



Code of Practice

Human Fertilisation and Embryology Authority

Presented to Parliament pursuant to section 26 of the Human Fertilisation and Embryology Act 1990

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1.1 Origins and functions of the HFEA

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

The Human Fertilisation and Embryology Act 1990 (HFE Act) (as amended by the Human Fertilisation and Embryology Act (Quality and Safety) Regulations 2007) covers all uses of sperm, eggs and embryos for human application and all research involving the use of live human embryos. It imposes obligations upon centres to maintain appropriate standards of quality and safety, to give and record information, provide counselling and take account of the welfare of the children born as a result of certain fertility treatments.

The Authority's principal task is to regulate those activities covered by the HFE Act. It does this by means of a system of licensing, audit and inspection. Section 25 of the HFE Act requires the HFEA to maintain a Code of Practice giving guidance about the proper conduct of licensed activities and the proper discharge of the functions of licensees. The standards and guidance contained in this document are central to the HFEA's regulatory function.

1.2 Principles underlying the Code of Practice

The Act recognises that, while those seeking assisted reproductive treatment deserve, and can expect, proper consideration of their medical and social needs, licensed treatments may result in children who would not otherwise have been born and whose interests must be taken into account. The object of the HFEA Code of Practice is therefore wider than to secure the safety or efficacy of particular clinical or scientific practices. It is concerned with areas of practice which raise fundamental ethical and social questions.

In framing the Code of Practice, the HFEA has been guided both by the requirements of the HFE Act and by:

- the respect which is due to human life, appropriate to each stage of development;
- the right of people seeking assisted reproductive treatment to fair and reasonable consideration of their request in the context of current legal, clinical and ethical guidelines laid down for the type of treatment requested;
- the duty of the HFEA and licensees to deal with others without unfair discrimination, whether direct or indirect, in particular on grounds of gender, marital status, race, religion, age, sexual orientation or disability;



- a concern for the welfare of any child who may be born as a result of treatment services (including the need of that child for a father), and of any other child who may be affected by the birth, 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.

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

1.3 Compliance and enforcement

The Code of Practice is regularly reviewed and amended in light of experience and to keep pace with both the latest developments in legislation, clinical practice and evolving public concerns. In response, in particular, to new European legislation covering the handling, testing and storage of gametes and embryos in treatment, this seventh edition is arranged in two main divisions, Standards and Guidance:

- Division I (Standards) contains a set of agreed, common specifications for relevant aspects of an assisted conception service or research project involving the use of human embryos. Conformity to standards will be mandatory insofar as they express a legal requirement or a condition of licence. Evidence of conformity with these standards will be sought during an HFEA inspection and will be considered by HFEA licence committees in considering whether to grant, renew, vary or revoke a licence.
- Division II (Guidance) gives further information concerning the manner in which licensable activities are expected to be carried out and the functions and responsibilities of licensees discharged. The guidance is intended to assist licensees to meet the criteria set out in legislation and specified in the HFEA Standards, and thereby to ensure good practice in the provision of treatment services or the conduct of research. Compliance with the guidance may, and in certain circumstances must, be taken into account in determining whether a licence should be varied or revoked.

The standards have been developed in collaboration with UK bodies representing the professions involved in providing assisted conception services. Both the standards and guidance have been subject to extensive public consultation.

In addition to the standards and supporting guidance, this new edition of the Code also contains references to the underlying legislation and licence conditions by which requirements are enforced, as well as extensive cross references between the two divisions.



Where conformity to a standard is obligatory (i.e. because it expresses a requirement of legislation or one determined by the HFEA in accordance with a statutory power) this is clearly indicated in the text.

The effect of the new European legislation being laid over the licensing scheme which already existed in the UK is that requirements from two distinct sources with slightly different inspirations now coexist in domestic law. In the majority of cases (e.g. all IVF treatment and insemination services) both schemes will apply. In the case of human embryo research, however, only certain requirements – broadly those of the HFE Act prior to the implementation of the European legislation – will apply. In yet other cases (e.g. insemination services using only the woman’s husband’s or partner’s sperm) the new requirements will apply but some of the original 1990 Act requirements will not apply (although they should nevertheless be regarded as good practice). This complex situation is reflected in the Code in relation to each standard through the use of the following classification:

- Requirement (scheme A): where the standard relates to a requirement that derives from domestic legislation independently of the incorporation of the European legislation
- Requirement (scheme B): where the standard relates to a requirement that derives from the incorporated European legislation
- Requirement (schemes A and B): where the standard relates to a requirement that is common to both schemes

The consequences of failing to comply with a Requirement include, in some cases, criminal penalties, and revocation or variation of a licence. However, a failure to comply with any provision of the Code of Practice (the Standards or Guidance) may be taken into account by the HFEA in deciding whether to renew, vary or revoke a licence.

1.4 How to use the Code of Practice

The seventh edition of the Code has been designed in consultation with users to make it both easier to use and easier to update. Online users will be able to benefit from enhanced functionality, such as easy navigation between standards and supporting guidance, search tools, and direct links to related legislation, licence conditions and HFEA Directions, and other external sources of information. Those using the print version will be able to replace any updated versions of pages directly in their copies rather being required to incorporate information contained in a variety of Chair’s letters and other communications. Furthermore, robust version control measures will identify immediately whether the document is fully up to date or, alternatively, make it easy to identify what measures were in force on any particular date in the past.

1. Introduction



It is anticipated that users (be they practitioners, HFEA inspectors or licence committees) will approach the Code first by identifying the standard in Division I which is applicable to the activity under consideration and then, where relevant, following the reference to the supporting guidance in Division II for further information on how conformity with the standard should be achieved.

Centres may wish to use the Standards and Guidance to design their quality manuals and standard operating procedures, or for purposes of carrying out self assessment or inter-centre audit.

S.1.1 Scope

In April 2006 the European Tissues and Cells Directive came into force. Under Regulations that transpose the Requirements of the Directive into domestic law the HFEA is the UK authority with responsibility for regulating the use of human reproductive material for the purposes of the Directive. These Standards incorporate the technical and other Requirements of both the EU Directives and the HFE Act, and set out the measures that Centres must take to comply with these Requirements.

Compliance with these Standards requires a knowledge of those professional guidelines that are specific to individual disciplines, and relevant legislation (e.g. health and safety) and guidance on topics such as consent to examination, and treatment and information for users. (www.hfea.gov.uk).

The Standards are designed to be comprehensive but at a level of detail that takes account of the variation between the different types of service provided by Centres.

S.1.2 Purpose

The Standards are intended to help Centres to comply with the Requirements of the EU Directives and the HFE Act and to assist them in preparing for an HFEA inspection or during self inspection / internal audit. It is intended that the Standards will support the drive towards Continual Improvement and consistency in quality across all Centres.

The Standards will also be used by the HFEA as a key part of the inspection process to assess compliance against those Requirements.

S.2.1 Source references

The following references are the source material used in the preparation of these Standards:

- (a) Directive 2004/23/EC on setting the standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells;
- (b) Directive 2006/17/EC implementing Directive 2004/23/EC as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the donation, procurement and testing, of human tissues and cells;
- (c) Directive 2006/86/EC implementing Directive 2004/23/EC as regards certain technical requirements for the coding, processing, preservation, traceability, storage, distribution of human tissues and cells and adverse events and reactions;
- (d) Human Fertilisation and Embryology Act 1990;
- (e) ISO 9001:2000 Quality management systems – Requirements;
- (f) ISO 9000:2000 Quality management systems – Fundamentals and vocabulary;
- (g) ISO 15189: Medical laboratories - Particular requirements for quality and competence.

