HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

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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 parts 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 Authority's principal task is to regulate, by means of a licensing system, any research or treatment which involves the creation, keeping and use of human embryos outside the body, or the storage or donation of human eggs and sperm. It must also maintain a Code of Practice giving guidance about the proper conduct of the licenced activities. The HFE Act also allows the Authority to give guidance on any procedure involving the placing of eggs and sperm in a woman.

The Code of Practice includes provisions of the Human Fertilisation and Embryology Act 1990 that are mandatory (and referenced throughout the Code) as well as guidance and advice on good practice. However, *the HFE Act requires the Person Responsible to take all provisions of the Code into* account. It should also be remembered that any section of the Code may, and in certain circumstances must, be taken into account by a Licence Committee when exercising its licensing jurisdiction.

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 HFE 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 HFE 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. Annex F also contains guidance given by other authorities or professional bodies on particular points.

The HFE 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 the 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 Code is regularly reviewed and amended in the light of experience and to keep abreast of both the latest developments in clinical practice and public concerns. This fifth revision of the Code has a new structure. While the main structure has been retained, individual chapters have been divided into a General section applicable to all individuals followed by more specific sections for:

- People seeking treatment
- People providing gametes and embryos for donation
- People seeking long-term storage of gametes
- People involved in egg sharing arrangements

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

- Advertising
- Annex of guidelines produced by professional organisations
- Calculating the limit of ten for donors
- Clinical responsibility
- Data Protection Act
- Egg sharing
- Embryo donation
- Home insemination
- Long term storage
- Payment of expenses to donors
- Production of sperm at home
- Reduction of the upper age limit of sperm donors
- Research licensing
- Safe cryopreservation
- Screening for surrogacy arrangements
- Screening of people considering donation

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

General Standards

1.1 In order to protect the interests and privacy of people seeking treatment or those considering donation, and to guard against the misuse of gametes and embryos, 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]

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

b. that proper equipment is used;

c. that proper arrangements are made for the keeping and disposal of gametes and embryos;

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

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

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 HFEA 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 who is on the General Medical Council Specialist Register, having completed training recognised by the Royal College of Obstetricians and Gynaecology. In addition, participation in a recognised program of continuing medical education and professional development is also important.

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 should follow relevant training programmes under proper supervision.

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[1] Human Fertilisation and Embryology Act 1990 section 16(2)(a)

[2] Human Fertilisation and Embryology Act 1990 section 17(1)(a-e)

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 should be appropriately qualified and 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 counselling staff has a recognised counselling, clinical psychology or psychotherapy qualification to diploma level or above, or a Certificate of Qualification in Social Work, or be working towards accreditation under the BICA/BFS system or, where this is not practical, that a person with such a qualification is available as an advisor to counselling staff and as a counsellor to clients as required. Counselling staff should have evidence of membership of a professional body that is relevant to their qualification, that has a Code of Ethics and Practice which they have agreed to abide by and that has a complaints/disciplinary procedure.

Staff Engaged in Scientific Services

1.11 All clinical scientists working in licensed centres should be registered or working towards registration with the Council for Professions Supplementary to Medicine (CPSM) or its successor body.

1.12 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 (see reference to ACE guidelines in Annex F). Where centres undertake the genetic testing of people seeking treatment and people considering donation, 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.

1.13 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. All andrologists working in licensed centres should be appropriately trained.

1.14 The person in charge of the cryopreservation facilities should be adequately trained and experienced in relevant techniques.

In-Service Training

1.15 Centres should arrange relevant training for all staff taking part in specialist scientific, clinical, nursing 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

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

1.17 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

1.18 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 people considering donation, people seeking treatment, gametes and embryos or records about these, unless the person responsible is satisfied that the applicant is suitable for the post in question.

1.19 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.

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[3] Human Fertilisation and Embryology Act 1990 section 38 (1-3)

PART 2 FACILITIES & ADMINISTRATIVE PROCEDURES

General

General Standards

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]

2.3 Centres must operate their transport and satellite IVF arrangements in accordance with Directions made by the HFEA[6].

Administration

2.4 2.4 Centres should have appropriate clinical governance procedures in place. These should be in accordance with those required within the NHS and, for private clinics, as required by the Care Standards Commission, and as otherwise set out in this Code.

Clinical Facilities

2.5 Backup and emergency clinical facilities for each technique practised should be available at the centre, equivalent to those that are standard practice in other specialities and appropriate to the degree of risk involved. There should be appropriate staff available; for example, someone able to resuscitate the patient should this be necessary during egg recovery.

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

2.7 Centres should be sensitive to the need for comfort and privacy of people seeking treatment and people considering donation, and take all reasonable steps to ensure that facilities are acceptable to them. In particular:

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

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

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

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[4] Human Fertilisation and Embryology Act 1990 section17(1)(b) and (d)

[5] Human Fertilisation and Embryology Act 1990 section12(a)

[6] Human Fertilisation and Embryology Act 1990 sections12(f);13(2)(e)&(f);14(1)(d);15(2); 24(3)

Laboratory Facilities and Safe Cryopreservation

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

2.10 Centres should be aware of the microbiological hazards of handling gametes and embryos and comply with Control of Substances Hazardous to Health (COSHH) regulations.

2.11 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.

2.12 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.

2.13 Centres should have customised, secure, dedicated facilities for the cryopreservation of gametes and embryos, which are adequate to provide for the volume and type of activity to be carried out.

2.14 Appropriate emergency procedures should be in place to respond to failure of, or damage to, storage vessels and systems.

2.15 Written procedures should be in place for the safe use of straws and ampoules to minimise any risk of sample loss or contamination.

2.16 Centres should have written standard operating procedures on the following:

a. itemised procedures for:

i. cleaning vessels

ii. filling vessels

iii. securing vessels

b. freezing and thawing procedures.

c. the location and duration of storage; which tanks hold which samples and for how long.

d. how contaminated samples should be handled.

2.17 Steps should be taken to ensure that no increased risk arises from the transfer of material between centres.

Counselling Facilities

2.18 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.[7] Detailed guidance is given in Part 8.

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

2.20 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 that can provide local information. They should make the list available to clients who wish to seek counselling outside the centre.

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[7] Human Fertilisation and Embryology Act 1990 section 13(6); Schedule 3 paragraph 3(1)(a)

2.21 Centres should so far as practicable establish and maintain good relationships with independent counselling organisations, so that people considering donation and people seeking treatment may be given the maximum help in obtaining the counselling they need.

2.22 Centres should designate an individual responsible for ensuring that counselling facilities are provided as described above and in Part 8.

Secure Storage for Gametes and Embryos

2.23 Centres should provide secure storage for gametes and embryos, access to which is controlled. Detailed guidance is given in Part 10.

Maintaining and Improving Standards

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

2.25 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 people seeking treatment, people considering donation and people seeking storage of gametes and embryos.

2.26 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 2.25, above.

Advertising

2.27 Centres may wish to circulate information about the kinds of treatment that they provide. All publicity material should conform to the general principles in the guidelines of the GMC 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. Any data included should comply with the instructions given in paragraph 6.5c.

Professional Standards

2.28 The HFEA's Code of Practice sets out the minimum standards that centres are required to meet and contains the standards on which centres are inspected. However, a number of specialised organisations produce professional standards that relate to their specific areas of expertise (see Annex F).

