professional bodies on particular points.

The Act covers both *in vitro* fertilisation and donor insemination, and imposes obligations upon centres to give information, provide counselling and take account of the welfare of children. It recognises that, while infertile people 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 needs must also be taken into account.

The Act also allows the HFEA to give guidance on any procedure involving the placing of eggs and sperm in a woman. A basic guideline appears at paragraph 7.9 which is of general application.

The Code is regularly reviewed and amended in the light of experience and to keep abreast of the latest developments in both clinical practice and public concerns. This third revision of the Code contains guidance on matters which have been brought to the HFEA's attention since the Code was last revised in December 1995. There are three major additions. New guidance has been included on the genetic testing of donors and patients. Although the testing of gamete donors for cystic fibrosis has not been made mandatory, it is strongly recommended, and clinics are required to make genetic counselling available to patients and donors in order that the implications of genetic testing are properly understood following the principles set out by the Advisory Committee on Genetic Testing. General guidance has been included on the statutory storage period for embryos following on from the Regulations introduced in 1996 and this reflects the guidance that was issued to clinics on 15 April 1996. Finally, the guidelines on the welfare of the child were reviewed following concerns about the treatment of HIV positive patients.

This revised Code of Practice has been approved by the Secretary of State and laid before Parliament in accordance with section 26 of the Human Fertilisation and Embryology Act 1990.

PART 1 - STAFF

General Standards

1.1 In order to protect the interests and privacy of donors and clients, and to guard against the misuse of genetic material, it is essential that all those responsible for or taking part in licensed activities have high standards of integrity and responsibility.

1.2 The skill mix of clinical, nursing, counselling and scientific staff should reflect the requirements of the work undertaken in the centre.

The Person Responsible

1.3 A licence application **must** name the person under whose supervision the licensed activities will be carried on ("the person responsible").[1]

1.4 The person responsible **must** ensure:[2]

* that the character, qualifications and experience of anyone carrying out licensed activities are suitable for those activities;

* that proper equipment is used;

* that proper arrangements are made for the keeping and disposal of genetic material;

* that suitable practices are used in carrying out the licensed activities; and

* that the centre complies with the conditions of its licence.

[1] Human Fertilisation and Embryology Act 1990 section 16(2)(a)
[2] HF&E Act 1990 s.17(1)

1.5 The person responsible will need to have sufficient insight into the scientific, medical, legal and other aspects of the centre's work to enable them to supervise its activities properly, but the qualities of integrity, responsibility and managerial capability are more important than any particular professional qualification. The Authority will expect the person responsible to take whatever specialist advice is necessary.

Staff Engaged in Clinical Services

1.6 Overall clinical responsibility for treatment services using *in vitro* fertilisation should be held by someone with accredited consultant status or an equivalent appropriate training recognised by the Royal College of Obstetricians and Gynaecologists.

1.7 Medical staff engaged in treatment services using *in vitro* fertilisation who do not have overall clinical responsibility should be fully registered Medical Practitioners with a sufficient period of experience under supervision in *in vitro* fertilisation to qualify them to take part in that activity. Medical staff engaged in laparoscopy should also be Fellows or Members of the Royal College of Obstetricians and Gynaecologists. Medical staff in a training capacity are exempt from this requirement but should only carry out these activities under proper supervision.

1.8 If the centre is licensed to provide donor insemination but not *in vitro* fertilisation, the person with overall clinical responsibility should be a fully registered Medical Practitioner with a sufficient period of experience in an established infertility clinic to qualify them to take full charge of the centre's treatment services.

Nursing Staff

1.9 All nursing staff must be appropriately qualified and effectively registered by the United Kingdom Central Council for Nursing, Midwifery and Health Visiting (UKCC), for the duties they carry out.

Counselling Staff

1.10 Unless it is engaged only in research, a centre should ensure either that at least one of its staff has a Certificate of Qualification in Social Work or an equivalent qualification recognised by the Central Council for Education and Training in Social Work, or is accredited by the British Association of Counsellors, or is a Chartered Psychologist, or that a person with such a qualification is available as an advisor to counselling staff and as a counsellor to clients as required.

Staff Engaged in Scientific Services

1.11 The person in charge of an embryology laboratory should have an appropriate scientific or medical degree, plus a period of experience in an embryology laboratory sufficient to qualify the person to take full charge of the laboratory. Where clinics undertake the genetic testing of patient and donors, centres should ensure that a person is available who understands the nature of the tests used, their scope and limitations, and the accuracy, implications and use of the result.

1.12 The person in charge of a seminology laboratory should have a degree or an HND in a relevant discipline, plus a period of experience in a seminology laboratory sufficient to qualify the person to take full charge of the laboratory.

1.13 The person in charge of an endocrinology laboratory should have a degree or an HND in a relevant discipline, plus a period of experience in an endocrinology laboratory sufficient to qualify the person to take full charge of the laboratory.

In-Service Training

1.14 Centres should arrange relevant training for all staff taking part in specialist scientific, clinical or counselling activities for which existing formal qualifications are not entirely sufficient. Centres with too few staff to provide adequate training themselves should make arrangements for staff to be trained where there are such facilities. All staff taking part in specialist activities should also receive regular updating.

Conscientious Objection

1.15 Anyone who can show a conscientious objection to any of the activities governed by the Act is not obliged to participate in them.[3]

1.16 Prospective employees should be provided with a full description of all the activities carried out at the centre. Interviewers should raise the issue of conscientious objection during the recruitment process and explain the right of staff to object.

Criminal Convictions

1.17 When deciding whether a person is suitable to take part in a licensed activity, the person responsible should take account of any relevant criminal convictions. Applicants who have such convictions should not be appointed to posts in which they will have access to donors, clients, genetic material or records about these, unless the person responsible is satisfied that the applicant is suitable for the post in question.

1.18 Relevant convictions will depend upon the particular post and the gravity of the particular offence, but may include any offence of violence or dishonesty, blackmail, sexual offences and offences against children, drugs offences and breaches of regulatory machinery.

[3] HF&E Act 1990 s.38

PART 2 - FACILITIES

General

2.1 The person responsible **must** ensure that proper equipment and suitable practices are used.[4]

2.2 If a centre decides to use outside facilities, the person responsible should be satisfied that those facilities comply with any relevant provisions of this Code. Licensed activities **must** only take place on the licensed premises.[5]

Clinical Facilities

2.3 Backup and emergency clinical facilities for each technique practised should be available at the centre, equivalent to those which are standard practice in other specialties and appropriate to the degree of risk involved.

2.4 Further emergency facilities should be available locally to cater for all reasonably foreseeable eventualities.

2.5 Centres should be sensitive to their clients' and donors' needs for comfort and privacy, and take all reasonable steps to ensure that facilities are acceptable to them. In particular:

* centres should provide a private and comfortable room for the examination and treatment of clients, out of the sight and hearing of others, and not subject to unannounced and uninvited entry by staff or others;

* similar facilities should be provided in which semen specimens can be produced.

2.6 If the centre is licensed to provide treatment services using *in vitro* fertilisation, a member of staff should be available to clients at all times.

[4] HF&E Act 1990 s.17(1)(b) and (d)
[5] HF&E Act 1990 s.12(a)

Laboratory Facilities

2.7 It is essential that centres follow good laboratory practice, whether their laboratories are used for research or for clinical services.

2.8 All blood products, other than those of the woman receiving treatment, with which gametes or embryos might come into contact should be pre-tested for HIV, Hepatitis B and Hepatitis C.

2.9 The room where eggs are collected for *in vitro* fertilisation should be as close as practicable to the laboratory where fertilisation is to take place.

Counselling Facilities

2.10 People seeking licensed treatment (i.e. *in vitro* fertilisation or involving donated gametes) or consenting to the use or storage of embryos, or to the donation or storage of gametes **must** be given a suitable opportunity to receive proper counselling.[6] Detailed guidance is given in Part 6.

2.11 Centres should provide a private and comfortable room for counselling, where discussion can take place undisturbed.

2.12 Centres should so far as practicable maintain an up-to-date list of different types of counselling which are available locally and of national organisations which can provide local information. They should make the list available to clients who wish to seek counselling outside the centre.

2.13 Centres should so far as practicable establish and maintain good relationships with independent counselling organisations, so that donors and clients may be given the maximum help in obtaining the counselling they need.

2.14 Centres should designate an individual responsible for ensuring that counselling facilities are provided as described above and in Part 6.

[6] HF&E Act 1990 s.13(6); Schedule 3 para 3(1)(a)

Secure Storage for Gametes and Embryos

2.15 Centres should provide secure storage for gametes and embryos, access to which is controlled. Detailed guidance is given in Part 8.

Maintaining and Improving Standards

2.16 Centres should inform the Authority as soon as possible of any breach of the Code of Practice or of any serious problem that has occurred at that centre.