S.3.1 Terms and definitions

For the purposes of these Standards, the terms and definitions given in the EU Directives are adopted. Additional definitions given in ISO 9000:2000 are used when appropriate and these are identified with a reference, e.g. ISO 9000:2000 3.2.3.

In many cases, explanatory notes have been added to facilitate understanding of the terms and definitions or to highlight a relationship, e.g. between terms used in the EU Directives and in ISO 9000. Unless otherwise stated, these notes do not form part of the Standards.

NOTE: Where terms defined below occur in the Standards, these are typeset with initial capitals to indicate the sense intended.

S.3.1.1 Adverse Incident

Any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to Patients, their embryos and/or gametes, or to staff or a licensed Centre including Serious Adverse Events and Serious Adverse Reactions.

S.3.1.2 Centre

An establishment licensed by the HFEA. Separate licences are required for licensed premises that are in different places. A person who has a third party agreement with the establishment licensed by the HFEA is not included within this definition.

Related Information

Directive 2004/23/EC, Art.3(o)

S.3.1.3 Centre Management

A group of people (that includes the Person Responsible) who direct and control a Centre at the highest level.

NOTE: The term 'Centre Management' can also be considered equivalent to the term 'top management'. 'Top management' is defined in ISO 9000 as a 'person or group of people who direct and controls an organisation at the highest level'

Related Information

International Organization for Standardization

S.3.1.4 Clinical and Scientific Activities

Activities carried out in a clinical or scientific setting which relate to the provision of licensed treatment or the carrying out of licensed research.

S.3.1.5 Competence

Demonstrated ability to apply knowledge and skills.

NOTE: The term 'Competence' can be applied both to an individual and to an organisation; thus an individual can be competent to perform a particular task and an organisation such as an assisted conception Centre can be competent to fulfil the requirements or expectations of these Standards by virtue of having the necessary capability.

Related Information

International Organization for Standardization

S.3.1.6 Continual Improvement

Recurring activity to increase the ability to fulfil requirements or expectations.

NOTE: These ongoing activities in the Assisted Conception Centre involve establishing objectives and quality indicators and using Evaluation activities including audit findings and user satisfaction surveys, management reviews and other means, to find opportunities for improvement that may require corrective or preventative action.

Related Information

International Organization for Standardization

S.3.1.7 Distribution

Transportation and delivery of reproductive tissues intended for human application.

S.3.1.8 Donor

A person providing sperm, eggs or resulting embryos to a third person.

S.3.1.9 Documented Procedure

Written instructions describing the steps in a specific Process, including the materials and methods to be used and the expected end product.

NOTE: This is synonymous with the terms 'standard operating procedures' or 'SOPs' used in the EU Directives and may include a manufacturer's or supplier's guide, handbook, or instructions or other documentation provided that it is subject to document control as specified in these standards.

Related Information

Directive 2006/17/EC, Art.1(e)

Directive 2006/86/EC, Art.2(e)

International Organization for Standardization

S.3.1.10 EU Directives

These comprise:

- (a) Directive 2004/23/EC on setting the Standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells;
- (b) Directive 2006/17/EC implementing Directive 2004/23/EC as regards certain technical requirements for the donation, procurement and testing of human tissues and cells;
- (c) Directive 2006/86/EC implementing Directive 2004/23/EC as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.

S.3.1.11 Evaluation

Processes that assess fulfilment of specified requirements or expectations.

NOTE 1: The 'Processes' may include assessment of User Satisfaction, monitoring and resolution of complaints, staff suggestions, internal audit of the Quality Management System and assisted conception Processes, participation in inter-Centre comparisons and external reviews.

NOTE 2: The 'requirements and expectations' include those set out in these Standards and those specified by management in order to ensure that the needs and requirements of the user are met.

S.3.1.12 Incident

Any occurrence that is inconsistent with the routine care of the Patient or the routine operation of the organisation, including Adverse Incidents and Serious Adverse Events and Reactions.

S.3.1.13 Near Miss

Any occurrence, which but for luck, skill or judgement would, in all probability, have become an Incident.

S.3.1.14 Nonconformity

Non-fulfilment of a requirement or expectation of these Standards.

NOTE: In the context of a Centre, any failure to protect the quality and safety of gametes or embryos during donation, procurement, testing, Processing, preservation, storage and Distribution Processes would be regarded as major 'Nonconformity' requiring immediate investigation and corrective action.

Related Information

International Organization for Standardization

S.3.1.15 Patient

A person who is receiving treatment services involving the use of gametes or embryos. Also, a person whose gametes or embryos are stored.

S.3.1.16 Patient Partner

A person who is being treated with the Patient and who will be the legal parent of any resulting child.

S.3.1.17 Process

Set of interrelating or interacting activities which transform inputs to outputs.

Related Information

International Organization for Standardization

S.3.1.18 Processing

All operations involved in the preparation, manipulation, preservation and packaging of gametes or embryos intended for human application.

Related Information

Directive 2004/23/EC, Art.3(g)

S.3.1.19 Procurement

Process by which gametes or embryos are made available.

Related Information

Directive 2004/23/EC, Art.3(f)

S.3.1.20 Quality

Degree to which a set of inherent characteristics fulfils requirements or expectations.

Related Information

International Organization for Standardization

S.3.1.21 Quality Management System

The organisational structure, defined responsibilities, procedures, Processes and resources for implementing quality management (i.e. the co-ordinated activities to direct and control an organisation with regard to Quality), including all activities which contribute to Quality, directly or indirectly.

NOTE: This definition indicates that every Process and activity that takes place in the Centre is an integral part of the Quality Management System.

Related Information

Directive 2006/17/EC, Art.1(d)

Directive 2006/86/EC, Art.2

International Organization for Standardization

S.3.1.22 Quality Policy

Overall intentions and direction of an organisation related to Quality as formally expressed by Centre Management.

NOTE: A Quality Policy statement defines or describes an organisation's intentions and commitment to Quality and provides a framework for setting Quality objectives and planning.

Related Information

International Organization for Standardization

S.3.1.23 Record

Legible and indelible evidence of whether the Documented Procedures and other Requirements and expectations of these Standards have been complied with.

Related Information

Directive 2006/86/EC, Annex I, Part E
International Organization for Standardization

S.3.1.24 Requirement

Specification, direction or constraint prescribed in relevant legislation, or by the HFEA pursuant to a power conferred by relevant legislation, e.g. as a condition of a Centre's licence.

NOTE: Failure to comply with a Requirement may constitute grounds for the variation or revocation of a Centre's licence or, in certain cases, a criminal offence.

Related Information

International Organization for Standardization

S.3.1.25 Serious Adverse Event

An untoward occurrence associated with the Procurement, testing, Processing, storage or Distribution of gametes or embryos that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for a Donor of gametes or a person who receives treatment, or which might result in, or prolong, hospitalisation or morbidity.

NOTE: Any type of gamete or embryo misidentification or mix up shall be considered to be a Serious Adverse Event.

Related Information

Directive 2004/23/EC, Art.3(m)
HFE Act 1990, s.2(1) (as amended)

S.3.1.26 Serious Adverse Reaction

An unintended response, including a communicable disease, in a Patient or Donor associated with the Procurement or human application of gametes and embryos that is fatal, life-threatening, disabling, incapacitating or which might result in, or prolongs, hospitalisation or morbidity.