PART 3 ASSESSING PEOPLE SEEKING TREATMENT AND WELFARE OF THE CHILD

People Seeking Treatment

General Obligations

3.1 Centres should take all reasonable steps to ensure that people seeking 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.[8]

3.2 Centres should therefore ensure that the medical needs of the people seeking treatment are fully assessed, and that any treatment offered is the most suitable to meet their needs and that people considering donation and gametes are properly screened in accordance with the guidance given below (paragraphs 4.10-4.19).

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 that may appear arbitrary or discriminatory. Further guidance is given in paragraphs 3.8-3.32 below.

Age of People Seeking Treatment

3.4 Where gametes are taken from women over 35 and men over 45, these should only be used for their own treatment, or the treatment of their partner (see paragraphs 4.20-4.21 and 4.23 for exceptions). They should be offered clinical advice and counselling before deciding whether to proceed with treatment.

3.5 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 (see paragraphs 7.7-7.10, below). Effective consent to use or storage of gametes and embryos may only be given by the person who provided the gametes.

3.6 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 (see paragraphs 7.1-7.10, below).

3.7 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 HFEA.

Welfare of the Child

3.8 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

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[8] Human Fertilisation and Embryology Act 1990 section13(5)

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 woman's household or family.

3.9 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 HFE Act and particularly if it involves the use of donated gametes.

3.10 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.

Factors to be Considered

3.11 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 people seeking treatment 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.

3.12 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.

3.13 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.

3.14 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;

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[9] Human Fertilisation and Embryology Act 1990 section13(5)

c. the implications for the welfare of the child if the person providing the gametes for donation 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 3.15, 3.17 and 7.27-7.29, below).

3.15 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 could become the child's legal parents. Centres should therefore consider the factors listed in paragraphs 3.13-3.14 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.

3.16 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.

3.17 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 that 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 D. Annex D also contains information about birth registration of children born through surrogacy arrangements.

3.18 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 person providing gametes for donation. This does not allow the prospective parents to choose, for social reasons alone, a donor of different ethnic origin(s) from themselves. People seeking treatment with donated gametes should be advised that the result of any attempt at matching physical characteristics cannot be guaranteed.

Enquiries to be Made

3.19 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 3.8-3.15, above.

3.20 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 that might adversely affect the welfare of any resulting child.

3.21 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.

3.22 In the event that a client's consent to approaching the GP is refused, centres should consider asking for proof of an individual's identity by means of a birth certificate, passport or similar documentation. Failure to provide such evidence of identification should also be taken into account when considering whether or not to offer treatment.

3.23 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.

3.24 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

3.25 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. People seeking treatment 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.

3.26 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 that is of such gravity that confidentiality <u>cannot</u> 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.

3.27 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.

3.28 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 that remain open and tell clients where they can obtain counselling.

3.29 Centres should record in detail the information that 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 the people seeking treatment.

People Seeking Long Term Storage of Gametes and Embryos

Additional Information

3.30 As well as considering the general advice given above (paragraphs 3.1-3.29), 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.

3.31 Centres should obtain the person's consent before approaching the GP (see guidance in paragraphs 3.21 and 3.23). 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.

People Involved in an Egg Sharing Arrangement

Additional Information

3.32 As well as considering the general advice given above (paragraphs 3.1-3.29), centres should have clear written procedures to follow for the Welfare of the Child assessments of both the egg provider and the egg recipient(s) and their partners. In addition, the Welfare of the Child assessment should take into account that the egg recipient is receiving donated gametes (paragraphs 3.13-3.14).

3.33 As well as considering the advice given above (paragraphs 3.1-3.29) Centres should ensure that the medical suitability of egg providers participating in egg sharing arrangements is fully assessed and care is taken in the selection of these patients. The treatment offered should be the most suitable to meet the medical needs of both the egg provider and the egg recipient.

3.34 Both the egg provider and the egg recipient should have access to an individual, such as a nurse, who would be available to provide impartial support throughout the egg sharing treatment cycle. The person providing support for the egg provider should be different from the person providing support for the egg recipient(s). This should be in addition to the counselling provision.

PART 4 ASSESSING AND SCREENING OF PEOPLE CONSIDERING DONATION

People Providing Gametes and Embryos for Donation

General Standards

4.1 Centres should draw the screening procedure to the attention of people considering donation 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 people considering donation whether they have ever provided gametes at another centre. If they have, the centre should satisfy itself that the limit of 10 live birth events per donor will not be exceeded (see paragraphs 9.30 and 9.31, below).

4.2 Payment may only be made, or benefits given, in exchange for gametes or embryos in accordance with Directions made by the HFEA[10] (see paragraph 4.24). This includes payments or benefits that a centre knows have been given, or will be given, through the involvement of an agency or intermediary.

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

History

4.4 A medical and family history should be taken before any gametes are provided. This should include details of any donations that the person considering donation has made elsewhere. People providing gametes and/or embryos for donation 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.

4.5 Centres should wherever practicable ask the GP of people considering donation whether they know of any reason why the potential donor might not be suitable to donate gametes for the treatment of others.

4.6 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.

4.7 In the event that a client's consent to approaching the GP is refused, centres should consider asking for proof of an individual's identity by means of a birth certificate, passport or similar documentation. Failure to provide such evidence of identification should also be taken into account in deciding whether or not to accept the gametes or embryos for research or treatment.

Suitability as Donors

4.8 Centres should give careful consideration to the suitability of the person considering donation before accepting or using their gametes for the treatment of others. The views of all those at the centre

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[10] Human Fertilisation and Embryology Act 1990 section12(e)

who have been involved with the person considering donation 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 where appropriate;

d. whether the person considering donation has children of their own; and

e. the attitude of the person considering donation towards the donation.

Potential Donors who are Undergoing Treatment

4.9 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.

Scientific Tests

4.10 All reasonable steps should be taken to prevent transmission of a serious genetic disorder. In most situations this will be served by taking a thorough family history from the person considering donation. Genetic testing should be limited to the determination of carrier status for inherited recessive disorders in which an abnormal test result carries no significant direct health implications for the person considering donation. Centres should ensure whenever genetic testing of people considering donation is carried out it is with the same level of support and counselling as for recipients. This means that people considering donation should be informed of the result of their test and offered post-test counselling.

4.11 In relation to cystic fibrosis, centres should normally screen people considering donation, 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 a known cystic fibrosis carrier. When this is necessary the patients should be made aware of the risks involved and be offered screening and counselling.

4.12 Screening for Tay-Sachs, thalassaemia and sickle cell anaemia should be carried out in appropriate population groups.

4.13 In relation to HIV testing, centres should adopt as a minimum the procedure set out in "HIV Screening for People Providing Gametes and/or Embryos for Donation" by the Human Fertilisation and Embryology Authority and the Department of Health, (Annex C).

4.14 Centres should screen all people considering donation for cytomegalovirus (CMV) antibodies. Wherever possible, centres should use CMV seronegative donors. Centres should ensure that gametes from people who are CMV seropositive are only used for CMV seropositive recipients. Only those seropositive people that are IgG positive and IgM negative should be used, indicating that they are unlikely to have an active infection. Gametes from a person considering donation who is initially seronegative and seroconverts whilst donating must not be used for treatment services.

4.15 Testing of people considering donation for other infections should follow the guidelines of the British Andrology Society (sperm) and the British Fertility Society (egg and embryo) (Annex F).

4.16 It is essential that all recipients of gamete donations should receive information explaining the limitations of the testing procedures used and any risks associated with the treatment.

4.17 Centres should re-screen people considering donation where appropriate, and adopt any other test which may come to be regarded as a matter of good practice by the standards of professional colleagues in relevant specialities or may be indicated in a particular case while this Code is in force.