2.17 Centres should have an effective system for monitoring and assessing laboratory, clinical and counselling practice, to ensure that both the procedures and the outcomes are and can be shown to be satisfactory by the standards of professional colleagues in relevant disciplines elsewhere. This system should include obtaining feedback from clients, donors and people seeking storage of gametes and embryos.

2.18 Centres should have procedures for improving and updating laboratory, clinical and counselling practice, so that every effort is made to achieve optimum procedures and outcomes by the standards of professional colleagues elsewhere. These procedures should include obtaining feedback as in paragraph 2.17, above.

Advertising

2.19 Centres may wish to circulate information about the kinds of treatment which they provide. All publicity material should conform to the guidelines of the General Medical Council and the Code of Professional Conduct of the United Kingdom Central Council for Nursing, Midwifery and Health Visiting. To the extent that these permit centres or their services to be publicised to the general public, their material should conform to the guidelines of the Advertising Standards Authority.

PART 3 - ASSESSING CLIENTS, DONORS AND THE WELFARE OF THE CHILD

INTRODUCTION

General Obligations

3.1 Centres should take all reasonable steps to ensure that people receiving treatment and any children resulting from it have the best possible protection from harm to their health. Before providing any woman with treatment, centres **must** also take account of the welfare of any child who may be born or who may be affected as a result of the treatment.[7]

3.2 Centres should therefore ensure that clients' medical needs are fully assessed, and that any treatment offered is the most suitable to meet their needs and that donors and gametes are properly screened in accordance with the guidance given below.

3.3 In addition, in deciding whether or not to offer treatment, centres should take account both of the wishes and needs of the people seeking treatment and of the needs of any children who may be involved. Neither consideration is paramount over the other, and the subject should be approached with great care and sensitivity. Centres should avoid adopting any policy or criteria which may appear arbitrary or discriminatory. Further guidance is given in paragraphs 3.12 to 3.32 below.

Confidentiality

3.4 Any information which centres obtain from potential donors or clients **must** be kept confidential unless disclosure is authorised by law.[8] Certain types of information may only be disclosed in the circumstances authorised in the Act (see paragraph 11.8, below). If a centre is in doubt about whether or not it should disclose information, it should refer to the Authority.

[7] HF&E Act 1990 s.13(5)
[8] HF&E Act 1990 s.33(5)

3.5 The Act states that information about the provision of treatment services for, or the keeping or use of the gametes of any identifiable individual can, in general, only be disclosed either to the Authority or to another person covered by a licence or to the individual concerned. However, identifying information about the provision of treatment services can be disclosed either:

a. with the consent of the person to whom the information relates;

or

b. in an emergency, i.e. where disclosure is necessary to avert an imminent danger to the health of the person to whom the information relates and it is not reasonably practicable to obtain that person's consent. It follows that if it is practicable to obtain consent in an emergency, and that consent is refused or not requested, then the information must not be disclosed.

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

3.6 Where information is disclosed with consent, the following conditions must be met:

a. before this consent is given, reasonable steps must have been taken to explain the implications of disclosure to the person whose consent is requested; and

b. the person(s) to whom the information is to be disclosed must either:

i. be specified in the consent, e.g. a solicitor or interpreter; or,

ii. be someone who needs to know in connection with providing treatment services or other medical, surgical or obstetric services for the person giving consent (for the other circumstances in which information can be disclosed see paragraph 11.8, below).

3.7 It is generally in the interests of the person concerned that relevant information be passed on to other clinicians involved in their treatment or diagnosis. But, except in an emergency, it is that person's right to decide what information will be passed on and to whom. In seeking consent, therefore, centres should:

a. obtain the client's consent in writing. The consent of each person whose identity is to be disclosed should be obtained. Where a woman and a man are being treated together it is desirable to use the same form. A model consent form is at Annex A;

b. tell the client whose consent is requested what information is to be disclosed;

c. give a full explanation of the reasons for wanting to disclose the information (for example so that a GP can be kept informed of a client's fertility treatment), and the implications of disclosing this information, so that the client can make an informed judgement about consent. Implications will include the fact that once disclosed, the information will no longer be covered by the special provisions of the Act, but only by the ordinary law on confidentiality (see paragraph 11.10, below).

d. so far as possible specify the person to whom the information is to be disclosed and, if that is not possible, to identify the unit or clinic concerned.

e. renew the consent of the client(s) if treatment which has not initially involved consent subsequently does so.

3.8 Wherever consent is given for information to be disclosed to an unspecified person, particular care should be taken to ensure that any person to whom the information is disclosed does indeed need to know the information in connection with the provision of treatment services or other medical, surgical or obstetric services, (for disclosure in connection with medical and financial audit, see paragraph 11.8 below).

3.9 When passing on information with consent, centres should also make clear to the recipient(s) the terms of the consent given.

3.10 Centres should as far as possible ensure that those receiving information record details of treatment services only on the client's medical record and not on that of any resulting child.

3.11 If a centre refers a client to another centre for licensed infertility treatment, the requirements of good clinical practice should be followed in supplying any relevant information to that centre. Any information relevant to the welfare of the child should always be supplied.

PROSPECTIVE PARENTS AND THE WELFARE OF THE CHILD

Welfare of the child

3.12 One of the conditions of a treatment licence is that "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".[9] This applies to every woman whether or not she is resident in or a citizen of the United Kingdom. "Any other child" includes children who already exist within the client's household or family.

3.13 The condition applies only to centres with a treatment licence, but it covers any of the services they offer to assist conception or pregnancy, whether or not these require a licence. However, the degree of consideration necessary will be greater if the treatment is required to be licensed under the Act and particularly if it involves the use of donated gametes.

3.14 Centres should have clear written procedures to follow for assessing the welfare of the potential child and of any other child who may be affected. The HFE Act does not exclude any category of woman from being considered for treatment. Centres should take note in their procedures of the importance of a stable and supportive environment for any child produced as a result of treatment.

[9] HF&E Act 1990 s.13(5)

Factors to be Considered

3.15 Centres should take all reasonable steps to ascertain who would be legally responsible for any child born as a result of the procedure and who it is intended will be bringing up the child. When clients come from abroad, centres should not assume that the law of that country relating to the parentage of a child born as a result of donated gametes is the same as that of the United Kingdom.

3.16 People seeking treatment are entitled to a fair and unprejudiced assessment of their situation and needs, which should be conducted with the skill and sensitivity appropriate to the delicacy of the case and the wishes and feelings of those involved.

3.17 Where people seek licensed treatment, centres should bear in mind the following factors:

a. their commitment to having and bringing up a child or children;

b. their ability to provide a stable and supportive environment for any child produced as a result of treatment;

c. their medical histories and the medical histories of their families;

d. their health and consequent future ability to look after or provide for a child's needs;

e. their ages and likely future ability to look after or provide for a child's needs;

f. their ability to meet the needs of any child or children who may be born as a result of treatment, including the implications of any possible multiple births;

g. any risk of harm to the child or children who may be born, including the risk of inherited disorders or transmissible diseases, problems during pregnancy and of neglect or abuse; and

h. the effect of a new baby or babies upon any existing child of the family.

3.18 Where people seek treatment using donated gametes, centres should also take the following factors into account:

a. 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;

b. the possible attitudes of other members of the family towards the child, and towards their status in the family;

c. the implications for the welfare of the child if the donor is personally known within the child's family and social circle; and

d. any possibility known to the centre of a dispute about the legal fatherhood of the child (see paragraphs 5.6 to 5.8, below).

3.19 Further factors will require consideration in the following cases:

a. where the child will have no legal father. Centres are required to have regard to the child's need for a father and should pay particular attention to the prospective mother's ability to meet the child's needs throughout their childhood. Where appropriate, centres should consider particularly whether there is anyone else within the prospective mother's family and social circle willing and able to share the responsibility for meeting those needs, and for bringing up, maintaining and caring for the child.

b. where it is the intention that the child will not be brought up by the carrying mother. In this case, centres should bear in mind that either the carrying mother and in certain circumstances her husband or partner, or the commissioning parents may become the child's legal parents. Centres should therefore consider the factors listed in paragraphs 3.17 and 3.18 as applicable in relation to all those involved, and any risk of disruption to the child's early care and upbringing should there be a dispute between them. Centres should also take into account the effect of the proposed arrangement on any child of the carrying mother's family as well as its effect on any child of the commissioning parent's family.

3.20 The application of assisted conception techniques to initiate a surrogate pregnancy should only be considered where it is physically impossible or highly undesirable for medical reasons for the commissioning mother to carry the child.

3.21 Centres should be aware of the Parental Orders (Human Fertilisation and Embryology) Regulations 1994 and the Parental Orders (Human Fertilisation and Embryology) (Scotland) Regulations 1994 which came into effect on 1 November 1994. Under these Regulations, parental rights and obligations relating to a child born from a surrogacy arrangement may be transferred from the birth parents to the commissioning parents. The conditions that must be fulfilled before an application can be made are set out in Annex B. Annex B also contains information about birth registration of children born through surrogacy arrangements.

