Human Fertilisation & Embryology Authority

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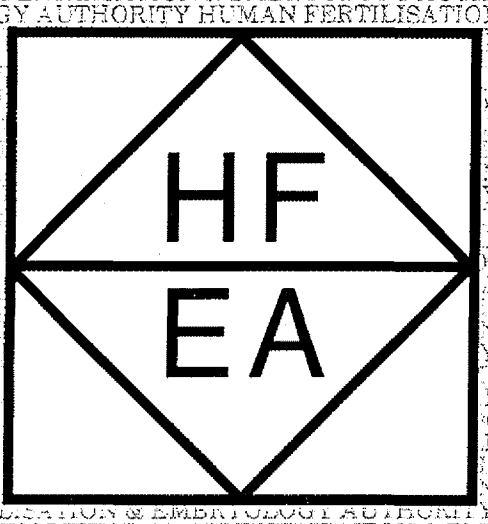

CODE OF PRACTICE

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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 using of human embryos outside the body, or the storage or donation of human eggs and sperm. It must also maintain a Code of Practice giving guidance about the proper conduct of the licensed activities.

The object of the Code is wider than to secure the safety or efficacy of particular clinical or scientific practices. It is concerned with areas of practice which raise fundamental ethical and social questions. In framing it, we have been guided both by the requirements of the Human Fertilisation and Embryology Act and by:

- the respect which is due to human life at all stages in its development;
- the right of people who are or may be infertile to the proper consideration of their request for treatment;
- a concern for the welfare of children, which cannot always be adequately protected by concern for the interests of the adults involved; and
- a recognition of the benefits, both to individuals and to society which can flow from the responsible pursuit of medical and scientific knowledge.

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

The Code assumes that all those involved in providing treatment or conducting research will observe the standards and requirements of good clinical and scientific practice. It also adopts the guidance given by other authorities or professional bodies on particular points.

The Act covers both in vitro fertilisation and donor insemination, and imposes new obligations upon centres to give information, provide counselling and take account of the welfare of children. It recognises that, while infertile people deserve and can expect proper consideration of their medical and social needs, licensed treatments may result in children who would not otherwise have been born and whose needs must also be taken into account. The scope of the Act means that this Code has to be both longer and more complex than the pioneering guidelines produced by the Voluntary - subsequently Interim Licensing Authority.

The Act also allows the Authority to give guidance on any procedure involving the placing of eggs and sperm in a woman. We have decided, however, that it would be premature to cover treatments other than in vitro fertilisation or those involving donated gametes (apart from the basic guideline in paragraph 7.6 which is of general application). However, we intend to keep the Code under regular review, in order to ensure that it continues to give the clearest and most up-to-date guidance possible to centres in achieving all the objectives of the Act.

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

PART 1 - STAFF

General Standards

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

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

The Person Responsible

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

1.4 The person responsible must ensure:[2]

- that the character, qualifications and experience of anyone carrying out licensed activities are suitable for those activities;
- that proper equipment is used;
- that proper arrangements are made for the keeping and disposal of genetic material;
- that suitable practices are used in carrying out the licensed activities; and
- that the centre complies with the conditions of its licence.

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

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

Staff Engaged in Clinical Services

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

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

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

Nursing Staff

1.9 At least one of a centre's available nursing staff should be a registered general nurse, or a nurse qualified in the nursing of adults, or a registered midwife, whose name is currently and effectively registered on Parts 1, 12 or 10 of the register held by the United Kingdom Central Council for Nursing, Midwifery and Health Visiting.

Counselling Staff

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

Staff Engaged in Scientific Services

1.11 The person in charge of an embryology laboratory should have an appropriate scientific or medical degree, plus a period of experience in an embryology laboratory sufficient to qualify the person to take full charge of the laboratory.

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

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

In-Service Training

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

Conscientious Objection

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

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

Criminal Convictions

1.17 When deciding whether a person is suitable to take part in a licensed activity, the person responsible should take account of any relevant criminal convictions. Applicants

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3. HF&E Act 1990 s.38

who have such convictions should not be appointed to posts in which they will have access to donors, clients, genetic material or records about these, unless the person responsible is satisfied that the applicant is suitable for the post in question.