Related Information

Directive 2004/23/EC, Art.3(n)
HFE Act 1990, s.2(1) (as amended)

S.3.1.27 Third Party

A person with whom a Centre has a written agreement under which the Third Party either:

- (a) procures, tests or processes gametes and/or embryos on behalf of a Centre; or
- (b) supplies goods or services (including Distribution services) which may affect the quality and safety of gametes or embryos, to a Centre.

Related Information

HFE Act 1990, s.2(1) (as amended)

S.3.1.28 Traceability

The ability:

- (a) to identify and locate gametes and embryos during any step from Procurement to use for human application or disposal;
- (b) to identify the Donor, or provider, and recipient of particular gametes or embryos;
- (c) to identify any person who has carried out any activity in relation to particular gametes or embryos; and
- (d) to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

Related Information

Directive 2006/17/EC, Art.1(g)
Directive 2006/86/EC, Art.2(g)
HFE Act 1990, s.2(1) (as amended)
International Organization for Standardization

S.3.1.29 User Satisfaction

A measure of the performance of the Quality Management System and whether the Centre has met Patients' and Donors' needs and requirements.

Related Information

International Organization for Standardization

S.3.1.30 Validation

Establishing documented evidence that provides a high degree of assurance that a specific Process, SOP, piece of equipment or environment will consistently produce a product meeting its predetermined specifications and Quality attributes; a Process is validated to evaluate the performance of a system with regard to its effectiveness based on intended use.

Related Information

Directive 2006/17/EC, Art.1(f)

Directive 2006/86/EC, Art.2(f)

International Organization for Standardization

S.3.1.31 Verification

Confirmation, through the provision of objective evidence, that specified Requirements or expectations have been fulfilled.

NOTE: The term 'Verification' is used, for example in the context of the 'receipt of reproductive tissue by the Centre', to mean that on receipt that the expected specifications for the reproductive tissue and the accompanying documentation are met.

Related Information

International Organization for Standardization



S.4.1 Organisation

- S.4.1.1 General** — Centre Management shall ensure it has an organisational structure and operational procedures appropriate to the activities for which it is licensed.

Centre Management, or the parent organisation, shall appoint a responsible person (referred to hereafter as the “Person Responsible”) and ensure that the Centre has access to a nominated registered medical practitioner to advise on and oversee Clinical Activities.

Requirement (Scheme B)

Related Information

Directive 2004/23/EC, Art.17(1)

Directive 2006/86/EC, Annex I, Part A, para.2

- S.4.1.2** The Person Responsible shall be appointed only subject to prior approval by the HFEA.

Requirement (Scheme A)

Related Information

HFE Act 1990, s.16 (as amended)

- S.4.1.3** The organisational structure shall facilitate the creation of an environment in which all medical, nursing, scientific, counselling and other staff, are fully involved in order that the Quality Management System can work effectively, and the Requirements of these Standards are met.

Centre Management, shall ensure that the Centre has access to a nominated registered scientist to advise on and oversee Scientific Activities.

- S.4.1.4 Qualifications for the role of Person Responsible** — The Person Responsible shall at least meet the following qualification criteria:

- (a) possession of a diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences awarded on completion of a university course of study, or other course of study recognised in the United Kingdom as equivalent, or is otherwise considered by the Authority to be suitably qualified on the basis of academic qualifications in the field of nursing; and
- (b) at least two years’ practical experience in relevant fields.

G.1.1.1 Person Responsible: general

Requirement (Scheme B)

Related Information

Directive 2004/23/EC, Art.17
Directive 2006/86/EC, Annex I, Part A, para.1

- S.4.1.5** The Person Responsible shall have successfully completed the HFEA's PR assessment process.

G.1.1.1 Person Responsible:
general

Related Information

Directive 2004/23/EC, Art.17(3)
HFE Act 1990, s.16(2)(c) (as amended)

- S.4.1.6** The Centre shall provide information to the HFEA concerning the proposed Person Responsible. Where a new Person Responsible is proposed, or the Person Responsible is permanently or temporarily replaced, the Centre shall immediately inform the HFEA of the name of the new proposed Person Responsible for approval.

G.1.1.1 Person Responsible:
general

Requirement (Schemes A and B)

- S.4.1.7 Responsibilities of the Person Responsible** — The Person Responsible shall have responsibility for:

G.1.1.1 Person Responsible:
general

- (a) ensuring that the character, qualifications and experience of those carrying out HFEA licensed activities are suited to the work they are carrying out at the Centre,
- (b) ensuring that proper equipment is used,
- (c) ensuring that proper arrangements are made for the keeping and disposal of gametes and embryos,
- (d) ensuring that suitable practices are used in the course of activities carried on under the Centre's licence,
- (e) ensuring that the conditions of the licence are complied with.

Requirement (Scheme A)

Related Information

HFE Act 1990, s.17(1)



Related Sections

S.4.1.8 The Person Responsible shall have responsibility for:

- (a) ensuring that the gametes and embryos, in the Centre, intended for human application are procured, tested, processed, stored and distributed in accordance with the EU Directives and the HFE Act,
- (b) providing a report analysing the cause and the ensuing outcome of any Adverse Incidents,
- (c) ensuring that information published or otherwise disseminated by the Centre is appropriate, accurate, and up to date, and complies with relevant legislation, Directions and guidance.

G.1.1.1 Person Responsible: general

G.14.1 Adverse incidents: general

Requirement (Scheme B)

Related Information

Directive 2004/23/EC, Art.11(3)
Directive 2004/23/EC, Art.12(2)
Directive 2004/23/EC, Art.17(2)

S.4.1.9 The Person Responsible shall have responsibility for notifying the HFEA of any Incidents or Near Misses.

Requirement (Schemes A and B)

Related Information

Directions D.2007/3
Directive 2004/23/EC, Art.17(2)

G.1.1.1 Person Responsible: general

G.14.1 Adverse incidents: general

S.4.1.10 The Person Responsible shall also have responsibility for ensuring compliance with the conditions set out in any third party agreement and that any third party premises are suitable for the activity to be being carried out there.

NOTE: Third party premises may be inspected as part of the licensing process and during the investigation of any Adverse Incidents. If third party premises are not suitable the licence holder may face variation or revocation of their licence.

G.1.1.1 Person Responsible: general

G.2.1.1 Unlicensed services and facilities: general

Related Information

Directive 2004/23/EC, Art.12(2)

S.4.1.11 Integrity — Centre Management shall have in place arrangements to ensure that there is no involvement in any activities that would diminish confidence in its competence, impartiality, judgement, or operational integrity.



S.4.2 Management responsibility

S.4.2.1 Management commitment — Centre Management (including the Person Responsible) shall demonstrate its commitment to the establishment and maintenance of the Quality Management System and the improvement of its effectiveness by:

- (a) communicating to Centre personnel the importance of the needs and requirements of users and of fulfilling statutory and regulatory Requirements,
- (b) establishing the Quality Policy,
- (c) ensuring that Quality objectives are established,
- (d) defining responsibilities, authorities and reporting relationships and establishing appropriate internal communication within the Centre,
- (e) appointing a quality manager,
- (f) conducting management reviews,
- (g) the establishment and review of contracts with third parties,
- (h) ensuring the availability of resources.