3.22 When selecting donated gametes for treatment, centres should take into account each prospective parent's preferences in relation to the general physical characteristics of the donor. This does not allow the prospective parents to choose, for social reasons alone, a donor of different ethnic origin(s) from themselves. Clients should be advised that the result of any attempt at matching physical characteristics cannot be guaranteed.

Enquiries to be Made

3.23 Centres should take a medical and social history from each prospective parent. They should be seen together and separately. This should include all the information relevant to paragraphs 3.12 to 3.19 above.

3.24 Centres should seek to satisfy themselves that the GP of each prospective parent knows of no reason why either of them might not be suitable for the treatment to be offered. This would include anything which might adversely affect the welfare of any resulting child.

3.25 Centres should obtain the client's consent before approaching the GP. However, failure to give consent should be taken into account in considering whether or not to offer treatment.

3.26 If any of these particulars or inquiries give cause for concern, e.g., evidence that prospective parents have had children removed from their care, or evidence of a previous relevant conviction, the centre should make such further inquiries of any relevant individual, authority or agency as it can.

3.27 Centres should obtain the client's consent before approaching any individual, authority or agency for information. However, failure to give consent should be taken into account in deciding whether or not to offer treatment.

Multidisciplinary Assessment

3.28 The views of all those at the centre who have been involved with the prospective parents should be taken into account when deciding whether or not to offer treatment. Prospective parents should be given a fair opportunity to state their views before any decision is made and to meet any objections raised to providing them with treatment.

3.29 If a member of the team has a cause for concern as a result of information given to them in confidence, they should obtain the consent of the person concerned before discussing it with the rest of the team. If a member of the team receives information which is of such gravity that confidentiality cannot be maintained, they should use their own discretion, based on good professional practice, in deciding in what circumstances it should be discussed with the rest of the team.

3.30 The decision to provide treatment should be taken in the light of all the available information. Treatment may be refused on clinical grounds. Treatment should also be refused if the centre believes that it would not be in the interests of any resulting child, or any child already existing, to provide treatment, or is unable to obtain sufficient information or advice to reach a proper conclusion.

3.31 If treatment is refused for any reason, the centre should explain to the woman and, where appropriate, her husband or partner, the reasons for this and the factors, if any, which might persuade the centre to reverse its decision. It should also explain the options which remain open and tell clients where they can obtain counselling.

3.32 Centres should record in detail the information which has been taken into account when considering the welfare of the child or children. The record should reflect the views of all those who were consulted in reaching the decision, including those of potential parents.

Prospective Donors and People Seeking Storage of Gametes and Embryos

3.33 Centres should draw the screening procedure to the attention of potential donors at the outset and ensure that they understand which tests will be carried out and that the procedure may reveal previously unsuspected defects, including genetic anomalies and HIV infection. Centres should ask a prospective donor whether they have ever provided gametes at another centre. If they have, the centre should satisfy itself that the limit of 10 offspring per donor will not be exceeded (see paragraphs 7.18 and 7.19, below).

3.34 Payment may only be made, or benefits given, in exchange for gametes or embryos in accordance with directions made by the Authority.[10] This includes payments or benefits that a centre knows have been given, or will be given, through the involvement of an agency or intermediary.

3.35 If an egg donor becomes ill as a direct result of making a donation, centres should reimburse any direct expenses that the donor incurs.

Age and Mental Capacity

3.36 Gametes should not be taken for the treatment of others from female donors over the age of 35, and from male donors over the age of 55, unless there are exceptional reasons for doing so. If there are exceptional reasons, these should be explained in the treatment records.

[10] HF&E Act 1990 s.12(e)

3.37 Gametes taken from women over 35 and men over 55 may be used for their own treatment, or the treatment of their partner. They should be offered clinical advice and counselling before deciding whether to proceed with treatment.

3.38 Gametes should not be taken for the treatment of others from anyone under the age of 18.

3.39 Gametes **must not** be taken from anyone who is not capable of giving a valid consent or who has not given a valid consent to examination and treatment and an effective consent to the use or storage of those gametes.[11]

3.40 In exceptional circumstances, gametes may be taken from people under the age of 18 if it is the intention to use them for their own treatment or that of their partner, provided that the centre is satisfied that the person from whom the gametes are taken is capable of giving an effective consent to the use or storage of those gametes and has done so. Effective consent to the use or storage of gametes and embryos may only be given by the person who provides the gametes.[12]

3.41 Sperm taken from a male under 18 may only be stored for the purpose of research if he is capable of giving an effective consent, and that consent has been obtained.

3.42 Eggs should not be taken from females under 18 either to be stored for the purpose of research or to be used for research requiring a licence without first referring to the Authority.

History

3.43 A medical and family history should be taken before any gametes are provided. This should include details of any donations which the potential provider of gametes has made elsewhere. Donors should also be encouraged to provide as much other non-identifying biographical information about themselves as they wish, to be made available to prospective parents and any resulting child.

[11] This is an obligation under the general law and Schedule 3 of the HFE Act 1990, respectively. When obtaining consent to examination and treatment centres should follow Department of Health guidelines.
[12] HF&E Act 1990 Schedule 3

3.44 Centres should wherever practicable ask a potential donor's GP whether they know of any reason why the potential donor might not be suitable to donate gametes for the treatment of others.

3.45 Centres should wherever practicable ask the GP of any person seeking storage of gametes or embryos for their own or partner's use whether the GP has any relevant information.

3.46 Centres should obtain the person's consent before approaching the GP. Failure to give such consent should be taken into account in deciding whether or not to accept the gametes or embryos for research or treatment.

Suitability as Donors

3.47 Centres should give careful consideration to the suitability of individual donors before accepting or using their gametes for the treatment of others. The views of all those at the centre who have been involved with the potential donor should be taken into account. Centres should consider in particular:

a. any personal or family history of heritable disorders;

b. any personal history of transmissible infection;

c. the level of potential fertility indicated by semen analysis;

d. whether the donor has children of their own; and

e. the attitude of the donor towards the donation.

Scientific Tests

3.48 Centres should adopt whatever is current best practice in the scientific testing of semen samples and of donors of gametes and embryos.

3.49 All reasonable steps to prevent transmission of a serious genetic disorder should be taken. In most situations this will be served by taking a thorough family history from the prospective gamete donor. Genetic testing should be limited to the determination of carrier status for inherited recessive disorders in which an abnormal result carries no significant direct health implications for the donor. The use of genetic tests other than in the setting of the doctor/patient relationship raises a number of issues that will be the subject of review and guidance from the Advisory Committee on Genetic Testing (ACGT). Centres should ensure that where genetic testing of gamete donors is carried out it is with the same level of support and counselling as for recipients. This means that gamete donors should be informed of the result of their test and offered post-test counselling.

3.50 In relation to cystic fibrosis, centres should normally screen donors especially those from population groups with high frequencies of cystic fibrosis carriers. If a centre uses unscreened donors, the centre should inform the patient and offer screening and counselling. If a centre uses screened donors, the centre should caution the patient about the limits of the test, and the likelihood of a screened donor being a cystic fibrosis carrier. In exceptional circumstances such as where a donor would be difficult to replace, centres may use a donor who is known to be a cystic fibrosis carrier. When this is necessary the patients should be made aware of the risks involved and be offered screening and counselling.

3.51 For other common recessive disorders, centres should follow the BAS guidelines which already specify screening for Tay-Sachs, thalassaemia and sickle cell anaemia in appropriate population groups. The screening of egg donors for recessive diseases should be the same as that carried out for sperm donors.

3.52 In relation to HIV testing, centres should adopt as a minimum the procedure set out in "HIV Screening for Gamete Donors" by the Human Fertilisation and Embryology Authority and the Department of Health, (Annex C).

3.53 In relation to the testing of donors for other infections and of semen samples, centres should as a minimum follow the guidelines of the British Andrology Society. It is for centres to ensure that the most up-to-date guidance is followed.

3.54 Centres should also re-screen potential donors 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 specialties or may be indicated in a particular case while this Code is in force.

Potential Donors who are Undergoing Treatment

3.55 The possibility of donating gametes or embryos should not be raised during the potential donor's treatment cycle. The possibility should be raised by someone other than the staff involved in the treatment.

People Unsuitable as Donors

3.56 If a centre decides that someone is unsuitable as a donor, it should record the reasons for the decision and explain these to the person concerned. Centres should present the explanation sensitively, encourage the person to seek further information, and answer questions in a straightforward, comprehensive and open way.

3.57 If a centre refuses to accept someone as a donor because of a physical or psychological problem which requires separate treatment or specialised counselling, the centre should give the person all reasonable assistance in obtaining this.

3.58 If information suggesting that someone might not be suitable as a donor becomes available after the selection process is complete, the centre should review the donor's suitability in the light of that information and take any necessary action.