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

PART 2 - FACILITIES

General

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

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

Clinical Facilities

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

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

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

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

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

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

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

Laboratory Facilities

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

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

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

Counselling Facilities

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

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

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

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

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

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

Secure Storage for Gametes and Embryos

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

Maintaining and Improving Standards

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

2.17 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 2.16, above.

Advertising

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

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

Introduction

General Obligations

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

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

3.3 In addition, in deciding whether or not to offer treatment, centres should take account both of the wishes and needs of the people seeking treatment and of the needs of any children who may be involved. Neither consideration is paramount over the other, and the subject should be approached with great care and sensitivity. Centres should avoid adopting any policy or criteria which may appear arbitrary or discriminatory. Further guidance is given in paragraphs 3.10 to 3.27 below.

Confidentiality

3.4 Any information which centres obtain from potential donors or clients must be kept confidential unless disclosure is authorised by law.[8] Certain types of information may only be disclosed in the circumstances authorised in the Act (see paragraph 10.7, below). If a centre is in doubt about whether or not it should disclose information, it should refer to the Authority.

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

3.5 It is generally in the interests of the person concerned that relevant information be passed on to other clinicians involved in his or her treatment or diagnosis. However, the Act states that information about the provision of treatment services for, or the keeping or use of the gametes of any identifiable individual can in general only be disclosed either to the Authority, another person covered by a licence or to the individual concerned. The following principles are to be strictly observed if such information is to be passed on to clinicians who are not covered by a licence:

a. the person to whom the information relates is entitled to decide whether or not that information is passed on and if so, how; and

b. he or she is entitled to know exactly what that information is.

3.6 In general, therefore, there are two ways in which such information may be passed on:

a. by writing to the person concerned, enclosing a copy for him or her to pass on to the general practitioner (GP) or other clinician, preferably with a stamped addressed envelope or other instructions as to how to do this; or

b. particularly in cases where an emergency may arise, for example where it is the intention to administer superovulatory drugs, by providing the person with a treatment card on which the details of any treatment such as ovarian stimulation are entered at each visit. The clinician should ensure that the person understands what is written on the card and explain to him or her (and, where appropriate, his or her partner) the importance of keeping the card safely and showing it to any other clinician by whom he or she may be treated for any reason.

3.7 In some cases, the person concerned may request that the centre sends a copy of the letter addressed to him or her direct to the GP or other clinician. If this occurs, centres should use the request form at Annex A. The person concerned is not to be asked to sign the form until he or she knows exactly what the letter is to contain. The envelope in which the copy is sent should be clearly marked "to be opened by addressee only".

3.8 If a centre wishes to refer a person to another specialist who is not covered by a licence, whether for diagnostic tests or for treatment or for any other purpose, the

centre may write to the other specialist requesting an appointment. A copy of the letter to the client or donor concerned, giving the relevant information, may either be given to the client or donor for him or her to pass on (as in paragraph 3.6 above) or, at his or her request, enclosed with the centre's letter (as in paragraph 3.7 above).

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

Prospective Parents and the Welfare of the Child

Welfare of the child

3.10 One of the conditions of a treatment licence is that "a woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for a father), and of any other child who may be affected by the birth".[9] This applies to every woman whether or not she is resident in or a citizen of the United Kingdom. "Any other child" includes children who already exist within the client's household or family.

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

Factors to be Considered

3.12 Centres should take all reasonable steps to ascertain who would be the legal parents (or parent) of any child born as a result of the procedure, and who it is intended will be bringing him or her up. When clients come from abroad, centres should not assume that the law of that country relating to the parentage of a child born as a result of donated gametes is the same as that of the United Kingdom.

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9. HF&E Act 1990 s.13(s)

3.13 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.