4.18 Where an embryo is donated for clinical treatment both parties who produced gametes from which the embryo was created should undergo the full screening process as recommended for people considering donation of gametes as given above (paragraphs 4.10-4.18).

4.19 All providers of gametes in a surrogacy arrangement should be screened in accordance with the usual requirements for people considering donation. This screening should comply with the advice given above (in paragraphs 4.10 –4.18) and that set out in Annex C.

Age of People Considering Donation

4.20 Sperm should not be taken for the treatment of others from donors over the age of 45, unless there are exceptional reasons for doing so. If there are exceptional reasons, these should be explained in the treatment records.

4.21 Eggs should not be taken for the treatment of others from donors over the age of 35, unless there are exceptional reasons for doing so. If there are exceptional reasons, these should be explained in the treatment records.

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

4.23 Where gametes are used to produce embryos specifically for donation, or embryos are donated following licenced fertility treatment, centres should follow the age-limits that exist for gamete donors, i.e. 35 for egg donors and 45 for sperm donors, unless there are exceptional reasons for not doing so. If there are exceptional reasons, these should be explained in the treatment records.

Payment and Expenses for People Providing Gametes for Donation

4.24 People providing gametes for donation must be paid no more than £15 for each donation plus reasonable expenses in accordance with Directions[11] (see guidance in Annex G).

People Unsuitable as Donors

4.25 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, comprehensible and open way.

4.26 If a centre refuses to accept someone as a provider of gametes for donation because of a physical or psychological problem that requires separate treatment or specialised counselling, the centre should give the person all reasonable assistance in obtaining this.

4.27 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 suitability of the person considering donation in the light of that information and take any necessary action.

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[11] Human Fertilisation and Embryology Act 1990 section 12(e)

4.28 Where a centre becomes aware that a person who has provided gametes for donation has a previously unsuspected genetic disease or is a carrier of a deleterious recessively inherited condition (for example through the birth of a baby with cystic fibrosis) the centre should immediately inform both the supplying centre and the HFEA. The supplying centre should inform any centre that has received gametes from that person of their carrier status. The supplying centre should also consider informing the person who has provided gametes for donation that they may be a carrier and, if they do so, should offer them counselling and testing. Centres should inform patients who have received treatment at their centre using that person's gametes 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 person's gametes, centres should consider carefully when and how she should be informed of the person's carrier status.

People Involved in an Egg Sharing Arrangement

Additional Information

4.29 Egg providers should be treated in the same way as other people considering donation of gametes (paragraphs 4.10-4.18 and Annex C).

4.30 Egg providers and recipients should be made aware of the screening that will be undertaken before treatment is commenced.

PART 5 CONFIDENTIALITY

General

General Obligation

5.1 Any information that centres obtain from people considering donation or people seeking treatment <u>must</u> be kept confidential unless disclosure is authorised by law.[12] Certain types of information may only be disclosed in the circumstances authorised in the HFE Act (see paragraph 12.11). If a centre is in doubt about whether or not it should disclose information, it should refer to the HFEA.

5.2 The HFE 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 HFEA or to another person to whom a licence applies or to the individual concerned. However, identifying information about the provision of treatment services can be disclosed <u>either</u>:

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 <u>must</u> not be disclosed[13].

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

5.4 Where information is disclosed with consent, the following conditions <u>must</u> be met:

a. before this consent is given, reasonable steps <u>must</u> have been taken to explain the implications of disclosure to the person whose consent is requested[14]; and

b. the person(s) to whom the information is to be disclosed <u>must</u> 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 12.11)[15].

5.5 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: obtain the client's consent in writing. The consent of each person whose identity is to be disclosed should be obtained. A model consent form is at Annex B;

a. tell the person whose consent is requested what information is to be disclosed;

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[12] Human Fertilisation and Embryology Act 1990 section 33(5)

[13] Human Fertilisation and Embryology Act 1990 section 6E(a) as amended by Human Fertilisation and Embryology (Disclosure of Information) Act 1992

[14] Human Fertilisation and Embryology Act 1990 section 6D Human Fertilisation and Embryology (Disclosure of Information) Act 1992

[15] Human Fertilisation and Embryology Act 1990 section 6C Human Fertilisation and Embryology (Disclosure of Information) Act 1992

b. 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 person's fertility treatment), and the implications of disclosing this information, so that the person 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 12.13, below).

c. 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 centre concerned.

d. renew the consent of the person/people if treatment which has not initially involved consent subsequently does so.

5.6 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 12.11, below).

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

5.8 Centres should, as far as possible, ensure that those receiving information record details of treatment services only on the medical record of the person seeking treatment and not on that of any resulting child.

5.9 If a centre refers a person seeking treatment 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.

People Involved in an Egg Sharing Arrangement

Additional Information

5.10 As well as considering the general advice given above (paragraphs 5.1-5.9), in anonymous egg sharing arrangements every care should be taken to ensure that this confidentiality is not compromised. To achieve this, centres should give special consideration to the physical and/or temporal separation of provider and recipient notes, facilities and procedures.

PART 6 INFORMATION

General

General Obligation

6.1 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".[16] This should be distinguished from the requirement to offer counselling, which people who are seeking treatment, providing gametes/embryos for donation or wishing to store their gametes/embryos need not accept.

6.2 People seeking treatment, providing gametes/embryos for donation or wishing to store their gametes/embryos 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.

6.3 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.

6.4 Information should be given on the following points:

a. that counselling is available;

b. that they are free to withdraw or vary the terms of their consent at any time, up to the point that the gametes or embryos have been used in treatment services or in a project of research;

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

d. the procedures involved in collecting gametes, including (where relevant) the possible deterioration of gametes or embryos associated with storage; in addition any possible pain, discomfort and risks to that person, e.g. from the use of superovulatory drugs;

e. any costs, fees or reimbursements relevant to treatment, donation or storage;

f. the statutory storage period for gametes and embryos; and the regulations for extension of storage;

g. the options available to them in the event of their death or mental incapacity and the consent required to ensure their wishes are fulfilled.

People Seeking Treatment

Additional Information

6.5 As well as considering the general advice given above (6.1-6.4), information should be given to people seeking treatment on the following points:

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[16] Human Fertilisation and Embryology Act 1990 section13(b); Schedule 3 paragraph 3(1)(b)

a. 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;

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

c. the limitations and possible outcomes of the treatment proposed, and variations of effectiveness over time. Any data given in publicity material should be accompanied by the centre's own live birth rate per treatment cycle as verified by the HFEA and the national live birth rate per treatment cycle;

d. the centre's statutory duty to take account of the welfare of any resulting or affected child; and (where relevant) the advantages and disadvantages of continued treatment after a certain number of attempts;

e. the possible side effects and risks of the treatment to the woman and any resulting child. This should include: the possible side effects and risks of ovarian stimulation (where relevant) for the woman, including the risks associated with ovarian hyperstimulation syndrome (OHSS) and the putative risk of cancer;

f. the availability of embryo freezing facilities, including the likelihood of success of embryo freezing, thawing, transfer and implications of storage; including (where relevant) the possible deterioration of gametes or embryos associated with storage;

g. 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;

h. the importance of telling the treatment centre about any resulting birth.

6.6 In addition, if the treatment involves donated gametes, people seeking treatment should receive information on the following:

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

b. the availability of genetic screening, especially if the people providing gametes at the centre are not screened for cystic fibrosis;

c. who will be the child's parent or parents under the HFE 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 3.11);

d. the information which centres <u>must</u> 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[17];

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

f. the child's right to seek information about their origins on reaching 18 or 16 years if contemplating earlier marriage.