3.59 Where a centre becomes aware that a sperm donor has a previously unsuspected genetic disease or is a carrier of a deleterious recessively inherited condition through the birth of a child with that condition (rather than from a genetic test) the centre should immediately inform both the supplying centre and the Authority. The supplying centre should inform any centre that has received sperm from that donor of his carrier status. The supplying centre should also consider informing the donor that he may be a carrier and, if they do so, should offer him counselling and testing. Centres should inform patients who have received treatment at their centre using that donor's sperm and whose treatment has resulted in a live birth. They should also offer the patients counselling. If a woman is pregnant as a result of treatment with that donor's sperm, centres should consider carefully when and how she should be informed of the donor's carrier status.

3.60 Where a centre becomes aware that an egg donor has a previously unsuspected genetic disease or is a carrier of a deleterious recessively inherited condition through the birth of a child with that condition (rather than from a genetic test) the centre should inform the Authority immediately. The centre should inform any centre that has received embryos created from the eggs of the donor of the donor's carrier status. The centre who recruited her should also consider informing the egg donor that she may be a carrier and, if they do so, should offer her counselling and testing. Centres should inform patients who have received treatment using that donor's eggs and whose treatment has resulted in a live birth of the donor's carrier status. They should also offer patients counselling. If a woman is pregnant as a result of treatment with that donor's eggs, centres should consider carefully when and how she should be informed of the donor's carrier status.

PART 4 - INFORMATION

General Obligation

4.1 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".[13] This should be distinguished from the requirement to offer counselling, which clients and donors need not accept.

4.2 Clients and donors should be given oral explanations supported by relevant written material. They should be encouraged to ask for further information and their questions should be answered in a straightforward, comprehensive and open way.

4.3 Centres should devise a system to ensure that:

a. the right information is given;

b. the person who is to give the information is clearly identified, and has been given sufficient training and guidance to enable them to do so; and

c. a record is kept of the information given.

Information to be Given to Clients

4.4 Information should be given to people seeking treatment on the following points:

a. the limitations and possible outcomes of the treatment proposed, and variations of effectiveness over time. This should include the centre's own live birth rate per treatment cycle and the national live birth rate per treatment cycle;

[13] HF&E Act 1990 s.13(b); Schedule 3 para 3(1)(b)

b. the possible side effects and risks of the treatment to the woman and any resulting child. This should include:

i) the possible side effects and risks of ovarian stimulation (where relevant) for the women, including the risks associated with ovarian hyperstimulation syndrome (OHSS)

ii) the risks to the women and fetus associated with multiple pregnancy and the possible practical, financial and emotional impact of a multiple birth on the family unit;

c. the genetic and other screening that donors at that centre undergo. This should include the sensitivity of the tests that are carried out and the likelihood that a screened donor will be a carrier;

d. the availability of genetic testing, especially if the donors that are used at the centre are not screened for cystic fibrosis;

e. the possible disruption of the client's domestic life which treatment will cause, and the length of time he or she will have to wait for treatment;

f. the techniques involved, including (where relevant) the possible deterioration of gametes or embryos associated with storage, and the possible pain and discomfort;

g. the availability of embryo freezing facilities, including the likelihood of success of embryo freezing, thawing, transfer and implications of storage;

h. any other infertility treatments which are available, including those for which a licence is not necessary;

i. that counselling is available;

j. the cost to the client of the treatment proposed and of any alternative treatments;

k. the importance of telling the treatment centre about any resulting birth;

l. who will be the child's parent or parents under the Act. Clients who are nationals or residents of other countries, or who have been treated with gametes obtained from a foreign donor should understand that the law in other countries may be different from that of the United Kingdom (see paragraph 3.15, above);

m. the child's right to seek information about their origins on reaching 18 or on contemplating earlier marriage;

n. the information which centres must collect and register with the HFEA and the extent to which that information may be disclosed to people born as a result of the donation;

o. a child's potential need to know about their origins;

p. the centre's statutory duty to take account of the welfare of any resulting or affected child; and

q. (where relevant) the advantages and disadvantages of continued treatment after a certain number of attempts.

Information to be given to people providing gametes and embryos

4.5 Information should be given to people consenting to the use or storage of embryos, or to the donation or storage of gametes, on the following points:

a. the procedures involved in collecting gametes, the degree of pain and discomfort and any risks to that person, e.g., from the use of superovulatory drugs;

b. the screening which will be carried out, and the practical implications of having an HIV antibody test, even if it proves negative;

c. the genetic testing that will be carried out, its scope and limitations and the implications of the result for the donor and their family;

d. the purposes for which their gametes might be used;

e. whether or not they will be regarded under the Act as the parents of any child born as a result;

f. that the Act generally permits donors to preserve their anonymity;

g. the information which centres must collect and register with the HFEA and the extent to which that information may be disclosed to people born as a result of the donation;

h. that they are free to withdraw or vary the terms of their consent at any time, unless the gametes or embryos have already been used;

i. the possibility that a child born disabled as a result of a donor's failure to disclose defects, about which they knew or ought reasonably to have known, may be able to sue the donor for damages;

j. in the case of 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;

k. that donated gametes and embryos created from them will not normally be used for treatment once the number of children believed to have been born from them has reached 10, or any lower figure specified by the donor; and

l. that counselling is available.

PART 5 - CONSENT

Consent to Examination and Treatment

5.1 People generally have the right to give or withhold consent to examination and treatment. Centres' attention is drawn to the general guidance given in "A Guide to Consent for Examination and Treatment" by the Department of Health.

5.2 No licensed treatment should be given to any woman without her written consent to that particular treatment. The written consent should explain the nature of the treatment and the steps which are to be taken, and indicate that she has been given all the information referred to in paragraph 4.4 above. The woman should be given the opportunity to decide whether she wishes to consent to all stages of her IVF and GIFT treatment before it begins, or whether she would prefer to consider the number of eggs or embryos to be replaced after they have been retrieved. If she is to undergo frozen embryo replacement she should be asked to consider the number of embryos to be replaced at that stage. Examples of consent forms appear in Annex D. A copy of the consent form should be given to the person giving consent.

5.3 If it is possible that the question of treatment with donated gametes or embryos derived from them may arise, the centre should raise the matter with the client or clients beforehand. The centre should allow clients sufficient time to reflect before asking for consent to treatment with donated material.

Treatment without Consent

5.4 Centres may examine or treat people without first obtaining their consent only in exceptional circumstances.[14] The only circumstances likely to arise in the course of infertility treatment services are where the procedure is necessary to save the patient's life, cannot be postponed, and she is unconscious and cannot indicate her wishes.

[14] This is an obligation under the general law.

Consent to the Presence of Observers

5.5 If a member of the centre's team wishes an observer to be present when a client is being examined, treated or counselled, they should explain, preferably beforehand, who the observer is and why this is desirable, and ask the client whether there is any objection. If the client objects, the observer should not attend.

Consent of the Husband or Male Partner and Legal Fatherhood

5.6 Centres should adopt the procedures described in the following paragraphs in the interests of preventing or resolving a dispute at a later stage about the fatherhood of a child. (Centres are also referred to paragraph 3.17(a), above.)

5.7 A woman's husband will be the legal father of a child born as a result of treatment using donated sperm, unless they are judicially separated or he can prove that he did not consent to the treatment. If a married woman is being treated with donated sperm, centres should explain the position and ask her whether her husband consents to the treatment. If he does, the centre should take all practicable steps to obtain his written consent. If the woman does not know, or he does not consent, centres should, if she agrees, take all practicable steps to ascertain the position and (if this is the case) obtain written evidence that he does not consent.

5.8 If a woman is being treated together with a male partner, using donated sperm, and she is unmarried or judicially separated or her husband does not consent to the treatment, her male partner will be the legal father of any resulting child. Centres should explain this to them both and record at each appointment whether or not the man was present. Centres should try to obtain the written acknowledgement of the man both that they are being treated together and that donated sperm is to be used. Centres should also explain that when a child is born to an unmarried couple the male partner may not have parental responsibility for that child.[15] Unmarried couples concerned about how parental responsibility affects their legal rights should seek their own legal advice.

[15] Children Act 1989

CONSENT TO THE STORAGE AND USE OF GAMETES AND EMBRYOS

Consent to Storage

5.9 Anyone consenting to the storage of their gametes, or of embryos produced from them, **must**:[16]

a. specify the maximum period of storage (if this is to be less than the statutory storage period);

b. state what is to be done with the gametes or embryos if they die, or become incapable of varying or revoking their consent.

5.10 Centres should ensure that anyone wanting to store an embryo for more than 5 years satisfies the conditions for an extended storage period before their consent is obtained.

5.11 In the case of sperm which was already in store on 1 August 1991, the written consent of the person who provided the sperm is not needed in order for storage to continue legally. However, there is no obligation on a centre to continue to store sperm where there is no written agreement to do so.