S.5.1 Quality management: general

S.6.1 Provision of resources

Related Information

Directive 2004/23/EC, Art.16
Directive 2004/23/EC, Art.24
Directive 2006/86/EC, Annex I, Part E
Directive 2006/86/EC, Annex I, Part F

S.4.2.2 Needs and requirements of users — Centre Management shall ensure that the assisted conception services provided are designed to meet the needs and requirements of the users.

S.9.2.1 Evaluation: general

Related Information

HFE Act 1990, s.17(1)(d)

S.4.2.3 Quality Policy — Centre Management shall ensure that the Quality Policy includes a commitment:

- (a) to the provision of a service that meets the needs and requirements of the users,
- (b) to meet the Requirements of these Standards and to the Continual Improvement of the effectiveness of the Quality Management System,



- (c) to good professional practice,
- (d) to the health, safety and welfare of all staff and visitors to the Centre.

The Quality Policy shall be signed and issued by a person with appropriate authority, be communicated, understood and available throughout the Centre, and reviewed for continuing suitability.

Related Information

Directive 2006/86/EC, Annex I, Part E

- S.4.2.4 Quality objectives and plans** — Centre Management shall establish documented Quality objectives, including those needed to meet the needs and requirements of the users that are measurable and consistent with the Quality Policy.

Centre Management shall have plans to achieve and maintain its Quality objectives. The objectives and plans shall be regularly reviewed.

Related Information

Directive 2004/23/EC, Art.16
Directive 2006/86/EC, Annex I, Part E
Directive 2006/86/EC, Annex I, Part F

- S.4.2.5 Responsibility, authority and communication** — Centre Management shall ensure that accountabilities and reporting relationships are defined and presented in an organisational chart.

Requirement (Scheme B)

Related Information

Directive 2006/86/EC, Annex I, Part A, para.2

- S.4.2.6** Centre Management shall ensure that the accountabilities and reporting relationships presented in the organisational chart are communicated within the Centre.

Centre Management shall ensure that communication Processes are established that include communication regarding the effectiveness of the Quality Management System and the service provided to users.

Related Information

Directive 2006/86/EC, Annex I, Part A, para.2



S.4.2.7 Quality manager — Centre Management shall appoint a quality manager who, irrespective of other responsibilities, shall have designated responsibility and authority that includes:

- (a) ensuring that the Quality Management System is implemented and maintained,
- (b) reporting to Centre Management on the functioning and effectiveness of the Quality Management System, and
- (c) co-ordinating awareness of users' needs and requirements.

Related Information

Directive 2004/23/EC, Art.16

S.4.2.8 Management review — Centre Management shall conduct a regular review of the Centre's Quality Management System and all its services. The review shall assess the need for changes to the Quality Management System and opportunities for improvement.

NOTE: The maximum interval between management reviews should be twelve months but shorter intervals should be adopted when a Quality Management System is being established.

Requirement (Scheme B)

Related Information

Directive 2006/86/EC, Annex I, Part F, para.4

S.4.2.9 The review of the Quality Management System shall include, but not be limited to, consideration of changes in the volume and scope of work, personnel, premises, and the performance of third parties (suppliers) that could affect the Quality Management System or the service provided to users and the results of the following ongoing Evaluation and improvement activities:

- (a) assessment of User Satisfaction,
- (b) monitoring and resolution of complaints,
- (c) staff suggestions,
- (d) internal audit of all elements of the Quality Management System, including the assisted conception Processes,

S.9.1.2 Evaluation and improvement: activities

G.11.3.3 Complaints register: general (1)

G.14.1.4 Adverse incident: procedure

S.9.2.1 Evaluation: general



Related Sections

- (e) participation in inter-Centre comparisons and inter-laboratory comparisons,
- (f) Quality indicators for monitoring the Centre's performance in Patient care,
- (g) external reviews,
- (h) identification, investigation, control, recording and notification of Serious Adverse Events and Reactions,
- (i) results of Continual Improvement including current status of corrective and preventive actions.

S.9.2.6
Inter-center and inter-laboratory comparisons

S.9.3 External reviews

S.9.4 Adverse incidents

S.9.5 Improvement

The results of the management review shall be recorded and include the decisions and actions related to improvement of the Quality Management System and the services provided to users and consequent resource implications.

Centre personnel shall be informed of the results of the management review.

Related Information

Directive 2004/23/EC, Art.4(2)
Directive 2006/86/EC, Annex I, Part F, para.4

S.4.2.10 Establishment and review of contracts with Third Parties —

Centre Management shall establish documented agreements with third parties when an activity takes place which influences the quality and safety of gametes and embryos procured or processed and in particular where:

- (a) the Centre entrusts one of the stages of gamete or embryo Processing to a Third Party,
- (b) a Third Party provides goods or services that affect gamete or embryo quality and safety, including the Process of Distribution,
- (c) the Centre provides services to another centre that is not licensed,
- (d) the Centre distributes gametes or embryos processed by Third Parties.

G.2.1 Use of unlicensed facilities and services: general

G.2.2 Transport and satellite arrangements

Centre Management shall evaluate and select third parties on the basis of their ability to meet the Requirements of these Standards

The Centre shall keep a complete list of the agreements established with third parties and the agreements shall specify the responsibilities of the third parties and detailed procedures. Copies of these agreements shall be made available to the HFEA upon request.

Centres must make arrangements to ensure that, in the event of termination of activities for whatever reason, stored samples, gametes and embryos shall be transferred to other licensed Centres.

Requirement (Scheme B)

Related Information

Directive 2004/23/EC, Art.21(5)
Directive 2004/23/EC, Art.24
Directive 2006/86/EC, Annex I, Part A, para.6.
Directive 2006/86/EC, Annex I, Part A, para.8.

S.4.2.11 Centres that import gametes and embryos from a country outside the EEA and Gibraltar shall ensure, where appropriate with the assistance of the HFEA, that such imports meet the quality and safety Requirements set out in these Standards. Similar Requirements shall apply where the Centre exports gametes or embryos to a country outside the EEA and Gibraltar.

G.9.8 Transport of gametes and embryos

Requirement (Schemes A and B)

Related Information

Directions D.1991/8
Directions D.2006/1
Directions D.2007/2
Directive 2004/23/EC, Art.9
HFE Act 1990, s.24(4) (as amended)

S.4.2.12 Reporting to the HFEA — The Centre shall:

- (a) seek prior written approval from the HFEA of substantial changes to its activities,
- (b) report to the HFEA on the activity of the Centre, including types and numbers of treatments, number of embryos used in each treatment episode and the numbers of gametes and embryos discarded.

NOTE: IVF centres must report via the EDI system (except for small clinics). IUI/GIFT centres must report annually.

Requirement (Scheme B)



Related Information

Directions D.2007/1

Directions D.2007/7

Directive 2004/23/EC, Art.10(1)

Directive 2004/23/EC, Art.17(2)

Directive 2004/23/EC, Art.6(3)

HFE Act 1990, s.12(1)(d) (as amended)



S.5.1 Quality management: general

S.5.1.1 The Centre shall establish a Quality Management System and continually improve its effectiveness as set out in these Standards and based on the principles of good practice.

Requirement (Scheme B)

Related Information

Directive 2004/23/EC, Art.16

S.5.1.2 The Centre shall:

- (a) identify the Processes needed for quality management activities, provision and management of resources, assisted conception Processes, Evaluation and Continual Improvement and the interaction between them;
- (b) ensure that the resources and information necessary to support the operation and monitoring of these Processes are available; and
- (c) implement actions necessary to ensure the effectiveness and Continual Improvement of these Processes.