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

a. their commitment and that of their husband or partner (if any) to having and bringing up a child or children;

b. their ages and medical histories and the medical histories of their families;

c. the needs of any child or children who may be born as a result of treatment, including the implications of any possible multiple births, and the ability of the prospective parents (or parent) to meet those needs;

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

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

3.15 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 his or her 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 his or her status in the family;

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

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

3.16 Further factors will require consideration in the following cases:

a. where it is the intention that the child will not be brought up by the carrying mother. In this case, centres should bear in mind that either the carrying mother, and in certain circumstances her husband or partner, or the commissioning parents may become the child's legal parents. Centres should therefore consider the factors listed in paragraphs 3.14 and 3.15 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 commissioning parents' family;

b. 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 his or her childhood, and where appropriate whether there is anyone else within the prospective mother's family and social circle with who is willing and able to share the responsibility for meeting those needs and for bringing up, maintaining and caring for the child.

3.17 When selecting donated gametes for treatment, centres should take into account each prospective parent's preferences in relation to the general physical characteristics of the donor which can be matched in accordance with good clinical practice. Clients should be advised that the result of any attempt at matching physical characteristics cannot be guaranteed.

Enquiries to be Made

3.18 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 3.10 to 3.16 above.

3.19 Centres should seek to satisfy themselves that the client's GP knows of no reason why the client might not be suitable to be offered treatment, including anything which might adversely affect the welfare of any resulting child.

3.20 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.

3.21 If any of these particulars or inquiries give cause for concern, eg, 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.

3.22 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

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

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

3.25 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.

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

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

Prospective Donors and People Seeking Storage of Gametes and Embryos

3.28 Centres should draw the screening procedure to the attention of potential donors at the outset and ensure that they understand that the procedure may reveal previously unsuspected defects, including HIV infection.

3.29 Payment may only be made, or benefits given, in exchange for gametes or embryos in accordance with directions made by the Authority.[10]

Age and Mental Capacity

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

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

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

3.33 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 a valid consent and has done so. It is not necessary also to obtain the consent of his or her parent or guardian.

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

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

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

3.36 Sperm or eggs **must not** be taken from anyone who is not capable of giving a valid consent or who has not given a valid consent.[11]

History

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

3.38 Centres should wherever practicable ask a potential donor's GP whether he or she knows of any reason why the potential donor might not be suitable to donate gametes for the treatment of others.

3.39 Centres should wherever practicable ask the GPof any person seeking storage of gametes or embryos for his or her own or partner's use whether the GPhas any relevant information.

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

Suitability as Donors

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

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11. HF&E Act 1990 Schedule 3

a. any personal or family history of heritable disorders;

b. any personal history of transmissible infection;

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

d. whether the donor has children of his or her own; and

e. the attitude of the donor towards the donation.

Scientific Tests

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

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

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

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

Potential Donors who are Undergoing Treatment

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

People Unsuitable as Donors

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

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

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

PART 4 - INFORMATION

General Obligation

4.1 Before anyone is given licensed treatment (ie, 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, he or she must be given "such relevant information as is proper".[12] This should be distinguished from the requirement to offer counselling, which clients and donors need not accept.

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

4.3 Centres should devise a system to ensure that:

a. the right information is given;

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

c. a record is kept of the information given.

Information to be Given to Clients

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

a. the limitations and possible outcomes of the treatment proposed, and variations of effectiveness over time;

b. the possible side effects and risks of the treatment to the woman and any resulting child, including (where relevant) the risks associated with multiple pregnancy;

c. 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;

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

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

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

f. that counselling is available;

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

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

i. who will be the child's parent or parents under the Act. Clients who are nationals or residents of other countries, or who have been treated with gametes obtained from a foreign donor should understand that the law in other countries may be different from that of the United Kingdom (see paragraph 3.12, above);

j. the child's right to seek information about his or her origins on reaching 18 or on contemplating earlier marriage;

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

l. a child's potential need to know about his or her origins;

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

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

Information to be Given to People Providing Gametes and Embryos

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

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

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

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

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

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

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

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

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

i. in the case of egg donation, that the woman will not incur any financial or other penalty if she withdraws her consent after preparation for egg recovery has begun;

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

k. that counselling is available.