Consent to Use

5.12 If the intention is to donate gametes for the treatment of others, including the creation of an embryo for that purpose, the donor **must** consent in writing to their use for that purpose.[17]

5.13 If the intention is to create an embryo outside the body, the person giving consent to the use of an embryo produced from their gametes **must** specify the purpose or purposes for which it may be used, namely one or more of:[18]

a. to provide treatment for themselves, or themselves and a named partner;

[16] HF&E Act 1990 Schedule 3 para 2(2)
[17] HF&E Act 1990 Schedule 3 paras 2(1)(a) and (b), 5(1), 6(1) and (3)
[18] HF&E Act 1990 Schedule 3 para 2(1)

b. to provide treatment for others;

c. for research.

5.14 If consent to use sperm was given before 1 August 1991, that consent must be in writing and remain effective (i.e. not have been subsequently withdrawn).

5.15 If no written consent has been given before or after 1 August 1991, no use can be made of the sperm unless and until a consent to use is obtained. It follows that where a person providing sperm has died and there is no written consent in existence no use can be made of the sperm.

General Consent

5.16 In all cases, people giving consent may specify additional conditions subject to which their gametes or embryos produced from them may be used or stored, and may vary or withdraw their consent at any time provided that the genetic material has not already been used.

5.17 Centres should ensure that people do not feel under any pressure to give their consent.

5.18 Centres should allow potential donors and those seeking storage sufficient time to reflect on their decision, before obtaining written consent. A copy of the consent form should be given to the person giving consent.

5.19 The centre does not have to obtain the consent of a donor's partner to the donation of their gametes. However, if the donated gametes are to be used for treatment, and the donor is married or has a long-term partner, centres should encourage donors to ask their partner to consent in writing to the use of the gametes for treatment.

5.20 The centre should be prepared to accept the financial loss if the woman withdraws after preparation for egg recovery has begun.

Consent to Export

5.21 The specific consent of people providing gametes must be obtained to the export of those gametes or of embryos produced using them (see also paragraph 7.23, below).

PART 6 - COUNSELLING

General

6.1 People seeking licensed treatment (i.e. *in vitro* fertilisation or treatment using donated gametes) or consenting to the use or storage of embryos, or to the donation or storage of gametes, **must** be given "a suitable opportunity to receive proper counselling about the implications of taking the proposed steps", before they consent.[19]

6.2 Counselling should be clearly distinguished from:

a. the information which is to be given to everyone, in accordance with the guidance in Part 4;

b. the normal relationship between the clinician and the person offering donation or seeking storage or treatment, which includes giving professional advice; and

c. the process of assessing people in order to decide whether to accept them as a client or donor, or to accept their gametes and embryos for storage, in accordance with the guidance given in Part 3.

6.3 No-one is obliged to accept counselling. However, it is generally recognised as beneficial.

6.4 Three distinct types of counselling should be made available in appropriate cases:

a. **implications counselling**: this aims to enable the person concerned to understand the implications of the proposed course of action for themselves, for their family, and for any children born as a result. It may include genetic counselling;

[19] HF&E Act 1990 s.13(6); Schedule 3 para 3(1)(a)

b. **support counselling**: this aims to give emotional support at times of particular stress, e.g. when there is a failure to achieve a pregnancy;

c. **therapeutic counselling**: this aims to help people to cope with the consequences of infertility and treatment, and to help them to resolve the problems which these may cause. It includes helping people to adjust their expectations and to accept their situation.

Centres **must** make implications counselling available to everyone.[20] They should also provide support or therapeutic counselling in appropriate cases or refer people to sources of more specialist counselling outside the centre.

6.5 Centres should present the offer of counselling as part of normal routine, without implying either that the person concerned is in any way deficient or abnormal, or that there is any pressure to accept. Centres should allow them sufficient time to consider the offer.

6.6 Centres should allow sufficient time for counselling to be conducted sensitively, in an atmosphere which is conducive to discussion. The length and content of counselling, and the pace at which it is conducted, should be determined by the needs of the individual concerned.

6.7 Centres should offer people the opportunity to be counselled by someone other than the clinician responsible for their treatment, donation or storage. Such counselling should be independent of the clinical decision-making process.

6.8 Centres should offer people the opportunity to be counselled individually and with their partner if they have one. Group counselling sessions may also be offered, but it is not acceptable for a centre to offer only group sessions.

6.9 People should be able to seek counselling at any stage of their investigation or treatment. However, counselling should normally be made available after the person seeking treatment or providing the gametes or embryos has received the oral and written explanations described in paragraphs 4.4 and 4.5, above. Discussion may then focus on the meaning and consequences of the decision, rather than on its practical aspects.

[20] HF&E Act 1990 s.13(6); Schedule 3 para 3(1)(a)

Implications Counselling

6.10 Counsellors should invite potential clients or providers of gametes and embryos to consider the following issues:

a. the social responsibilities which centres and providers of genetic material bear to ensure the best possible outcome for all concerned, including the child;

b. the implications of the procedure for themselves, their family and social circle, and for any resulting children;

c. their feelings about the use and possible disposal of any embryos derived from their gametes;

d. the possibility that these implications and feelings may change over time, as personal circumstances change;

e. the advantages and disadvantages of openness about the procedures envisaged, and how they might be explained to relatives and friends.

6.11 Counsellors should invite **clients** to consider in particular:

a. the client's attitude to their own, or partner's infertility;

b. the possibility that treatment will fail.

6.12 Where treatment using donated gametes or embryos is contemplated, clients should also be invited to consider:

a. their feelings about not being the genetic parents of the child;

b. their perceptions of the needs of the child throughout their childhood and adolescence.

6.13 If a woman is already undergoing infertility treatment when the question of treatment with donated gametes or embryos derived from them arises, counselling about the implications of receiving donated material should be offered separately from counselling about the other implications of treatment. Treatment with donated material should not proceed unless the woman and, where appropriate, her partner have been given a suitable opportunity to receive counselling about it.

6.14 If a woman is undergoing infertility treatment and the possibility of her or her partner becoming a donor also arises, counselling about the implications of donation should be undertaken separately from counselling about the implications of treatment in the first instance. If the possibility of donation arises at a later stage in the treatment, donation should not proceed unless the woman and, where appropriate, her partner have been given a suitable opportunity to receive counselling about it.

6.15 Counselling about the implications of donation may be combined with counselling about the other implications of treatment at a later stage, if this is advisable in the light of the initial counselling sessions and the client's or potential donor's wishes.

6.16 Counsellors should invite potential donors of gametes and embryos to consider in particular:

a. their reasons for wanting to become a donor;

b. their attitudes to any resulting children, and their willingness to forego knowledge of and responsibility for such children in the future;

c. the possibility of their own childlessness;

d. their perception of the needs of any children born as a result of their donation;

e. their attitudes to the prospective legal parents of their genetic offspring;

f. their attitudes to allowing embryos which have been produced from their gametes to be used for research.

6.17 If a person seeking to donate or store genetic material is married or has a long-term partner, the centre should counsel them together if they so wish. If a partner wishes to be counselled separately about the implications of donation or storage, centres should take all practicable steps to offer counselling at the centre, or to assist them in contacting an external counselling organisation.

Genetic Counselling

6.18 Centres should have arrangements in place to make genetic counselling available for patients and donors. Centres should ensure that when patients and donors are referred for genetic counselling the confidentiality provisions of the HFE Act are taken into account.

Later Counselling

6.19 Centres should 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 client returns to the centre asking for further counselling, the centre should take all practicable steps to help them obtain it.

Support Counselling

6.20 Centres should also take all practicable steps to offer support to people who are not suitable for treatment, whose treatment has failed, prospective donors who are found to be unsuitable and people who have previously unsuspected defects, to help them come to terms with their situation.

6.21 These steps should include, wherever practicable, reasonable assistance in contacting or establishing a support group.

6.22 Centres should ensure that, as part of their training, all staff are prepared to offer appropriate emotional support at all stages of their investigation, counselling and treatment to clients who are suffering distress.

Therapeutic Counselling

6.23 Procedures should be in place to identify people who suffer particular distress and to offer them, as far as is practicable, therapeutic counselling, with the aim of helping them to come to terms with their situation.

6.24 If a client experiences mental ill-health or a severe psychological problem which may or may not be related to infertility, for which it would be more appropriate to seek help and advice outside the centre, the centre should take all practicable steps to help them to obtain it.

Records

6.25 A record should be kept of all counselling offered and whether or not the offer is accepted.

6.26 All information obtained in the course of counselling should be kept confidential, subject to paragraph 3.29, above.

PART 7 - USE OF GAMETES AND EMBRYOS

Obtaining gametes and embryos

7.1 Centres may only import and export gametes and embryos in accordance with directions made by the HFEA.[21]

7.2 Centres may only transport gametes and embryos between licensed premises in accordance with directions made by the HFEA.[22]

7.3 Centres should only allow a donor to provide sperm produced at home in exceptional circumstances. If a centre does allow a donor to provide sperm produced at home the centre should take all reasonable steps to satisfy itself that the sperm has been produced by that man, not more than two hours previously, and that it has not subsequently been interfered with (so as to ensure that the screening procedures outlined in paragraphs 3.48 and 3.52 remain effective).