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[17] Human Fertilisation and Embryology Act 1990 section 31

People Providing Gametes and Embryos for Donation

Additional Information

6.7 As well as considering the general advice given above (paragraphs 6.1-6.4), 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 screening which will be carried out, and the practical implications of having an HIV antibody test, even if it proves negative;

b. the genetic testing that will be carried out, its scope and limitations and the implications of the result for the person considering donation and their family;

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

d. that donated gametes and embryos created from them will not normally be used for treatment once the number of live birth events believed to have been born as a result of their donation has reached 10, or any lower figure specified by the person considering donation;

e. that the HFE Act generally permits people providing gametes to preserve their anonymity;

f. the information which centres <u>must</u> 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[18];

g. 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[19];

h. in the case of altruistic egg donation where the woman is not undergoing infertility treatment herself, she will not incur any financial or other penalty if she withdraws her consent after preparation for egg recovery has begun;

6.8 As well as considering the general advice given above (paragraphs 6.1-6.4), people consenting to the use of gametes or an embryo for the purpose of any project of research may specify conditions subject to which the gametes or embryo may be so used[20] and should be given the following information:

a. that research is experimental and any gametes and embryos used and created for the purposes of any project of research will not be transferred for treatment;

b. that only those gametes and embryos (fresh or frozen) that are surplus to treatment will be used for research;

c. that research will not affect the treatment cycle;

d. that the donation of gametes and embryos to research will not compromise treatment;

e. that they are under no obligation to donate their gametes and embryos to research;

f. that they have the right to vary or withdraw their consent from the study at any time up until the gametes and embryos are used for the purposes of any project of research;

g. that they should have had an opportunity to ask questions and discuss the research project;

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[18] Human Fertilisation and Embryology Act 1990 section 31

[19] Human Fertilisation and Embryology Act 1990 section 35

[20] Human Fertilisation and Embryology Act 1990 Schedule 3 paragraph 3(1)

h. that after the research has been completed, all donated gametes and embryos will be allowed to perish;

6.9 In addition, if the donated gametes and embryos could be used in secondary research the people giving consent should be informed of this and provided with the following information:

a. that it is possible that gametes and embryos or embryo cell samples may be fixed for future studies and his type of research is called secondary research;

b. that secondary research could include genetic research and the implications of this;

c. that as a means of protecting confidentiality, gametes and embryos for secondary research may be anonymised and this can be reversible or irreversible;

d. if the gametes and embryos are to be reversibly anonymised and if genetic research is proposed, people considering donation should be told that particular results may be fed back to them and offered counselling about the implications of this;

e. if the gametes and embryos are to be irreversibly anonymised, people considering donation should be fully informed of the implications of this i.e. the inability to feed results back.

People Seeking Long Term Storage of Gametes and Embryos

Additional Information

6.10 As well as considering paragraphs 6.1-6.4, centres should produce specific information tailored to the needs and circumstances of oncology patients covering, as a minimum, the requirements listed in paragraphs 6.1-6.4 and 6.5-6.6 above.

People Involved in an Egg Sharing Arrangement

Additional Information

6.11 As well as fulfilling the requirements sets out above in paragraphs 6.1-6.4 separate written information for egg providers and egg recipients should be available.

6.12 In addition to standard information, separate written information for providers and recipients should include the following:

a. The criteria used for selection of egg providers and recipients for egg sharing arrangements;

b. The centre's procedures for determining how the eggs will be shared between the provider and the recipient(s);

c. The screening egg providers will be required to undergo;

d. The terms of the agreement to be signed;

e. The law relating to consent and the rights of the egg provider to vary or withdraw her consent. Any implications that may result from the withdrawal of consent should be made clear to all parties prior to treatment commencing;

f. The alternative treatment options available.

6.13 In addition, egg recipients should receive the same information as other people seeking treatment with donated gametes given in paragraph 6.5 and 6.6.

6.14 Egg providers should receive information to be given to people considering donation detailed in paragraph 6.7.

PART 7 CONSENT

General

Consent to Examination and Treatment

7.1 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.

Treatment without Consent

7.2 Centres may examine or treat people without first obtaining their consent only in exceptional circumstances.[21] The only circumstances likely to arise in the course of infertility treatment services are where the procedure is necessary to save the person's life, cannot be postponed, and they are unconscious and cannot indicate their wishes.

Consent to the Presence of Observers

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

General Obligations

7.4 Centres should allow people seeking treatment, people considering donation 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.

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

7.6 In all cases, people giving consent may specify additional conditions subject to which their gametes or embryos may be used or stored, and may vary or withdraw their consent at any time provided that the gametes, or embryos created from them, have not been used in treatment services or a project of research.

7.7 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[22].

Children and Gillick Competence

7.8 The General Medical Council describes Gillick Competence in their guidelines 'Seeking patients' consent: the ethical considerations' (GMC, November 1998).

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[21] This is an obligation under general law

[22] Human Fertilisation and Embryology Act 1990 Schedule 3

7.9 In these guidelines they state the following: "You must assess a child's capacity to decide whether to consent or refuse proposed investigation or treatment before you provide it. In general, a competent child will be able to understand the nature, purpose and possible consequences of the proposed investigation or treatment, as well as the consequences of non-treatment."

7.10 Centres are also directed to the guidance issued by the British Medical Association.[23] Centres are advised that if they are in doubt they should seek their own legal advice.

Consent to Storage

7.11 Anyone consenting to the storage of their gametes, or of embryos produced from them, must:[24]

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.

Statutory Storage Period

7.12 The normal storage period for gametes is usually 10 years, extension of this storage period is detailed in paragraphs 7.34-7.35, below.

7.13 In the case of sperm that 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.

7.14 The normal storage period for embryos is usually five years, extension of this storage period is detailed in paragraphs 7.36-7.39, below.

Consent to Use

7.15 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:[25]

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

b. to provide treatment for others;

c. for research.

7.16 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).

7.17 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.

7.18 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.

7.19 If it is proposed that embryos are to be used, the terms of the consent of a person storing embryos produced using her eggs must be compatible with the consent of the man who provided the sperm.[26]

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[23] BMA 1995 'Assessment of Mental Capacity'

[24] Human Fertilisation and Embryology Act 1990 Schedule 3 paragraph 2(2)

[25] Human Fertilisation and Embryology Act 1990 Schedule 3 paragraph 2(1)

Consent to Export

7.20 The specific consent of people providing gametes must be obtained to the export of those gametes or of embryos produced using them[27] (see also paragraph 9.32, below).

Posthumous use

7.21 Insemination of a woman at a licensed centre using her late husband's or partner's sperm is regulated under the HFE Act. For this to take place the man must have given consent to the posthumous use of his sperm to treat the woman.[28]

7.22 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.[29]

7.23 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.

7.24 If donation of an embryo is being considered in the event of death or mental incapacity both partners should undergo screening as outlined in paragraphs 4.10 –4.18.

People Seeking Treatment

Additional Information

7.25 As well as considering the requirements of paragraphs 7.1-7.24 above, 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 that are to be taken, and indicate that she has been given all the information referred to in paragraph 6.1-6.6 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 E. A copy of the consent form should be given to the person giving consent.

7.26 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 person(s) seeking treatment beforehand. The centre should allow persons sufficient time to reflect before asking for consent to treatment with donated material.

Consent of the Husband or Male Partner and Legal Fatherhood

7.27 As well as the general advice given above (paragraphs 7.1-7.24), 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 (paragraph 3.15a).