PART 5 - CONSENT

Consent to Examination and Treatment

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

5.2 No licensed treatment should be given to any woman without her written consent to that particular treatment. The written consent should explain the nature of the treatment and the steps which are to be taken, and indicate that she has been given all the information referred to in paragraph 4.4 above. Examples of consent forms appear in Annex B. A copy of the consent form should be given to the person giving consent.

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

Treatment without Consent

5.4 Centres may examine or treat people without first obtaining their consent only in exceptional circumstances.[13] The only circumstances likely to arise in the course of infertility treatment services are where the procedure is necessary to save the patient's life, cannot be postponed, and she is unconscious and cannot indicate her wishes.

Consent to the Presence of Observers

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

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13. This is an obligation under the general law

Consent of the Husband or Male Partner and Legal Fatherhood

5.6 Centres should adopt the procedures described in the following paragraphs in the interests of preventing or resolving a dispute at a later stage about the fatherhood of a child. (Centres are also referred to paragraph 3.14(a), above.)

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

5.8 If a woman is being treated together with a male partner, using donated sperm, and she is unmarried or judicially separated or her husband does not consent to the treatment, her male partner will be the legal father of any resulting child. Centres should explain this to them both and record at each appointment whether or not the man was present. Centres should try to obtain the written acknowledgment of the man both that they are being treated together and that donated sperm is to be used.

Consent to the Storage and Use of Gametes and Embryos

5.9 Anyone consenting to the storage of their gametes, or of embryos produced from them, **must:**[14]

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 he or she dies, or becomes incapable of varying or revoking his or her consent.

5.10 If the intention is to donate the gametes for the treatment of others, including the creation of an embryo for that purpose, the donor must consent in writing to their use for that purpose.[15]

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14. HF&E Act 1990 Schedule 3 para 2(2)

15. HF&E Act 1990 Schedule 3 paras 2(1)(a) and (b), 5(1) and 6(1) and (3)

5.11 If the intention is to create an embryo outside the body, the person giving consent to the use of an embryo produced from his or her gametes must specify the purpose or purposes for which it may be used, namely one or more of:[16]

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

b. to provide treatment for others;

c. for research.

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

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

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

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

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

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16. HF&E Act 1990 Schedule 3 para 2(1)

PART 6 - COUNSELLING

General

6.1 People seeking licensed treatment (ie, 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.[17]

6.2 Counselling should be clearly distinguished from:

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

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

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

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

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

a. implications counselling: this aims to enable the person concerned to understand the implications of the proposed course of action for himself or herself, for his or her family, and for any children born as a result;

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

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

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

Centres must make implications counselling available to everyone.[18] They should also provide support or therapeutic counselling in appropriate cases or refer people to sources of more specialist counselling outside the centre.

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

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

6.7 Centres should offer people the opportunity to be counselled by someone other than the clinician responsible for their treatment, donation or storage.

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

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

Implications Counselling

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

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

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

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18. HF&E Act 1990 s.13(6) and Schedule 3 para 3(1)(a)

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

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

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

6.11 Counsellors should invite clients to consider in particular:

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

b. the possibility that treatment will fail.

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

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

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

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

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

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

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

a. their reasons for wanting to become a donor;

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

c. the possibility of their own childlessness;

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

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

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

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

Later Counselling

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

Support Counselling

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

6.20 These steps should include, wherever practicable, reasonable assistance in contacting or establishing an infertility support group.

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

Therapeutic Counselling

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

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

Records

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

6.25 All information obtained in the course of counselling should be kept confidential, subject to paragraph 3.24, above.

PART 7 - USE OF GAMETES AND EMBRYOS

Obtaining Gametes and Embryos

7.1 Centres may only import and export gametes and embryos in accordance with directions made by the Authority.[19]

7.2 Centres may only transport gametes and embryos between licensed premises in accordance with directions made by the Authority.[20]

Clinical Use

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

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

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

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

7.7 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.