7.4 Where any part of treatment services is to take place in premises not covered by a licence (a satellite centre), the law requires the licensed centre intending to carry out the subsequent embryo transfer to ensure that all the requirements of the Act and the Code of Practice are complied with before any part of the treatment begins. These requirements cover information, counselling, the welfare of the child and confidentiality. Copies of the Act and the Code of Practice should be supplied by the licensed centre to the satellite centre.

Clinical Use

7.5 Eggs or sperm which have been subjected to procedures which carry an actual or reasonable theoretical risk of harm to their developmental potential, and embryos created from them, should not be used for treatment. Treatment centres should satisfy the Authority that sufficient scientific evidence is available to establish that any procedures used do not prejudice the developmental potential of the gametes or embryos.

[21] HF&E Act 1990 s.24(4)
[22] HF&E Act 1990 s.24(3)

7.6 Similarly, embryos which have themselves been subject to procedures which carry an actual or reasonable theoretical risk of harm to their developmental potential should not be used for treatment. Treatment centres should satisfy the HFEA that sufficient scientific evidence is available to establish that any procedures used do not prejudice the developmental potential of the embryos.

7.7 Attempts to produce embryos *in vitro* should not be made if there is no intention to store or use the resulting embryo(s), 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, the reason should be explained to the woman, implications counselling should be offered and the written consent of each person providing the gametes must have been obtained.[23]

7.8 Gametes or embryos which have been exposed to a material risk of contamination which might cause harm to recipients or to any resulting children should not be used for treatment. If there is any doubt, centres should seek expert advice.

7.9 No more than three eggs or embryos should be placed in a woman in any one cycle, regardless of the procedure used.

7.10 Women should not be treated with the gametes or with embryos derived from the gametes of more than one man or woman during any treatment cycle.

7.11 Before donor insemination treatment begins, there should be discussion with the client about the number of treatment cycles to be attempted before further investigation into the causes of lack of success (if this arises). This matter should be reviewed at regular intervals.

7.12 Centres may supply sperm for home insemination if, but only if, there are exceptional circumstances making it impracticable or undesirable for the woman to be inseminated at the centre, and the procedures set out in paragraphs 7.13-7.17 below are followed.

7.13 Where sperm is supplied for home insemination this should always be noted and the exceptional circumstances explained in the treatment records.

[23] HF&E Act 1990 Schedule 3 paras 3 and 6

7.14 As with all other donor insemination treatment, the giving of information, assessment of the client, consideration of the welfare of the child and an offer of counselling are required in accordance with the Human Fertilisation and Embryology Act and other Code of Practice guidelines. If it is decided to offer home insemination, centres should obtain an undertaking in writing from the woman to be offered treatment that the sperm will be used by her alone.

7.15 Before supplying sperm for home insemination a centre should obtain an undertaking in writing from the woman to supply information to the centre about the outcome of the treatment.

7.16 The Act forbids the supply of frozen sperm[24] to a person not covered by a licence, and centres may therefore only supply sperm in the process of thawing. Provided that the woman has attended the clinic for assessment purposes, this may be supplied in a dry shipper, either to her in person, or by post or courier.

7.17 Centres should complete DI treatment cycle form (96)2 in the normal way, entering the date of supply or posting as the date of insemination and noting on the form that the sperm was supplied for home insemination.

7.18 Donated gametes or embryos should not be used for treatment once the number of live children believed to have been born as a result of donations from that donor has reached 10. It is the responsibility of the supplier and of the user to agree an appropriate procedure for ensuring that the limit is not exceeded.

7.19 This limit of 10 may be exceeded only in exceptional cases, e.g. where a recipient wishes to have a subsequent child from the same donor. The HFEA should be notified whenever the limit is exceeded. If the donor has specified a limit, this must never be exceeded.[25]

7.20 Centres should not select the sex of embryos for social reasons.

7.21 Centres should not use sperm sorting techniques in sex selection.

[24] HF&E Act 1990 s.2(2) and s.4(1)(a)
[25] HF&E Act 1990 Schedule 3 paras 2(1) and 2(2)

7.22 Centres **must not** attempt to produce embryos *in vitro* by embryo splitting for treatment purposes (see paragraph 10.5, below).[26]

7.23 Centres **must not** export gametes from donors who have produced ten live children in the UK (see paragraphs 5.21 and 7.18, above).[27]

Termination and Disposal

7.24 The special status of the human embryo is fundamental to the provisions of the Act. The termination of the development of a human embryo and the disposal of the remaining material are sensitive and delicate issues. Centres should take full account of this 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.

7.25 Where an embryo is no longer to be kept for treatment, the centre should decide how it is to be allowed to perish, and what is to happen to the perished material. The procedure should be sensitively devised and described, and should be communicated to the people for whom the embryo was being stored if they so wish.

7.26 In the case of embryos used for research, the centre should decide at the outset the duration of the culture period, the method which is to be used to terminate development, and the procedure which will ensure that embryos do not continue to develop after fourteen days or (if earlier) the appearance of the primitive streak.

[26] HF&E Act 1990 Schedule 2 para 3
[27] HF&E Act 1990 s.24(4)

PART 8 - STORAGE AND HANDLING OF GAMETES AND EMBRYOS

General

8.1 Centres should ensure that the highest possible standards are maintained in the storage and handling of gametes and embryos.

Security

8.2 Gametes and embryos should be stored in a designated security area, access to which is controlled.

8.3 The person responsible should allow access only to named individuals in the centre, for whom such access is essential to their work. No other person should have access to gametes and embryos.

8.4 The location of gametes and embryos in storage should be recorded in detail, in order to minimise the amount of handling required in retrieving them. Each occasion on which gametes or embryos are handled should be recorded.

8.5 There should be an effective monitoring system to ensure high standards of security wherever gametes and embryos are handled or stored.

Identification

8.6 The source of gametes and embryos should be accurately recorded and labelled in a manner which is not susceptible to unauthorised or undetectable alteration.

8.7 Records should enable authorised staff to trace what happens to an individual embryo, egg or sperm sample from the date of collection.

Storage Review

8.8 Centres should carry out a periodic review of the status of stored gametes and embryos at least once a year. The purpose of this review is two-fold. The first is to reconcile the centre's records with the genetic material actually in storage. The second is to review the purpose and duration of storage and to identify any action which needs to be taken.

8.9 Centres should also operate a "bring forward" system, which will alert the centre in good time that particular gametes or embryos are about to reach the end of the statutory storage period specified in the centre's licence, or any shorter period specified by the donor.

8.10 Centres should make efforts to maintain contact with couples so that they can be reminded when the storage period for their gametes or embryos is due to expire. Couples should be contacted in good time to give them a reasonable period in which to consider the options available to them. For couples who placed embryos in storage before 1 May 1996 this will include informing them of the possibility of extending the storage period beyond 5 years.

8.11 When embryos placed in storage before 1 May 1996 have been created from donor sperm or eggs or both the renewed consent of the donor(s) is required for storage of more than 5 years. Centres should attempt to contact the donors where it is reasonable to do so. Centres should consider carefully the interests of both the couple and the donor before attempting to contact the donor. Centres should approach each case on an individual basis and take appropriate advice if necessary. Centres should keep a full record of the reasons for the decision and any action taken in each case.

Contamination

8.12 Gametes and embryos which may in future be used for treatment should not be placed in close proximity to any radioactive material or any potential source of infection or chemical or atmospheric contamination.

Transfer of Gametes and Embryos

8.13 It is the responsibility of the receiving centre to ensure that effective consents have been given to the use and storage of any gametes or embryos that are transferred to their centre. This includes consent to the creation of embryos *in vitro* where donor sperm is being provided for use in IVF treatment.

8.14 Centres are responsible for ensuring that the standards of quality and security of genetic material 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.

8.15 Gametes and embryos may not leave licensed premises except in accordance with the HFEA's directions. If gametes or embryos are transferred from one site to another, adequate arrangements should also be made to protect their quality and security. Centres should operate a fail-safe mechanism to ensure that the correct gametes or embryos are transferred.

PART 9 - STORAGE OF GAMETES OR EMBRYOS FOR CANCER PATIENTS

Introduction

9.1 The following section draws together guidance which is relevant to the storage of sperm for male cancer patients and of embryos produced using the eggs of female cancer patients. The advice assumes that the cancer patient will wish to store gametes or embryos only for their own or partner's use in the future.

9.2 A patient presenting for oncology treatment who wishes to store gametes or embryos may have different immediate and future priorities. Provision should be made for supplying appropriate information and counselling as the health needs of the patient change.