NOTE: The EU Directives require that for all “critical” activities (Processes), the materials, equipment and personnel involved in such Processes must be identified and documented.

Related Information

Directive 2006/86/EC, Annex I, Part E

Directive 2006/86/EC, Annex I, Part F

S.5.2 Documentation requirements

S.5.2.1 General — The Centre shall have Quality Management System documentation that includes the Documented Procedures required by these Standards.

The Centre shall ensure that all documentation is available for inspection by the HFEA.

Requirement (Scheme B)

Related Information

Directive 2004/23/EC, Art.16 (4)

S.3.1.9
Documented
Procedure

Related Sections

S.5.2.2 The Centre's Quality Management System documentation shall also include:

- (a) a Quality Policy, and quality objectives and plans,
- (b) a quality manual,
- (c) documents needed to ensure the effective planning, operation and control of its Processes, and
- (d) Records required by these Standards.

NOTE 1: The extent of the Quality Management System documentation can differ from one organisation to another due to:

- (i) the size of the Centre and type of activities,
- (ii) the complexity of the Processes and their interactions, and
- (iii) the staffing arrangements.

NOTE 2: The documentation can be in any form or type of medium providing it is readily accessible.

Related Information

Directive 2004/23/EC, Art.16
Directive 2006/17/EC, Annex IV, para.1.4.3
Directive 2006/86/EC, Annex I, Part E

S.5.2.3 **Quality manual** — The Centre shall establish and maintain a quality manual that includes an organisational chart, that clearly defines accountability and reporting relationships within the Centre.

Requirement (Scheme B)

Related Information

Directive 2006/86/EC, Annex I, Part A, para.2

S.5.2.4 The Centre's quality manual shall also include:

- (a) a brief description of the Centre, including its legal identity, and the scope of the services provided,
- (b) the Quality Policy or reference to it,
- (c) text to accompany the organisational chart and a definition of the Centre's place in any parent organisation,

S.4.2.3 Quality policy

S.4.2.4 Quality objectives and plans

S.4.2.3 Quality policy

- (d) an outline of the Processes and documentation established for the Quality Management System.

Related Information

Directive 2006/86/EC, Annex I, Part A, para.2

S.5.2.5 Document control — The Centre shall establish a Documented Procedure to control all documents (internally generated and from external sources) required by the Quality Management System. This procedure shall ensure that

- (a) documents are regularly reviewed, revised as required, dated and re-approved promptly by authorised personnel,

NOTE: Review, revision and re-approval should be conducted at a frequency that ensures that they remain 'fit for purpose'. The maximum interval between reviews should be twelve months.

- (b) documents remain legible, indelible and readily retrievable,
- (c) there is a register of current approved versions and their distribution to ensure that only current versions are in use.

Requirement (Scheme B)

Related Information

Directive 2006/17/EC, Annex IV, para.1.4.3

Directive 2006/86/EC, Annex I, Part E

S.5.2.6 The document control procedure shall ensure that:

- (a) documents are approved by authorised personnel prior to use,
- (b) documents are uniquely identified: identification shall include a unique identifier, the edition or current revision date, or revision number, the number of page/total number of pages (where applicable), authority for issue, and author identification.

The Centre shall determine with regard to the needs of the service and in accordance with current legislation, regulations and guidelines, the appropriate retention times for documents removed from use.

Records are a special type of document and shall be controlled according to the Requirements given for Control of Records (below).



NOTE 1: When a Centre's documentation control system allows for the amendment of documents by hand pending the re-issue of documents, the procedures and authorities for such amendments are defined, amendments are clearly marked, initialled and dated, and a revised document is re-issued as soon as practicable

NOTE 2: A document is any information or instructions, including policy statements, text books, procedures, specifications, calibration tables, biological reference intervals and their origins, charts, posters, notices, memoranda, software, drawings, plans, and documents of external origin such as regulations, standards or procedures.

Related Information

Directions D.1992/1

Directive 2006/86/EC, Annex I, Part E, para.3

S.5.2.7 Control of Records — Records should be reliable and a true representation of results.

Records, including raw data, which are critical to the safety and quality of gametes and embryos, shall be kept in a manner that ensures access for at least 10 years after the expiry date, clinical use or disposal.

The Records shall include the data necessary to ensure that all gametes and embryos procured, processed, stored or distributed (on their territory) can be traced from Patient's partner or Donor to the Patient and vice versa, and the origin or a description of products and Processing steps having an effect on the Quality and/or safety of gametes or embryos (see also Traceability and coding). Records required for full Traceability shall be kept in a manner that ensures access for at least 30 years after clinical use or disposal (and for such longer period as may be specified in Directions). Access to registers and data shall be restricted to persons authorised by the Person Responsible and the HFEA for inspection purposes.

Records must be legible and indelible and may be hand-written or transferred to another system such as a computer or microfilm.

Requirement (Scheme B)

G.10.2.1 Access to confidential records

S.7.3 Traceability and coding



Related Information

Directions D.1992/1
Directive 2004/23/EC, Art.8
Directive 2006/17/EC, Annex IV, para.1.4.4
Directive 2006/86/EC Art.9
Directive 2006/86/EC, Annex I, Part E
Directive 2006/86/EC, Annex II, Part C, para.4

- S.5.2.8** The Centre shall establish a Documented Procedure to control all Records required to provide evidence of conformity to Requirements of the Standards, to the effective operation of the Quality Management System and to the conduct of assisted conception Processes. The procedure shall include the identification, collection, indexing, access, storage, maintenance, confidentiality and safe disposal of Records.

The Centre shall determine with regard to the needs of the service and in accordance with current legislation, regulations and guidelines, the appropriate retention times for all Records.

NOTE: Records can be in any form or type of medium providing they are readily accessible.

G.10.2.1 Access to confidential records

Related Information

Directions D.1992/1
Directions D.2007/1
Directions D.2007/7

S.6.1 Provision of resources

S.6.1.1 The Centre shall determine and provide the resources needed, in terms of personnel, facilities, equipment and materials, and data and information systems:

- (a) to implement and maintain the Quality Management System and continually improve its effectiveness,
- (b) to enhance User Satisfaction by meeting users needs and requirements, and
- (c) to make appropriate arrangements for their management.

S.6.2 Personnel

S.6.2.1 General — The Centre shall have sufficient numbers of staff, with the Competence to perform their designated tasks, to ensure that the Requirements of these Standards are met.

Personnel directly involved in activities relating to the Procurement, Processing, preservation, storage and Distribution of gametes and embryos shall be qualified and competent to perform such tasks.

Requirement (Scheme B)

Related Information

Directive 2004/23/EC, Art.18

Directive 2006/86/EC, Annex I, Part B, para.1

G.1.2 Medical Staff

G.1.3 Nursing Staff

G.1.4 Counselling Staff: general

G.1.5 Staff engaged in scientific services

G.12.1.1 Preimplantation testing: staff

S.6.2.2 Where appropriate, staff should be registered in accordance with the Requirements of any applicable legislation and possess the appropriate qualifications and/or experience set out in relevant HFEA and professional guidance.

The Centre shall establish Documented Procedures for personnel management that ensure that all staff have:

- (a) job descriptions,
- (b) initial basic training and update training,

G.1.2 Medical Staff

G.1.3 Nursing Staff

G.1.4 Counselling Staff: general

Related Sections

G.1.5 Staff engaged in scientific services

S.7.1.1 Assisted conception processes: general

- (c) Competence assessment,
- (d) annual joint review,
- (e) continuing education and professional development,
- (f) personnel Records,
- (g) appropriate access to meetings and communications.