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[26] Human Fertilisation and Embryology Act 1990 Schedule 3 paragraph 6(3)

[27] Human Fertilisation and Embryology Act 1990 section 24(4)

[28] Human Fertilisation and Embryology Act 1990 Schedule 3 paragraphs 2(2)(b) and 5(1)

[29] Human Fertilisation and Embryology Act 1990 section 28(6)(b)

7.28 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.

7.29 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.[30] Unmarried couples concerned about how parental responsibility affects their legal rights should seek their own legal advice.

People Providing Gametes and Embryos for Donation

Additional Information

7.30 As well as considering the requirements of paragraphs 7.1-7.24 above, if the intention is to donate gametes for the treatment of others, including the creation of an embryo for that purpose, the person considering donation must consent in writing to their use for that purpose.[31]

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

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

People Seeking Long Term Storage of Gametes and Embryos

Additional Information

7.33 As well as considering the requirements of paragraphs 7.1-7.23 above, people seeking long term storage of gametes may give consent to storage separately from consent to use.

7.34 In addition to the requirements of paragraphs 7.12-7.13 above centres should be aware that, the normal storage period for gametes is 10 years, although gametes may be stored for more than 10 years where the person seeking storage was under 45 years of age when the gametes were placed in storage and providing the other conditions for an extended storage period have been satisfied.[32]

7.35 Centres should ensure that anyone wanting to store gametes for more then 10 years satisfies all the conditions for an extended storage period before their consent is obtained.

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[30] England - Children Act 1989; Scotland - Children (Scotland) Act 1995; Northern Ireland - Children (Northern Ireland) Order 1995

[31] Human Fertilisation and Embryology Act 1990 Schedule 3 paragraphs 2(1)(a) and (b), 5(1), 6(1) and (3)

[32] Human Fertilisation and Embryology Act (Statutory Storage) Regulations 1991

7.36 As well as the requirements of paragraph 7.14 above centres should be aware that, the normal storage period for embryos is usually five years, although embryos may be stored for more than five years where the woman who would be treated by the embryos was under 50 years when the embryos were placed in storage and providing the other conditions for an extended storage period have been satisfied.[33]

7.37 Centres should ensure that anyone wanting to store an embryo for more then five years satisfies all the conditions for an extended storage period before their consent is obtained.

7.38 People storing embryos produced using their eggs <u>must</u> specify the purpose for which they may be used, namely to provide treatment for themselves, or themselves and a named partner.[34]

People Involved in an Egg Sharing Arrangement

Additional Information

7.39 As well as considering the requirements of paragraphs 7.1-7.7; 7.11 and 7.14-7.31 above, statutory HFEA consent forms should be completed and signed as follows:

a. The egg provider should complete a HFEA(00)7 for the use of the eggs and the storage of the embryos created for her own use. This HFEA(00)7 should be completed as though the egg provider was an IVF patient in accordance with HFEA guidance for the completion of HFEA (00)7.

b. The egg provider should also complete a SEPARATE HFEA(00)7 for the use of the donated eggs and the embryos created for use by the recipient couple. This second HFEA (00)7 should be completed as though the egg provider was an egg donor in accordance with HFEA guidance for the completion of HFEA(00)7.

7.40 This arrangement allows different conditions to be placed on the storage of any spare embryos that may be created and cryopreserved. Using only one (00)7 does not allow consent to be varied in this way. It should be emphasised that, in accordance with the HFE Act, the provider may withdraw or vary her consent up to the time an embryo containing her gametes is used in treatment services or research, including cryopreserved embryos.

7.41 Any implications that may result from the withdrawal of consent should be made clear to all parties prior to treatment commencing. This should be fully detailed in the information given to the egg provider and the egg recipient. It should also be included in the written agreements.

7.42 The male partner of the egg provider and of the egg recipient should complete HFEA (00)6 in accordance with HFEA guidance as necessary.

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[33] Human Fertilisation and Embryology Act (Statutory Storage Period for Embryos) Regulations 1991

[34] Human Fertilisation and Embryology Act 1990 Schedule 3 paragraph 2(1)(a)

PART 8 COUNSELLING

General

General Obligations

8.1 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.[35]

8.2 Counselling should be clearly distinguished from:

a. the information which is to be given to everyone, in accordance with the guidance in Part 6;

b. the normal relationship between the clinician and the person considering 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 for treatment or as a donor, or to accept their gametes and embryos for storage, in accordance with the guidance given in Parts 3 and 4.

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

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

i. 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;

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

iii. 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. Therapeutic counselling may be an ongoing process and can take place or continue after the course of treatment has ended.

8.5 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.

8.6 Centres should allow sufficient time for counselling to be conducted sensitively, in an atmosphere that is conducive to discussion.

8.7 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.

8.8 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.

8.9 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

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[35] Human Fertilisation and Embryology Act 1990 section13(6); Schedule 3 paragraph 3(1)(a)

considering providing gametes or embryos for donation has received the oral and written explanations described in Part 4, above. Discussion may then focus on the meaning and consequences of the decision, rather than on its practical aspects.

Implications Counselling

8.10 Centres must make implications counselling available to everyone.[36] They should also provide access to therapeutic counselling in appropriate cases or refer people to sources of more specialist counselling outside the centre.

8.11 Implications counselling may be given by counsellors and/or other professionals, but for the purposes of this section the term counsellor will be used to describe the person providing implications counselling.

8.12 The counsellor should invite people to consider the following issues:

a. the social responsibilities that centres and providers of gametes and embryos 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.

Genetic Counselling

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

Later Counselling

8.14 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 patient returns to the centre asking for further counselling, the centre should take all practicable steps to help them obtain it.

Support Counselling

8.15 Centres should also take all practicable steps to offer support to people who are not suitable for treatment, whose treatment has failed and people considering donation who are found to be unsuitable, to help them come to terms with their situation.

8.16 These steps should include, wherever practicable, reasonable assistance in contacting a support group.

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[36] Human Fertilisation and Embryology Act 1990 section13(6); Schedule 3 paragraph 3(1)(a)

8.17 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 people who are suffering distress.

Therapeutic Counselling

8.18 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.

8.19 If a person experiences mental ill-health or a severe psychological problem that 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

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

8.21 All information obtained in the course of counselling should be kept confidential, subject to paragraph 3.26, above.

People Seeking Treatment

Additional Information

8.22 As well as considering the requirements of paragraphs 8.1-8.21 above, counsellors should invite people seeking treatment to consider:

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

b. the possibility that treatment will fail.

8.23 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 (see guidance for people considering donation paragraphs 8.27-8.28). 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.

8.24 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 wishes of the people considering treatment.

8.25 In addition, where treatment using donated gametes or embryos is contemplated, people seeking treatment 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.

8.26 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.

People Providing Gametes and Embryos for Donation

Additional Information

8.27 As well as considering the requirements of paragraphs 8.1-8.21, counsellors should invite people considering donation of gametes and embryos to consider in particular:

a. their reasons for wanting to provide gametes for donation;

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.

8.28 If a person seeking to donate or store gametes and/or embryos 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.

People Seeking Long Term Storage of Gametes and Embryos

Additional Information

8.29 As well as considering the requirements of paragraphs 8.1-8.21, centres should ensure that sources of more specialist counselling outside the centre are available and may be more appropriate for oncology patients or others requiring long term storage of their gametes or embryos.

8.30 Centres should be aware of the special needs of people seeking long term storage of gametes and embryos and should ensure that counselling is available after storage.