Information to be given to cancer patients storing gametes or embryos

9.3 Before anyone consents to the storage of gametes or embryos they **must** be given "such relevant information as is proper".[28] Explanations should be oral and supported by relevant written information. Patients should be encouraged to ask for further information and their questions should be answered in a straightforward, comprehensive and open way.

9.4 Centres should devise a system to ensure that:

a. the right information is given;

b. the person who is to give the information is clearly identified, and has been given sufficient training and guidance to enable them to do so; and

c. a record is kept of the information given.

[28] HF&E Act 1990 s.13(b); Schedule 3 para 3(1)(b)

9.5 Information should be given to cancer patients consenting to the storage of gametes or embryos on the following points:

a. the procedures involved in collecting gametes, the degree of pain and discomfort and any risks to that person, e.g. from the use of superovulatory drugs;

b. the purposes for which their gametes may be used;

c. whether or not they will be regarded under the Act as the parents of any child born as a result of using the stored gametes or embryos;

d. that they are free to withdraw or vary the terms of their consent at any time, unless the gametes or embryos have already been used;

e. that counselling is available;

f. that the normal storage period for sperm is 10 years, although sperm may be stored for more than 10 years where the patient was under 45 years of age when the sperm was placed in storage.

g. that the normal storage period for embryos is 5 years, although embryos may be stored for more than 5 years where the woman who would be treated by the embryos was under 50 years when the embryos were placed in storage.

Counselling

9.6 People consenting to the use or storage of embryos and to the storage of gametes, **must** be given "a suitable opportunity to receive proper counselling about the implications of taking the proposed steps" before they consent.[29] Although not obligatory, counselling is generally recognised as beneficial.

[29] HF&E Act 1990 s.13(b); Schedule 3 para 3(1)(a)

9.7 Counselling should be distinguished from:

a. the information which is to be given to everyone;

b. the normal relationship between the clinician and the person seeking storage, which includes giving professional advice; and

c. the process of assessing people in order to decide whether to accept their gametes or embryos for storage.

9.8 Centres **must** make implications counselling available to everyone.[30] This aims to enable the person concerned to understand the implications of the proposed course of action for themselves, for their family, and for any children born as a result.

9.9 Centres should present the offer of counselling as part of normal routine. The patient should be allowed sufficient time to consider the offer. Centres should allow sufficient time for counselling to be conducted sensitively at the pace determined by the needs of the person concerned. Counselling should normally be made available after the patient has received the explanations described in paragraph 9.4.

9.10 Centres should offer people the opportunity to be counselled by someone other than the clinician responsible for storage.

9.11 Centres should take all practical steps to provide support and further opportunities for counselling about the implications of storage after consent has been given.

9.12 A record should be kept of all counselling offered and whether or not the offer is accepted. All information obtained in the course of counselling should be kept confidential.

[30] HF&E Act 1990 s.13(6); Schedule 3 para 3(1)(a)

Consent to the storage and use of gametes and embryos

9.13 Anyone consenting to the storage of their gametes, or of embryos produced from them, **must**:

a. specify the maximum period of storage (if this is to be less than the statutory storage period);[31]

b. state what is to be done with the gametes or embryos if they die, or become incapable of varying or revoking their consent.[32]

9.14 Cancer patients storing sperm may give consent to storage separately from consent to use.

9.15 Cancer patients storing embryos produced using their eggs **must** specify the purpose for which they may be used, namely to provide treatment for themselves, or themselves and a named partner.[33]

9.16 The terms of the consent of a cancer patient storing embryos produced using her eggs **must** be compatible with the consent of the man who provided the sperm.[34]

9.17 Centres should allow those seeking storage sufficient time to reflect on their decision before obtaining written consent. Consent should be obtained on a consent form provided by the HFEA for the purpose. A copy of the consent form should be given to the person(s) giving consent.

Storage Review

9.18 Centres should carry out a periodic review of the status of stored gametes and embryos at least once a year. The purpose is two-fold. The first is to reconcile the centre's records with the genetic material actually in storage. The second is to review the purpose and duration of storage and to identify any action which needs to be taken.

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[31] HF&E Act 1990 Schedule 3 para 2(2)(a)
[32] HF&E Act 1990 Schedule 3 para 2(2)(b)
[33] HF&E Act 1990 Schedule 3 paras 6(1) and 2(1)(a)
[34] HF&E Act 1990 Schedule 3 para 6(3)

9.19 Centres should operate a "bring forward" system, which will alert the centre in good time that particular gametes or embryos are about to reach the end of the statutory storage period specified in the centre's licence, or any shorter period specified by the donor.

Subsequent use of the stored gametes or embryos

9.20 Insemination of a woman at a licensed centre using her late husband's or partner's sperm is regulated under the Act. For this to take place the man **must** have given written consent to the posthumous use of his sperm to treat the woman.[35] The treatment centre **must** take account of the welfare of the potential child in considering whether to treat the woman.

9.21 People seeking treatment should be informed that the Human Fertilisation and Embryology Act states that if the sperm of a man is used after his death in treatment services i.e. for insemination, IVF or embryo transfer, he is not to be regarded in law as the father of any offspring produced from that treatment.

9.22 Similarly, if an embryo produced using the egg of a woman who has since died is used in treatment, the woman who provided the egg is not to be regarded in law as the mother of the child.

9.23 Frozen embryo transfer is a regulated activity. When a woman who has stored an embryo as a cancer patient wishes to have the embryo transferred in treatment the centre must consider her for treatment in the normal way, taking into account the welfare of the potential child.

Confidentiality

9.24 The attention of centres undertaking storage for cancer patients is drawn to the need for confidentiality of identifying information about people providing gametes (see Part 11, below).

[35] HF&E Act 1990 Schedule 3 para 2(2)(b) and 5(1)

PART 10 - RESEARCH

10.1 All research which involves the creation, keeping or using of human embryos outside the body **must** be licensed by the HFEA.[36] A centre **must** apply to the HFEA for a separate licence for each research project.[37]

10.2 The HFEA may grant licences for research projects for the following purposes only:

a. to promote advances in the treatment of infertility;

b. to increase knowledge about the causes of congenital disease;

c. to increase knowledge about the causes of miscarriages;

d. to develop more effective techniques of contraception;

e. to develop methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation.

10.3 The HFEA cannot grant a licence unless it is satisfied that the use of human embryos is essential for the purposes of the research.

10.4 The following activities are prohibited by law:

a. keeping or using an embryo after the appearance of the primitive streak or after 14 days, whichever is the earlier;

b. placing an embryo in a non-human animal;

c. replacing a nucleus of a cell of an embryo with a nucleus taken from the cell of another person, another embryo, or a subsequent development of an embryo;

[36] HF&E Act 1990 s.3(1)
[37] HF&E Act 1990 Schedule 2 para 4(2)(b)

d. altering the genetic structure of any cell while it forms part of an embryo.

10.5 The HFEA will not license research projects involving embryo splitting with the intention of increasing the number of embryos for transfer (see paragraph 7.22, above).

10.6 Embryos which have been appropriated for a research project **must not** be used for any other purposes.[38]

10.7 Centres should refer each research project to a properly constituted ethics committee for approval before applying for a research licence.

10.8 Centres within the NHS should refer research projects to the Local Research Ethics Committee (LREC) of the relevant District Health Authority. Centres outside the NHS may also refer projects to the LREC by prior arrangement, or may wish to set up their own committee. If so this should be an independent body of not fewer than 5 members. The chairman should be independent of the centre. No more than one third of its members should be employed by or have a financial interest in the centre. Membership of the ethics committee should be approved by the HFEA. For further information on the establishment and operation of a research ethics committee, centres should contact the Department of Health.

10.9 Proposals for research projects involving the use of embryos will be submitted for peer review to appropriate academic referees chosen by the HFEA.

10.10 Centres' attention is drawn to paragraphs 5.9 to 5.20 on consent to storage and use of gametes and embryos, paragraphs 7.5 and 7.6 on the use of gametes and embryos which have been subject to procedures which might prejudice their developmental potential, and paragraphs 7.24 to 7.26 on the termination and disposal of embryos which have been used for research.

[38] HF&E Act 1990 s.15(4)

PART 11 - RECORDS

Accuracy

11.1 All information which centres are required to keep by directions should be accurately recorded with proper cross references where this is required.

11.2 Centres' attention is drawn to paragraphs 3.36, 3.41, 3.56, 4.3(c), 5.2, 5.7, 5.8, 6.25, 8.4, 8.6, 8.7, 8.9, 8.11 and 12.1 of this Code, which set out additional matters about which records should be kept.

Access to Records

11.3 There should be a clearly identified individual in each centre whose responsibility it is to receive, check and arrange authorised access to confidential records. Apart from the access described in paragraphs 11.4, 11.5, 11.8 and 11.11, access to records must be limited to those covered by a licence.