NOTE: When the Centre is part of a larger organisation, where appropriate, some of these procedures may be undertaken by the personnel department of the parent organisation.

Related Information

Directive 2006/86/EC, Annex I, Part B

S.6.2.3 Conscientious objection — The Centre shall provide prospective employees with a full description of the Centre's activities and at interview draw their attention to the provision that any person who has a conscientious objection to participating in any particular activity carried out in the Centre shall not be under obligation to do so.

Related Information

Directive 2006/86/EC, Annex I, Part B
HFE Act 1990, s.38(1)

S.6.2.4 Criminal convictions — Centres shall require all prospective and existing staff to report promptly all criminal convictions to the Person Responsible. In deciding whether or not an individual shall take part in an HFEA licensed activity at the Centre, the Person Responsible shall take into account relevant previous convictions and breaches of regulations.

Related Information

HFE Act 1990, s.17(1)(a)

S.6.2.5 Job Descriptions — All personnel shall have up-to-date job descriptions that are clearly documented and understood. They shall include:

- (a) a job title,
- (b) accountability,
- (c) the designated tasks and responsibilities of the job.

Requirement (Scheme B)

Related Information

Directive 2006/86/EC, Annex I, Part B, para.2

- S.6.2.6** Job descriptions shall also include reporting relationships and a description of the purpose of the job.

A person specification may be part of the job description or be provided separately to job applicants.

- S.6.2.7 Initial/basic training and update training** — To enable them to carry out their designated activities, personnel shall be provided with appropriate initial/basic training which is updated as required when procedures change or scientific knowledge develops. Adequate opportunities shall be given for relevant professional development.

The training programme shall ensure and document that each individual

- (a) has the Competence in the performance of their designated tasks,
- (b) has an adequate knowledge and understanding of the scientific/technical Processes and principles relevant to their designated tasks,
- (c) understands the organisational framework, quality system and health and safety rules of the Centre in which they work,
- (d) is adequately informed of the broader ethical and legal context of their work.

NOTE: Update training is required when procedures change or scientific knowledge develops. See also Continuing education and professional development.

Requirement (Scheme B)

Related Information

Directive 2006/86/EC, Annex I, Part B, para.3
HFE Act 1990, s.17(1)(a)

G.1 Personnel

G.13.6
Witnessing:
training

Related Sections

G.7.1.1 Provision of counselling

S.6.2.8 The training programme shall also ensure and document that, where the individual is in contact with Patients, they are prepared to offer appropriate emotional support to people suffering distress at any stage of their investigation, counselling or treatment, understand and can explain the role of counselling, and know when and how to refer people to the qualified counsellor.

S.6.2.9 Competence assessment — Following initial/basic and update training, the Competence of each person to perform designated activities shall be evaluated at intervals specified in the Quality Management System and re-training undertaken when required.

Requirement (Scheme B)

Related Information

Directive 2006/86/EC, Annex I, Part B, para.3

S.6.2.10 Annual joint review — All personnel shall participate in an annual joint review that examines the needs of the Centre and of the individual in order to improve the Quality of the service given to users and to encourage productive working relationships.

Staff performing annual reviews shall receive appropriate training.

S.6.2.11 Continuing education and professional development — A continuing education programme shall be available to staff at all levels. Staff shall take part in regular professional development programmes that include audit of practice and in professional liaison activities.

G.1 Personnel

Resources shall be available for training and education that include access to library and information services and a quiet area for private study.

Related Information

Directive 2006/86/EC, Annex I, Part B

S.6.2.12 Personnel Records — Personnel Records shall include:

- (a) employment details,
- (b) job description,
- (c) terms and conditions of employment,
- (d) a Record of staff induction and orientation,

- (e) a Record of health and safety training,
- (f) a Record of education and training including continuing professional development,
- (g) relevant educational and professional qualifications,
- (h) certificate of registration, if relevant,
- (i) absence Record,
- (j) accident Record,
- (k) a Record of staff annual joint reviews,
- (l) occupational health Record,
- (m) Record of disciplinary action. The Centre shall ensure confidentiality of personnel Records in accordance with local guidelines and national legislation.

NOTE: If the Centre is part of a larger organisation staff Records may be held by the parent organisation but should be available for inspection by the HFEA if requested.

Related Information

Directive 2006/86/EC, Annex I, Part B

S.6.2.13 Meetings and communication — The Centre shall have an effective means for communicating information to staff and receiving suggestions from staff. Records shall be kept of meetings and made available to all staff.

S.9.2.3 Staff suggestions

S.6.3 Premises and facilities

S.6.3.1 General — The Centre shall have Documented Procedures for controlled access, cleaning and maintenance of the facilities, waste disposal and re-provision of services in case of emergencies.

Requirement (Scheme B)

Related Information

Directive 2006/86/EC, Annex I, Part D, para.9

S.6.3.2 The Centre shall have premises and facilities suitable for the activities for which it is licensed that include, as appropriate, facilities for reception, clinical and counselling activity, laboratory work, storage of gametes and embryos, and staff.

The Centre shall provide a safe working environment for all staff. The Centre shall have Documented Procedures for health, safety and welfare, including, appropriate procedures for lone workers,

Related Information

Directive 2006/17/EC, Art.2(6)
Directive 2006/86/EC, Annex I, Part D, para.1

S.6.3.3 Clinical facilities — Centres shall ensure that the clinical facilities available are appropriate for the activities for which the Centre is licensed.

Requirement (Scheme B)

Related Information

Directive 2006/86/EC, Annex I, Part D, para.1

S.6.3.4 Centres shall ensure that the clinical facilities available:

- (a) provide for the privacy and comfort of those
 - (i) considering donation and seeking treatment
 - (ii) undergoing examination and treatment
 - (iii) producing semen specimens
- (b) are equipped with backup and emergency clinical facilities, equivalent to those which are standard practice in other medical provision and appropriate to the degree of risk involved in any planned procedure and able to cope with predictable emergencies.

Related Information

Directive 2006/86/EC, Annex I, Part D

S.6.3.5 Counselling facilities — Centres shall ensure that counselling facilities provide quiet and comfortable surroundings in which sessions can be held that are private, confidential and without interruption.

G.1.4.1
Counselling:
oversight of
facilities

Related Sections

S.6.3.6 Laboratory facilities — The laboratory facilities shall ensure:

- (a) that all equipment and material shall be designated and maintained to suit its intended purpose and shall minimise any hazard to recipients and/or staff and that the risks inherent in handling gametes and embryos are identified and minimised,
- (b) the Processing of gametes and embryos, takes place in an environment with specified air quality and cleanliness, to protect their quality and safety and minimise the risk of contamination and cross-contamination between samples, and that the effectiveness of these measures is validated and monitored.

G.9.4 Air quality

Requirement (Scheme B)

Related Information

Directive 2004/23/EC, Art.20
Directive 2006/17/EC, Annex IV, para.1.3.7
Directive 2006/86/EC, Annex I, Part A, para.5
Directive 2006/86/EC, Annex I, Part C, para.1
Directive 2006/86/EC, Annex I, Part D

S.6.3.7 Storage facilities for gametes and embryos — The storage facilities for gametes and embryos shall:

- (a) provide for storage of gametes and embryos under conditions designed to ensure their quality and safety,
- (b) clearly separate and distinguish gametes and embryos prior to release/in quarantine from those released and those rejected to prevent mix up and cross contamination,
- (c) have physically separate areas/storage devices or secured segregation within the storage device for those gametes and embryos in quarantine and those released, in compliance with special criteria,
- (d) allow critical parameters such as temperature, humidity and air quality to be controlled, monitored and recorded, to demonstrate conformity to specified storage conditions.