People Involved in an Egg Sharing Arrangement

Additional Information

8.31 As well as considering the requirements of paragraphs 8.1-8.21, the HFEA strongly recommends that all couples contemplating participation in an egg sharing arrangement receive implications counselling.

8.32 Independent counsellors should be aware of the medical processes involved as well as the particular legal and social issues relevant to egg sharing arrangements.

8.33 Counselling equivalent to that provided for people seeking treatment and considering donation should be given to an egg provider and her partner as covered in paragraphs 8.22-8.28.

8.34 Implications counselling must be offered to both egg providers and recipients[37] and should cover the following issues:

a. the implications of not knowing whether the recipient has succeeded or not;

b. the implications if the provider remains childless;

c. the implications for the recipient of using a sub-fertile egg provider; and

d. the implications of there possibly being half-siblings of a similar age resulting from the treatment.

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[37] Human Fertilisation and Embryology Authority 1990 section13(6) and Schedule 3(1)(a)

PART 9 USE OF GAMETES AND EMBRYOS

General

Obtaining gametes and embryos

9.1 Centres may only import and export gametes and embryos in accordance with Directions made by the HFEA.[38]

9.2 Centres may only transport gametes and embryos between licensed premises in accordance with Directions made by the HFEA.[39]

9.3 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 HFE Act, the Code of Practice and any Directions made by the HFEA[40] 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 HFE Act and the Code of Practice should be supplied by the licensed centre to the satellite centre.

Clinical Use

9.4 Eggs or sperm that have been subjected to procedures that 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 HFEA that sufficient scientific evidence is available to establish that any procedures used do not prejudice the developmental potential of the gametes or embryos.

9.5 Similarly, embryos that have themselves been subject to procedures that 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.

9.6 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.[41]

9.7 Frozen embryo transfer is a regulated activity. When a woman who has stored an embryo and 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.

9.8 Gametes or embryos that have been exposed to a material risk of contamination that 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.

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

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[38] Human Fertilisation and Embryology Act 1990 section24(4)

[39] Human Fertilisation and Embryology Act 1990 section 24(3)

[40] Human Fertilisation and Embryology Act 1990 sections12(f);13(2)(e)&(f);14(1)(d);15(2); 24(3)

[41] Human Fertilisation and Embryology Act 1990 Schedule 3 (3) and (6)

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

9.11 Centres should not attempt to produce embryos *in vitro* by embryo splitting for treatment purposes.

Termination and Disposal

9.12 The special status of the human embryo is fundamental to the provisions of the HFE Act. The termination of the development of a human embryo and the disposal of the remaining material are sensitive and delicate issues. 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.

9.13 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.

9.14 In the case of embryos used for research, the centre should decide at the outset the duration of the culture period, the method that 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.

People Seeking Treatment

Additional Information

9.15 As well as considering the requirements of paragraphs 9.1-9.14, centres may allow a man to provide sperm produced at home in exceptional circumstances. Normally sperm should be produced in a licensed centre. If a centre does allow a man 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. That the sperm has been produced at home, and that the centre is satisfied the above conditions have been met, should be formally noted in patient records.

9.16 Centres should ensure that facilities as detailed in Paragraph 2.5 are still available to patients if required.

9.17 Where embryos have been created using partner sperm produced at home and donation is being considered, the fact that the sperm was not produced at a licenced centre should be taken into account.

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

9.19 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.

9.20 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.

9.21 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 9.22-9.26 are followed.

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

9.23 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 HFE 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.

9.24 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.

9.25 The HFE Act forbids the supply of frozen sperm[42] 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, the sperm may be supplied to either, her in person or by courier.

9.26 The use of a dry shipper, or any other containment vessel that would keep the sperm in a frozen or preserved state after leaving the licensed centre is strictly prohibited by the HFE Act.

9.27 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.

People Providing Gametes and Embryos for Donation

Additional Information

9.28 As well as considering the requirements of paragraphs 9.1-9.14, centres should only allow a donor to provide sperm produced at home in exceptional circumstances. Normally sperm should be produced in a licensed centre. 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 4.10-4.18 remain effective). That the sperm has been produced at home, and that the centre is satisfied the above conditions have been met, should be formally noted in patient records.

9.29 Where embryos have been created using partner sperm produced at home and donation is being considered, the fact that the sperm was not produced at a licenced centre should be taken into account.

9.30 Donated gametes or embryos should not be used for treatment once the number of live birth events that have occurred 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.

9.31 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

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[42] Human Fertilisation and Embryology Act 1990 s.2(2) and s.4(1)(a)

exceeded. If the person providing gametes for donation has specified a limit, this must never be exceeded.[43]

9.32 Centres must not export gametes from donors who have produced 10 live birth events in the UK (see paragraphs 9.30 and 9.31, above).[44]

People Seeking Long Term Storage of Gametes and Embryos

Additional Information

9.33 As well as considering the requirements of paragraphs 9.1-9.14, insemination of a woman at a licensed centre using her late husband's or partner's sperm is regulated under the HFE Act (see paragraphs 7.21-24).

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[43] Human Fertilisation and Embryology Act 1990 Schedule 3 paras 2(1) and 2(2)

[44] Human Fertilisation and Embryology Act 1990 section 24(4)

PART 10 STORAGE AND HANDLING OF GAMETES AND EMBRYOS

General

General Obligation

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

Security

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

10.3 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.

10.4 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.

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

Identification

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

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

Storage Review

10.8 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 that needs to be taken.

10.9 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 person providing gametes for donation.

10.10 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 five years (see also paragraphs 7.34-7.39).

10.11 Where embryos placed in storage before 1 May 1996 have been created from donor sperm or eggs or both, the renewed consent of the people who provided the gametes is required for storage of more then five years. Centres should attempt to contact the people who provided the gametes where it is reasonable to do so. Centres should consider carefully the interests of both the couple and the people who provided the gametes before attempting to contact the donor(s). 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

10.12 Gametes and embryos that 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 (see also paragraphs 2.9-2.17).

Transfer of Gametes and Embryos

10.13 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.

10.14 Centres are responsible for ensuring that the standards of quality and security of gametes and embryos are maintained, wherever the material happens to be on the premises. This includes material being transferred from the laboratory for treatment or preparation for treatment.

10.15 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 11 RESEARCH

General

General Standards

11.1 All research that involves the creation, keeping or using of human embryos outside the body must be licensed by the HFEA.[45] A centre must apply to the HFEA for a separate licence for each research project.[46]

11.2 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.

f. increasing knowledge about the development of embryos;

g. increasing knowledge about serious disease; or

h. enabling any such knowledge to be applied in developing treatments for serious disease.[47]

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

Prohibitions

11.4 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;

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

11.5 Embryos that have been appropriated for a research project must not be used for any other purposes.[48]

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[45] Human Fertilisation and Embryology Act 1990 section 3(1)

[46] Human Fertilisation and Embryology Act 1990 Schedule 2 paragraph 4(2)(b)

[47] In January 2001 Parliament passed regulations enabling licences to be granted for research purposes f, g and h. The HFEA are reviewing their research licensing procedures in the light of the Parliamentary debate. They will take account of the current House of Lords select committee's discussions before issuing further guidance. Anyone requiring further information should contact the HFEA.

[48] Human Fertilisation and Embryology Act 1990 section15(4)

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

11.7 Centres within the NHS should refer research projects to the relevant Multiple Centre Research Ethics Committees (MREC) and/or Local Research Ethics Committee (LREC) of the relevant 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 five 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.