11.4 Data to which the Data Protection Act 1984 applies and records to which the Access to Health Records Act 1990 applies will, unless exempted, be subject to the rights of access provided by those Acts. Centres with computerised records **must** ensure that they are registered with the Data Protection Registrar.[39]

11.5 Centres should 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, even if it does not fall within the scope of the 1984 and 1990 Acts.

Access to Health Records Act 1990

11.6 Centres should be aware that under the Access to Health Records Act 1990, patients, or their agents authorised in writing, are normally entitled to have access to their own health records. The person seeking access must apply in writing to the holder of the record and may choose either to see the record or be supplied with a copy. An

[39] Data Protection Act 1984 s.5

explanation of unintelligible terms must be given. If the records were made within 40 days proceeding the application, access must be allowed within 21 days. No charge is payable except the cost of making a copy and postage. Where records were made more than 40 days before the application, the record holder must allow access within 40 days. In this case a fee not exceeding £10 may be charged and the cost of copying and postage.

Confidentiality

11.7 Centres **must** ensure that information provided in confidence is kept confidential and only disclosed in the circumstances permitted by law.[40] People should not have access to any other person's records (including those of their spouse or partner) without their consent.

11.8 The Act puts strict limits on the disclosure of certain information by centres.[41] 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:

a. information about an identifiable person who receives treatment services or provides gametes can be disclosed to that person;

b. information about an identifiable person who receives treatment services can also be disclosed:

i. with that person's consent to specified people, or to unspecified people who need to know in connection with medical treatment or carrying out a medical or financial audit. The procedure for obtaining consent is set out in paragraphs 3.5-3.8. The consent should 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 should always satisfy themselves that the information is disclosed only to someone who really needs to know the client/patient's identity.

[40] This is an obligation under the general law
[41] HF&E Act 1990 s.33(5)-(7)

ii. 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 practicable to obtain consent in an emergency, and that consent is refused or not requested, then the information must not be disclosed.

c. information about an identifiable person may be disclosed if it is necessary for any purpose preliminary to, or in connection with, legal proceedings or formal complaints procedures. However, no information may be disclosed in these cases which links a donor's identity to an individual who was, or may have been, born as a result of treatment with that donor's gametes;

d. 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;

e. information potentially identifying a donor can be disclosed to enable a centre or person covered by a licence to defend proceedings in England and Wales under the Congenital Disabilities (Civil Liability) Act 1976, and to enable them to bring connected proceedings for compensation against that donor;

f. under the Access to Health Records Act 1990 information held on health records about a patient may be disclosed subject to certain safeguards to that patient, or to certain persons authorised to act on their behalf (applies only in Great Britain).

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

11.10 Centres should 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 should 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 3.8 - 3.10).

11.11 Centres should have clear security procedures which will prevent unauthorised access to records, and particular care should 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 should 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 should inform the police but where the centre is in any doubt it should consult the HFEA.

PART 12 - COMPLAINTS

General

12.1 All centres should ensure that procedures are in place for acknowledging and investigating complaints. These should include the following:

a. centres should nominate one of their senior staff as a complaints officer. The complaints officer should be responsible for the effective operation of the complaints procedure and the investigation of complaints, and should be the first point of contact to whom all complaints are referred;

b. the complaints officer (or someone whom they nominate) should keep an accurate log of complaints, including an explanation of the steps taken, records of any oral or written communication with the complainant and a record of the outcome. Centres should inform the HFEA annually of the number of all written complaints made in that year, and the number which remain unresolved;

c. centres should ensure that all their staff are fully conversant with people's rights to make complaints, and with the procedure to be followed if a complaint is made;

d. notices drawing attention to the complaints procedure should be displayed prominently in reception areas. The notices should give the name and location of the complaints officer.

12.2 Minor complaints and matters of immediate concern can often be dealt with as they arise, without the need for a formal complaint. Staff should deal promptly with issues which can be addressed in a short time, in a way which reassures the person concerned.

12.3 Nevertheless, complaints which may seem trivial to members of staff may be of great concern to the person complaining. Staff should not deter people from making a formal complaint about any matter if they wish to do so.

12.4 If someone is unable to discuss their grievance with the member of staff directly concerned, another member of staff of approximately equivalent seniority should be available to assist.

12.5 If someone has difficulty in formulating their complaint, centres should give them all reasonable assistance to do so.

Investigation of Complaints

12.6 Subject to paragraph 12.2 above, complaints should be given thorough consideration, and should be investigated and processed as swiftly as possible. An independent element should be included in the investigation where appropriate. Complainants should be kept informed of progress.

12.7 When an investigation has been completed, the centre should write a letter to the person who made the complaint, giving a full explanation of the outcome. If there has been any failure on the centre's part, the explanation should include the reasons, any steps to be taken to prevent it recurring, and an apology where appropriate. The letter should also inform the person complaining about any further action which remains open to them.

ANNEX A

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

1. The implications of consenting to the disclosure of identifying information about my/our treatment have 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 (specify name) .....
for the purpose of .....

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.

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 .....

ANNEX B

PARENTAL ORDERS IN SURROGACY CASES

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

i. The child must be genetically related to at least one of the commissioning couple;

ii. 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;

iii. The commissioning couple must be married to each other, and both must have attained the age of 18;

iv. The commissioning couple must have applied for an order within six months of the child's birth;

v. No money, other than expenses, must have been paid in respect of the surrogacy arrangement, unless authorised by a court;

vi. The child must be living with the commissioning couple;

vii. 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 (magistrates courts) in the commissioning couple's home area. Legal aid may be available to cover parental order proceedings.

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 should 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.

Further advice on parental orders is available from the Department of Health. Please contact:-

Department of Health
Health Promotion Division
Rm 417
Wellington House
133-155 Waterloo Road
London SE1 8UG Tel: 0171 972 2000

ANNEX C

HIV SCREENING FOR GAMETE DONORS

Guidance on screening for HIV infection for licensed centres produced by the Human Fertilisation and Embryology Authority in co-operation with the Department of Health.

As with all organs and tissues 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 3 or possibly 6 months after infection. In order to avoid transplanting gametes collected during this "window" period of infection, donors of gametes which can be stored before use (semen) should 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 should assess the suitability of individual donors including any possible history of transmissible infection. The informed consent of the person concerned should be obtained before any HIV test is carried out. Donors should be advised of the practical implications of having an HIV test, even if it proves negative. The centre should offer to arrange specialist HIV counselling for anyone whose behaviour has put them at high risk or whose test proves positive.

Semen should only be used for others when immediate and 180 day tests for HIV antibody are negative. In no circumstances should 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 should 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 should also be tested at the time of the initial assessment. The eggs should only be used if the HIV antibody test is negative. The small risk of HIV infection should be explained to recipients of donated eggs.

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

Centres should adopt any additional guidance on HIV testing which is given by the Health Departments.

ANNEX D

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

Name of Centre : .....

Address : .....

Full Name of Woman: .....

Address : .....

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

Patient'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 [ ]* *2 [ ]* *3 [ ]*	*egg(s) mixed with sperm*	*(b)*	*1 [ ]* *2 [ ]* *3 [ ]*	*embryo(s)*

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) : .....

.....

Patient's Signature: ..... Date: .....

5. All the information listed in paragraph 4.4 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

6. *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.*

7. *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 5.6-5.8 of the Code of Practice].

MALE PARTNER'S ACKNOWLEDGEMENT

8. *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.*

9. *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 acknowledgement 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 5.6-5.8 of the Code of Practice].

CONSENT TO DONOR INSEMINATION

Name of centre : .....

Address : .....

Full name of woman : .....

Address : .....

1. *I have asked the centre named above to provide me with treatment services to help me to bear a child. I consent to (delete/complete as applicable):*

i. the administration as necessary of the drugs described in the attached schedule;

ii. be inseminated with:

(a) the sperm of .....

(b) the sperm of an anonymous donor.

2. *I understand that if the donor has given effective consent under the Human Fertilisation & Embryology Act 1990, he will not be the legal father of any resulting child.*

3. *I understand that I will not be treated with the sperm of more than one man during any one treatment cycle.*

4. *I have discussed in full with ..... the procedures outlined above. I have been given information orally and in writing about them.*

5. *I have been given a suitable opportunity to take part in counselling about the implications of the proposed treatment.*

6. *Other remarks (if required): .....*

.....

Patient's Signature: ..... Date: .....

7. *All the information listed in paragraph 4.4 of the Human Fertilisation and Embryology Authority's Code of Practice has been given to the patient. The patient has been given 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 it is advisable in the interests of establishing the legal parenthood of the child. See paragraphs 5.6- 5.8 of the 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.

Signature of male partner: ..... Date: .....

Full name in block capitals: .....

Address: .....

.....

[NOTE: the centre is not required to obtain a partner's acknowledgement in order to make the treatment lawful but it is advisable in the interests of establishing the legal parenthood of the child. See paragraphs 5.6- 5.8 of the Code of Practice].

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