G.13 Witnessing clinical and laboratory procedures

G.9.3.1 Cryopreserved gametes and embryos: safety

G.9.3.2 Separating patients samples

G.9.7 Prevention of cross contamination

Requirement (Scheme B)

Related Information

Directive 2006/86/EC, Annex I, Part D

Related Sections

S.6.3.8 Gametes and embryos shall be stored in a designated security area with controlled access. Access to the security area shall be authorised by the Person Responsible and a monitoring system shall be in place to ensure high standards of security. Only named individuals, for whom access is essential in the course of their work, shall be authorised.

G.9.3.1
Cryopreserved gametes and embryos: safety

The storage facilities for gametes and embryos shall:

- (a) be dedicated for the purpose and adequate for the volume and types of activities,
- (b) be designed to avoid proximity to ionising radiation (radioactive material), any known potential source of infection, chemical or atmospheric contamination,
- (c) incorporate a storage location system that minimises the amount of handling required to retrieve gametes and embryos,
- (d) have emergency procedures to deal with damage to storage vessels and/or failure of storage conditions.

Related Information

Directive 2006/86/EC, Annex I, Part D, para.9
HFE Act 1990, s.12(1)(a) (as amended)

S.6.3.9 Staff facilities — The Centre shall provide appropriate garments and equipment for personal protection and hygiene, together with written instructions for their use.

S.6.2.2
Personnel:
management

Requirement (Scheme B)

Related Information

Directive 2006/86/EC, Annex I, Part D, para.5.

S.6.3.10 The Centre shall have staff facilities that are readily accessible and include:

- (a) toilet accommodation,
- (b) a rest area with basic catering facilities and a supply of drinking water,
- (c) a changing area and secure storage for personal effects,
- (d) storage for protective clothing.

Related Information

Directive 2006/17/EC, Annex IV, para.1.3.7

S.6.4 Management of equipment and materials

S.6.4.1 Where applicable, equipment and materials shall meet the Requirements of the relevant EU Directives, 93/42/EC Medical Devices and 98/79/EC In vitro Diagnostic Medical Devices.

NOTE: For the purpose of these Standards, 'equipment and materials' includes all equipment, disposables, reagents, calibration and control materials used in the conduct of assisted conception Processes. A major proportion of the items involved will be regulated by the Directives referred to above.

Related Information

Directive 1993/42/EEC

Directive 1998/79/EC

Directive 2006/86/EC, Annex I, Part C, para.6

S.6.4.2 The Centre shall ensure that:

- (a) all critical equipment is identified and validated, regularly inspected and preventatively maintained in accordance with the manufacturers' instructions. New and repaired equipment must be tested when installed and must be validated before use. Test results must be documented.
- (b) where equipment or materials affect critical Processing or storage parameters (e.g. temperature, pressure, particle counts, microbial contamination levels), are identified they must be the subject of appropriate monitoring, alerts, alarms and corrective action, as required, to detect malfunctions and defects and to ensure that the critical parameters are maintained within acceptable limits at all times.
- (c) maintenance, servicing, cleaning, disinfection and sanitation of all critical equipment must be performed regularly and recorded accordingly.

Requirement (Scheme B)

Related Information

Directive 2006/17/EC, Annex IV, para.1.3.9

Directive 2006/86/EC, Annex I, Part C, para.2

Directive 2006/86/EC, Annex I, Part C, para.3

Directive 2006/86/EC, Annex I, Part C, para.4



Related Sections

S.6.4.3 The Centre shall establish Documented Procedures for the management of equipment and materials that include:

- (a) the operation of each piece of critical equipment, detailing the action to be taken in the event of malfunctions or failure,
- (b) detailed specifications for all critical materials and reagents. In particular, specifications for additives (e.g. solutions) and packaging materials shall be defined,
- (c) Adverse Incident reporting,
- (d) Traceability of any materials that come in contact with gametes or embryos.

G.14.1.3 Adverse incidents: reporting

G.9.6 Coding and traceability

Requirement (Scheme B)

Related Information

Directive 2006/86/EC Art.9
Directive 2006/86/EC, Annex I, Part C
Directive 2006/86/EC, Annex IV, Part E
Directive 2006/86/EC, Art.5(2)
Directive 2006/86/EC, Art.6(3)

S.6.4.4 The Documented Procedures for the management of equipment and materials shall also include:

- (a) selection and Procurement,
- (b) the training of personnel,
- (c) inventory, stock control and Records.

The Centre shall maintain Records that provide evidence of conformity with the procedures for management of equipment and materials.

S.6.2.2
Personnel:
management

Related Information

Directive 2006/86/EC, Annex I, Part B, para.3
Directive 2006/86/EC, Annex I, Part C
Directive 2006/86/EC, Annex I, Part D

S.6.5 Information management

S.6.5.1 The Centre shall establish Documented Procedures for the management of data and information that include:

- (a) document control,

G.10.2.1 Access to confidential records



Related Sections

- (b) accurate recording of information,
- (c) history of document reviews and changes and to ensure that only current versions of documents are in use,
- (d) security of data and safeguards against unauthorised modification, addition, deletion, disclosure or transfer of information,

G.10.8.1 Breach of confidentiality: general

Requirement (Scheme B)

Related Information

Directive 2004/23/EC, Art.14(2)(a)
Directive 2006/86/EC, Annex I, Part E, para.1
Directive 2006/86/EC, Annex I, Part E, para.4

S.6.5.2 The Documented Procedures for the management of data and information systems shall also include:

- (a) resolution of data discrepancies,
- (b) maintenance and disaster recovery,
- (c) storage, archiving and retrieval,
- (d) secure disposal.

G.10.2.1 Access to confidential records

G.10.8.1 Breach of confidentiality: general

The Centre shall maintain Records that provide evidence of conformity with the procedures for management of data and information systems.

Related Information

Directive 2004/23/EC, Art.14(2)(b)

S.7.1 General

- S.7.1.1** The Centre shall ensure that all assisted conception Processes are conducted by authorised personnel in a manner that ensures the safety of Patients and Donors, the quality and safety of gametes and embryos, and meets the needs and requirements of the user.

Where any aspect of the assisted conception Processes are not undertaken by the Centre there shall be written agreements between the Centre and the Third Party that include a specification of the Processes and procedures to be used that is in conformity with the Requirements of these Standards.

Requirement (Scheme B)

Related Information

Directive 2004/23/EC, Art.20
Directive 2004/23/EC, Art.24
Directive 2006/17/EC, Annex IV, para.1.3.7
Directive 2006/17/EC, Art.2(5)
Directive 2006/86/EC, Annex II, Part B

G.1 Personnel

S.4.2.10 Third party contracts

- S.7.1.2** The Centre shall ensure that all assisted conception Processes are conducted in a manner that takes into account the welfare of any child that may be born as a result of treatment services.

Requirement (Schemes A and B)

Related Information

Directive 2006/17/EC, Annex III, para.2.1
HFE Act 1990, s.13(5) (as amended)

G.3.1 Welfare of the child provision

S.7.6.4 Welfare of the child (1)

- S.7.1.3** The Centre shall also ensure that all assisted conception Processes are conducted in a manner that takes into account the welfare of any other child who may be affected by the birth.