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19. HF&E Act 1990 s.24(4)

20. HF&E Act 1990 s.24(3)

7.8 Donated gametes or embryos should not normally be used for treatment once the number of live children believed to have been born as a result of donations from that donor has reached 10. This number may be exceeded only in exceptional cases, eg, where a recipient wishes to have a subsequent child from the same donor. The Authority should be notified whenever the limit is exceeded. If the donor has specified a limit, this **must never** be exceeded.[21]

Termination and Disposal

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

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

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

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21. HF&E Act 1990 Schedule 3 paragraphs 2(1) and 2(2)

PART 8 - STORAGE AND HANDLING OF GAMETES AND EMBRYOS

General

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

Security

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

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

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

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

Identification

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

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

Storage Review

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

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

Contamination

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

Transfer of Gametes and Embryos

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

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

PART 9 - RESEARCH

9.1 All research which involves the creation, keeping or using of human embryos outside the body must be licensed by the Authority.[22] A centre must apply to the Authority for a separate licence for each research project.[23]

9.2 The Authority may grant licences only for research projects for the following purposes:

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.

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

9.4 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.

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22. HF&E Act 1990 s.3(1)

23. HF&E Act 1990 Schedule 2 para 4(2)(b)

9.5 Embryos which have been appropriated for a research project **must not** be used for any other purposes.[24]

9.6 The science of all research projects involving the use of embryos should be supported by peer review undertaken by appropriate academic referees chosen by the Authority.

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

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

9.9 Centres' attention is drawn to paragraphs 5.9 to 5.16 on consent to storage and use of gametes and embryos, paragraphs 7.3 and 7.4 on the use of gametes and embryos which have been subject to procedures which might prejudice their developmental potential, and paragraphs 7.9 to 7.11 on the termination and disposal of embryos which have been used for research.

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24. HF&E Act 1990 s.15(4)

PART 10 - RECORDS

Accuracy

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

10.2 Centres' attention is drawn to paragraphs 3.30, 3.34, 3.47, 4.3(c), 5.2, 5.7, 5.8, 6.24, 8.4, 8.6, 8.7, 8.9 and 11.1 of this Code, which set out additional matters about which records should be kept.

Access to Records

10.3 There should be a clearly identified individual in each centre whose responsibility it is to receive, check and arrange authorised access to confidential records.

10.4 Data to which the Data Protection Act 1984 applies and records to which the Access to Health Records Act 1990 applies will, unless exempted, be subject to the rights of access provided by those Acts. Centres with computerised records **must** ensure that they are registered with the Data Protection Registrar.[25]

10.5 Centres should allow all donors and clients who provide information about themselves to the centre access to the record of that information and an opportunity to correct it, even if it does not fall within the scope of the 1984 and 1990 Acts.

Confidentiality

10.6 Centres **must** ensure that information provided in confidence is kept confidential and only disclosed in the circumstances permitted by law.[26] People should not have access to any other person's records (including those of their spouse or partner) without their consent.

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25. Data Protection Act 1984 s.5

26. This is an obligation under the general law

10.7 The Act puts strict limits on the disclosure of certain information by centres:[27]

a. information about any identifiable person who receives treatment services or provides gametes or embryos can only be disclosed to the person himself or herself, to members and staff of the Authority, or to someone else who is covered by a licence for the purpose of licensed activities. If centres want information to be passed on to anyone else, they should follow the guidance given in Part 3, above;

b. information about any identifiable person born as a result of treatment services can only be disclosed to the Authority or another licensed centre as above, but not to the person himself or herself, nor to anyone else;

c. information potentially identifying a donor can also be disclosed for certain purposes connected with proceedings in England and Wales under the Congenital Disabilities (Civil Liability) Act 1976;

d. information can be disclosed if it does not identify anyone to whom the information relates.

10.8 Centres should have clear security procedures which will prevent unauthorised access. If confidentiality is breached, the centre should investigate and deal with the breach and submit a full explanation to the Authority. If it appears that a criminal offence has been committed, the police should also be informed.

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27. HF&E Act 1990 s.33(5)-(7)

PART 11 - COMPLAINTS

General

11.1 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 he or she nominates) 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 Authority annually of the number of all written complaints made in that year, and the number which remain unresolved;

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

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

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

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

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

11.5 If someone has difficulty in formulating his or her complaint, centres should give him or her all reasonable assistance to do so.