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

11.9 Centres' attention is drawn to paragraphs 7.4-7.19 on consent to storage and use of gametes and embryos, paragraphs 9.4-9.11 on the use of gametes and embryos that have been subject to procedures that might prejudice their developmental potential, and paragraphs 9.12-9.14 on the termination and disposal of embryos that have been used for research.

PART 12 RECORDS

General

Accuracy

12.1 All information that centres are required to keep by Directions should be accurately recorded with proper cross references where this is required.

12.2 Centres' attention is drawn to paragraphs 3.6, 4.20, 4.21, 4.23, 4.25, 6.3c, 7.25, 7.28, 7.29, 8.20, 8.21, 9.15, 9.22, 10.4, 10.6, 10.7, 10.8, 10.9, 10.11 and 13.1b of this Code, which set out additional matters about which records should be kept.

Confidentiality

12.3 Centres must ensure that information provided in confidence is kept confidential and only disclosed in the circumstances permitted by law.[49] People should not have access to any other person's records (including those of their spouse or partner) without their consent.

Access to Health Records and the Data Protection Act 1998

12.4 Centres should establish written procedures for considering applications for access to confidential records. There should be a clearly identified individual in each centre whose responsibility it is to receive, check and arrange authorised access to confidential records.

12.5 Centres must ensure that they notify the Data Protection Commissioner in accordance with the Data Protection Act 1998[50].

12.6 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.

12.7 Centres should be aware that under the Data Protection Act 1998, the patient whose health records are being held (known as the "data subject") is *normally* entitled to their own health records, provided their request is made in writing and the required fee is paid. The maximum fee has been set at £10, although account should be taken of transitional provisions relating to fees[51]. The source of the information and an explanation of unintelligible terms should be given.

12.8 Centres should comply with a request promptly and in any event within 40 days of receipt of the request (providing the relevant fee has been paid); or if later, within 40 days of receipt of any additional information required, such as identifying information.

Access Exemptions to the Data Protection Act 1998

12.9 Information about the provision of treatment services, the keeping or use of gametes or embryos and whether identifiable individuals were born in consequence of treatment services are

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[49] This is an obligation under the general law

[50] Data Protection Act 1998 section 18

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

exempt from Section 7 of the Data Protection Act 1998[52]. This information may only be disclosed if such disclosure falls within the exemptions set out in the Human Fertilisation and Embryology Act 1990[53].

12.10 If the information referred to in paragraph 12.8 falls within the exceptions in Section 33 of the Human Fertilisation and Embryology Act 1990, it will be subject to the procedure for providing access set out in the Data Protection Act 1998 summarised in paragraph 12.6 above. Additional exceptions[54] and modifications[55] to the Data Protection Act 1998 should also have been taken into account before access is given.

The Human Fertilisation and Embryology Act 1990

12.11 The HFE Act puts strict limits on the disclosure of certain information by centres.[56] 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[57]:

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:

c. 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 7.4-7.7. 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 identity of the person seeking treatment.

d. 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.

e. 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;

f. 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;

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[52] Data Protection (Miscellaneous Subject Access Exemptions) Order 2000

[53] Human Fertilisation and Embryology Act 1990 sections 31 and 33

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

[55] Account must be taken of the Data Protection (Subject Access Modification) (Health) Order 2000

[56] Human Fertilisation and Embryology Act 1990 section 33(5)

[57] Human Fertilisation and Embryology Act 1990 section 33(6)-(7)

g. information potentially identifying a person who provided gametes for donation may 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;

h. under the Access to Health Records Act 1990 information held on health records about a patient that has died may be disclosed subject to certain safeguards to the patient's Personal Representative or to any person who may have a claim arising from the death. Access may not be given to any part of the patient's record if it contains a note, made at the patient's request, that he did not wish access to be given on such an application[58].

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

12.13 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 5.6-5.8).

12.14 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.

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

People Involved in an Egg Sharing Arrangement

Additional Information

12.16 In addition to paragraphs 12.1-12.15 above, the records of the egg provider and the egg recipient(s) should be kept separate to maintain anonymity.

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

PART 13 COMPLAINTS

General

General Obligations

13.1 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 that 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.

13.2 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 that can be addressed in a short time, in a way which reassures the person concerned.

13.3 Nevertheless, complaints that 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.

13.4 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.

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

Investigation of Complaints

13.6 Subject to paragraph 13.2 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.

13.7 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 that remains open to them.

ANNEX A

GUIDANCE FOR EGG SHARING ARRANGEMENTS

Introduction

The HFEA has drawn up guidance for licensed centres offering or intending to offer licensed treatments involving an egg sharing arrangement.

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

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

Egg sharing will be documented on a centre's licence.

General Principles

1) In addition to the statutory consent required, two additional separate agreements should be drawn up. One should be between the egg provider and the centre and the other between the egg recipient(s) and the centre (Detailed guidance for the writing of egg sharing agreements is set out below).

2) Where there are few eggs available the arrangement for egg sharing should not compromise the egg provider's treatment (see also the additional guidance given on the drafting of agreements set out below).

Guidance for the Drafting of Agreements for Egg Sharing Arrangements

Within the general principles set out by the HFEA for egg sharing arrangements centres are required to draw up agreements between themselves and the egg providers and themselves and the egg recipients. The following is a guide to the kind of information that could be included in these agreements. Centres should ensure that the information contained in the agreement for the egg provider is consistent with that in the agreements of the egg recipient(s).

The information is not intended to be exhaustive, and centres should obtain their own legal advice on the content and legal consequences of their agreements.

Agreement between a licensed centre and the egg provider

The agreement between the centre and the egg provider should set out the terms of the arrangement in full. It should be signed by both and should include a series of statements including those outlined below.

The document should clearly identify the egg provider and the centre.

i) Treatment

A statement from the patient confirming that they have:

a. had an opportunity to discuss the treatment procedures involved in providing her eggs as part of an egg sharing arrangement with a member of the centre's staff;

b. received verbal and written information about the treatment provided;

c. received all the required information listed in the relevant sections of the HFEA's Code of Practice. This information could be attached to the agreement; and

d. been offered counselling about the implications of the treatment.

The nature of the treatment should be set out in full. This should include:

a. the number of cycles of treatment involved;

b. the date upon which treatment will commence; and

c. full details of the egg sharing arrangement (more guidance on this is given later).

The nature and duration of the treatment covered by the agreement should be clear.

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

ii) Consent

A statement confirming:

a. that consent of the patient for the treatment has been obtained;

b. that two HFEA statutory consent forms 00(7) have been completed (see additional note on consent);

c. that this agreement does not override the terms of paragraph 4 of schedule 3 of the HFE Act. This means that the egg provider may withdraw or vary her consent in respect of any embryo created using her egg at any time until that embryo is used for treatment or research; and

d. the consequences of any withdrawal of consent and the liability of the parties involved and any additional costs that may be incurred.

iii) Cost

A statement describing:

a. what costs (if any) should be paid by the egg provider to the centre; and

b. the circumstances that would result in the egg provider being liable for the total cost and the total sums they would have to pay (also see part iv) Egg sharing arrangements below).

iv) Egg sharing arrangements

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

The agreement should also cover full details of the egg sharing arrangements, including:

a. the minimum number of eggs required for sharing;

b. how these will be allocated;

c. whether or not the egg provider will be liable to pay for any of the costs of the treatment. If the treatment is free, an appropriate caveat could be included if the egg provider becomes liable for payment if she varies her consent at any time before the embryos are used for treatment/or research.

v) General

A statement confirming that:

a. any patient consenting to donate eggs under the HFE Act will not be the legal parent of any child(ren) resulting from the donation;

b. in an anonymous egg sharing arrangement, neither the egg provider nor the egg recipient(s) will be made aware of the outcome of the other's treatment. No information will be available to either party that might identify the other or any resulting child(ren).

The agreement should be signed and dated by the egg provider and a representative of the centre.

Agreement between a licensed centre and the egg recipient

The agreement between the centre and the egg recipient should set out the terms of the arrangement in full. It should be signed by both and contain a series of statements including those outlined below.

The document should clearly identify the egg recipient and the centre.

i) Treatment

A statement from the patient confirming that they have:

a. had an opportunity to discuss with a member of the centre's staff the treatment procedures involved in receiving eggs as part of an egg sharing arrangement;

b. received verbal and written information about the treatment provided;

c. received all the required information listed in the relevant sections of the HFEA's Code of Practice. This information could be attached to the agreement; and

d. been offered counselling about the implications of the treatment.

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

a. the number of cycles of treatment involved;

b. the date upon which treatment will commence;

c. details of the egg sharing arrangement; and

d. as part of the treatment of the egg recipient she will be provided with eggs from an egg provider donor.

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

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

ii) Consent

A statement that this agreement does not override the terms of paragraph 4 of schedule 3 of the HFE Act. This means that the egg provider may withdraw or vary her consent in respect of any embryo created using her egg at any time until that embryo is used for treatment or research.

iii) Cost

A statement describing:

a. what costs the egg recipient is liable for; and

b. what treatment services these costs will cover. This may include all or part of the egg provider's treatment. This should be stated clearly in the agreement.

iv) Egg sharing arrangements

The full details of the egg sharing arrangements including:

a. the minimum number of eggs required for sharing;

b. how these will be allocated;

c. whether or not the egg recipient will be liable to pay for any of the costs of the egg provider's treatment, including an appropriate caveat dealing with altered consent.

d. the procedures, options and cost implications if one of the parties varies or withdraws their consent.

v) General

A statement confirming that:

a. any patient that has given effective consent to donate eggs under the HFE Act 1990 will not be the legal parent of any child(ren) resulting from the donation.

b. in an anonymous egg sharing arrangement, neither the egg provider nor the egg recipient(s) will be made aware of the outcome of the other's treatment. No information will be available to either party that might identify the other or any resulting child(ren).

The agreement should be signed and dated by the egg recipient and a representative of the centre.

ANNEX B

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

1. The implication 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 ....

<u>but</u>

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.

<u>but</u>

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 C

HIV SCREENING FOR GAMETE DONORS

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

As with all organs and tissue for transplantation donors of gametes (semen and eggs) must be shown to be free of infection with HIV. This entails testing the blood of donors for HIV antibody at the time donations are made. Antibodies may not appear in the blood for up to 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 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 recipient 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

PARENTAL ORDERS IN SURROGACY CASES

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

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

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;

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

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

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

The child must be living with the commissioning couple;

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
Area 651C
Skipton House
80 London Road
London SE1 6LH
Tel: 020 7972 2000

ANNEX E

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 anonymous donor has given effective consent under the Human Fertilisation and Embryology Act 1990, the donor will not be the legal parent of any resulting child.

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

4. I have been given a suitable opportunity to take part in counselling about the implications of the proposed treatment. (For GIFT using donated sperm or eggs, or any IVF treatment).

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 [ ] egg(s) mixed with sperm
          2 [ ]
          3 [ ]

b)   1 [ ] embryo(s)
          2 [ ]
          3 [ ]

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

Doctor's Signature ....   Date: ....

HUSBAND'S CONSENT

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

Any other remarks: ....

....

Signature of husband: .... Date: ....

Full name in block capitals: ....

Address: ....

....

[NOTE: the centre is not required to obtain a husband's consent in order to make the treatment lawful, but where donated sperm is used it is advisable in the interests of establishing the legal parenthood of the child. See paragraphs 7.27-7.29 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.

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 7.27-7.29 of the Code of Practice].

Annex E

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 anonymous donor has given effective consent under the Human Fertilisation and 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 6.5 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 where donated sperm is used it is advisable in the interests of establishing the legal parenthood of the child. See paragraphs 7.27-7.29 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 where donated sperm is used it is advisable in the interests of establishing the legal parenthood of the child. See paragraphs 7.27-7.29 of the Code of Practice].

ANNEX F

GUIDELINES FROM PROFESSIONAL ORGANISATIONS

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

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

- Accreditation Standards and Guidelines for IVF laboratories – Association of Clinical Embryologists (ACE) – Published March 1999

- Guidelines for the Screening of semen donors for donor insemination 1999 – British Andrology Society (BAS) - *Human Reproduction* 14 (7)1823-1826

- The Management of Infertility in Tertiary Care – Royal College of Obstetricians and Gynaecologists (RCOG) – Published January 2000

- Guidance on the Inspection and Provision of Counselling in Assisted Conception Centres – British Infertility Counselling Association (BICA) – Published October 1999

- Guidelines for Nurses Carrying Out Embryo Transfers and Intrauterine Insemination – Royal College of Nursing (RCN) – Published 2000

- Guidelines for Nurses Carrying out Egg Retrieval – Royal College of Nursing – Published 2000

- Recommendations for Good Practice on the Screening of Egg and Embryo Donors – British Fertility Society – Published 2000 - Human Fertility (2000) 3, 62-165

The Authority has tried to ensure that these Guidelines and its Code are complementary. Where there are differences, centres should be aware of the difference between the standards required by the Code of Practice, and the measures of best practice generally represented in professional guidelines.

As with the Code, these guidelines will no doubt be updated from time to time and centres should ensure that they remain up to date with such developments in professional practice.

ANNEX G

GUIDANCE ON REASONABLE EXPENSES FOR DONORS

The following indicates the types of expenses that centres should reimburse to people providing gametes for donation:

1. Receipts - are not required for any expense incurred that is less than £15, however centres should be provided with receipted evidence for expenses that exceed this amount;
2. Travel - all travel costs should be reimbursed to people providing gametes for donation provided that a reasonable route and standard class travel has been used to get to the centre. Taxis should normally only be used where public transport facilities are unavailable, but this is a discretionary rule that centres may apply flexibly if they so wish.

Rates:

Public Transport	Fully receipted if over £15
Taxi	Fully receipted if over £15
Car	£0.300 per mile
Motorcycle	£0.153 per mile
Bicycle	£0.053 per mile

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

3. Accommodation - where a centre judges that accommodation is needed, this should be arranged and paid for by the centre.

4. Subsistence Rates:

Absence from home or a place of business not exceeding five hours	£2.50 per day
Exceeding five hours but not exceeding ten hours	£5.00 per day
Over ten hours	£10.00 per day

5. Miscellaneous expenses - (costs such as telephone calls, car parking, postal costs etc.). Depending on the circumstances centres are at liberty to decide whether to reimburse a person proving gametes for donation for this type of expense.

6. Financial loss allowance - the maximum financial loss allowance is £50.00 per day. A centre should be provided with detailed evidence of the specific, financial loss incurred as a result of donating gametes.

7. Childminding expenses – people providing gametes for donation should claim for childminding expenses if these were directly incurred as a result of donating gametes. A receipt or a letter signed by the carer stating how much was paid to them should be provided to the centre.

Total daily amount that can be claimed for financial loss and childminding expenses - the total daily amount that may be claimed can not exceed the daily maximum limit of £50.00.

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