Investigation of Complaints

11.6 Subject to paragraph 11.2 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.

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

ANNEX A

REQUEST TO SEND A COPY OF A LETTER ADDRESSED TO A CLIENT OR DONOR DIRECT TO ANOTHER CLINICIAN WHO IS NOT COVERED BY A LICENCE

I understand that Dr ..... will be writing me a letter which contains confidential information about [the provision of treatment services to me/the keeping or use of gametes or embryos provided by me].

I ask Dr ..... to send on my behalf a copy of that letter direct to Dr ..... at .....

I understand that this will be done at the same time as the letter is sent to me.

The confidential information to be contained in the letter is set out below:*

(continue on a separate sheet if necessary)

I understand that no other such information about me will be passed on to Dr .....

Signed: ..... Date: .....

Full name: .....

Address: .....

.....

Doctor's signature: ..... Date: .....

* be as specific as possible

ANNEX B

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

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:*

i. be prepared for egg retrieval by the administration of hormones and other drugs described in the attached schedule;

ii. the removal of eggs from my ovaries by means of ..... ;

iii. the mixing of the following:

my egg(s)	☐	the sperm of my husband/partner	☐
eggs donated by	☐	sperm donated by.....	☐
an anonymous donor's egg(s)	☐	an anonymous donor's sperm	☐

iv. the placing in my ..... of:

(a) ..... (no.) of the eggs mixed with the sperm

(b) ..... (no.) resulting embryos;

vi. the administration of any drugs and anaesthetics as may be found necessary in the course of the operation(s);

vii. any further operative measures intended to assist me to carry any resulting fetus to full term as may be found necessary in the course of the operation(s).

*delete/complete as applicable

2. I understand that if sperm or eggs have been donated under the terms of the Human Fertilisation and Embryology Act 1990, the donor will not be the legal parent of any resulting child.

3. I understand that eggs mixed with the sperm of more than one man may not be replaced in 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. Any other remarks: _____

_____

_____

Signed: ..... Date: .....

7. All the information listed in paragraph 4.4 of the Human Fertilisation and Embryology Authority's Code of Practice has been given to the patient. The patient has been given a suitable opportunity to take part in counselling about the implications of the proposed treatment.

Doctor's signature: ..... Date: .....

HUSBAND'S CONSENT

8. 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.

9. Any other remarks: _____

_____

_____

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

Address:.....

[NOTE: the centre is not required to obtain a husband's consent before treatment begins, but it advisable in the interests of establishing the legal parenthood of the child.]

MALE PARTNER'S ACKNOWLEDGEMENT

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

11. Any other remarks: _____

_____

_____

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

Address:.....

[NOTE: the centre is not required to obtain a partner's acknowledgement before treatment begins, but it is advisable in the interests of establishing the legal parenthood of the child.]

CONSENT TO 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:*

   i. the administration of hormones and other drugs described in the attached schedule;

   ii. be inseminated with:

   (a) the sperm of my husband/partner;

   (b) sperm donated by .....;

   (c) the sperm of an anonymous donor.

2. I understand that if sperm has been donated under the terms of the Human Fertilisation and Embryology Act 1990, the donor will not be the legal father of any resulting child.

3. I understand that I may 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. Any other remarks: _____

_____

_____

Signed: ..... Date: .....

7. All the information listed in paragraph 4.4 of the Human Fertilisation and Embryology Authority's Code of Practice has been given to the patient. The patient has been given a suitable opportunity to take part in counselling about the implications of the proposed treatment.

Doctor'ssignature: ..... Date: .....

*delete/complete as applicable

HUSBAND'S CONSENT

8. 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.

9. Any other remarks: _____

_____

_____

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

Address: .....

[NOTE: the centre is not required to obtain a husband's consent before treatment begins, but it is advisable in the interests of establishing the legal parenthood of the child.]

MALE PARTNER'S ACKNOWLEDGEMENT

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

11. Any other remarks: _____

_____

_____

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

Address: .....

[NOTE: the centre is not required to obtain a partner's acknowledgement before treatment begins, but it is advisable in the interests of establishing the legal parenthood of the child.]