Requirement (Scheme A)

Related Information

HFE Act 1990, s.13(5) (as amended)

G.3.1 Welfare of the child provision

S.7.6.5 Welfare of the child (2)

- S.7.1.4** The Centre shall ensure that all aspects of the documentation of the assisted conception Processes are in conformity with the general documentation Requirements of these Standards.

S.5.2 Documentation requirements



S.7.2 Confidentiality and access to health records

S.7.2.1 The Centre shall have procedures to ensure that information provided in confidence is kept confidential and only disclosed in circumstances permitted by law.

NOTE: Patients should not have access to another person's Records (including those of spouse or partner) without that other person's prior consent.

The Centre shall ensure that all data, including genetic information, that is collated for any purpose, and to which Third Parties have access, is rendered anonymous so that neither Patients nor Donors remain identifiable. Arrangements shall ensure that the identification details of Donors and Patients are not disclosed to each other or to each other's family.

Requirement (Scheme B)

Related Information

Directive 2006/86/EC, Annex I, Part E, para.8
HFE Act 1990, s.33(5) (as amended)

G.10
Confidentiality
and access to
confidential
information

S.4.2.10 Third
party contracts

S.7.2.2 The Centre shall establish a Documented Procedure for control of access to health Records that ensures arrangements are in place for:

- (a) the prompt consideration and response to applications for access to confidential Records and the proper identification of applicants,
- (b) the designation of an identified individual in the Centre with responsibility to receive, check and arrange authorised access to confidential Records,
- (c) notification to the Information Commissioner in accordance with the Data Protection Act 1998,
- (d) providing all individual Donors and recipients who provide information about themselves, access to the Record of that information and an opportunity to correct it,
- (e) ensuring that individuals (data subjects) are aware of their rights under the Data Protection Act 1998 to access their own health Records.

G.10
Confidentiality
and access to
confidential
information



NOTE: When the Centre is part of a larger organisation, where appropriate, some of these procedures may be undertaken by the appropriate department of the parent organisation.

Related Information

Access to Health Records (Northern Ireland) Order 1993
Access to Health Records Act 1990
Data Protection Act 1998
Directive 2004/23/EC, Art.14
The Data Protection (Subject Access Modification) (Health) Order 2000

S.7.3 Traceability and coding

S.7.3.1 Traceability — The Centre shall establish Documented Procedures to ensure that all gametes and embryos are traceable from Procurement of gametes to Patient treatment or disposal, and vice versa, to ensure:

- (a) the unique and accurate identification of the Patient, Patient Partner or Donor and the gametes and embryos and labelling of their containers, received and distributed,
- (b) that quarantined, non quarantined and rejected material is clearly distinguishable at all stages of Processing,
- (c) that registers are kept of received, processed, stored and distributed or discarded gametes or embryos, enabling:
 - (i) identification of Processing steps applied to gametes and/or embryos and, if applicable, third parties involved in Processing,
 - (ii) investigation, post application of the gametes, if a problem with the donation is identified subsequently,
- (d) Records are kept of the equipment and materials used in the reception, Processing, storage and discarding of gametes and embryos.

G.13 Witnessing clinical and laboratory procedures

G.3.4.1 Verification of identity

G.4.6.2 Donation: verification of identity

G.9.6 Coding and traceability

S.7.8.10 Laboratory processes: storage (1)

Requirement (Scheme B)

Related Information

Directive 2004/23/EC, Art.19
Directive 2004/23/EC, Art.8
Directive 2006/86/EC Art.9
Directive 2006/86/EC, Annex I, Part A, para.9
Directive 2006/86/EC, Annex I, Part E, para.2
Directive 2006/86/EC, Annex II, Part C, para.3
Directive 2006/86/EC, Annex II, Part D, para.6
HFE Act 1990, s.13(2)
HFE Act 1990, s.14A (as amended)
HFE Act 1990, s.24(2)
HFE Act 1990, Sched.3A (as amended)

S.7.3.2 The procedures for traceability of gametes and embryos shall also ensure that registers are kept of received, processed, stored and distributed or discarded gametes or embryos, enabling identification of:

- (a) an individual Patient, Patient Partner or Donor,
- (b) individual Procurement and hospital or institution from which gametes and embryos have been received,
- (c) distributed gametes or embryos and hospitals or institutions to which gametes or embryos have been distributed (whether intended for application in the human body, or for research purposes).

Requirement (Schemes A and B)

Related Information

Directions D.2007/3
Directive 2004/23/EC, Art.10(1)
Directive 2006/86/EC, Art.9(2)
HFE Act 1990, s.13(2)
HFE Act 1990, s.24(2)

S.7.3.3 Coding — The Centre shall use an identifying code to ensure the Traceability of all gametes and embryos and provide information on their main characteristics, in accordance with the Documented Procedures on Traceability.

The minimum Requirements for information are:

- (a) for donors:

G.9.6 Coding and traceability

G.13.8 Identification of samples

S.7.3.1 Traceability



Related Sections

S.7.3.2
Traceability:
procedures

- (i) the unique identification of individuals, an
 - (ii) the identification of the Centre, and
- (b) for gametes and embryos:
- (i) a unique code
 - (ii) split number (if applicable), and
 - (iii) expiry date.

Requirement (Scheme B)

Related Information

Directive 2004/23/EC, Art. 8(2)
Directive 2004/23/EC, Art.19(5)
Directive 2006/86/EC, Annex VII
Directive 2006/86/EC, Art.10

S.7.4 Information for service users

- S.7.4.1** The Centre shall ensure that before any individual is given treatment or consents to the use, donation or storage of embryos or gametes, they are given appropriate oral and written information that explains the medical, scientific, legal, and psychosocial implications of their decision.

G.5 Providing
proper information

Requirement (Schemes A and B)

Related Information

Directive 2004/23/EC, Annex
Directive 2004/23/EC, Art.13
Directive 2006/17/EC, Annex IV, para.1.1.2
HFE Act 1990, s.13(6)
HFE Act 1990, Sched.3, para.3

S.7.5 Consent

- S.7.5.1 General** —The Centre shall establish Documented Procedures for individuals considering or giving consent to examination and treatment or donation, and storage to ensure that only personnel authorised by the Centre take consent.

G.13.7 Patient
and donor
identification

Requirement (Scheme B)

Related Sections

Related Information

Directive 2006/17/EC, Art.2(5)(b)

G.4.6 Donating for treatment: general

G.6 Obtaining consent from fertility patients

- S.7.5.2** The Centre shall establish Documented Procedures for individuals considering or giving consent to examination and treatment or donation, and storage to ensure that reasonable steps are taken to verify the identity of individuals from whom consent is obtained.

G.4.6.2 Donation: verification of identity

Requirement (Schemes A and B)

Related Information

Directive 2006/17/EC, Annex IV, para. 1.1.1
HFE Act 1990, s.13(7)(a)

G.6 Obtaining consent from fertility patients

- S.7.5.3** The Centre shall comply with current professional guidelines on consent and relevant HFEA guidance.

The Centre shall establish Documented Procedures for individuals considering or giving consent to examination and treatment or donation, and storage to ensure that:

G.4.6.2 Donation: verification of identity

- (a) reasonable steps are taken to verify the identity of any other person whose consent is required to be obtained,
- (b) appropriate verbal and written information is provided in conjunction with obtaining consent and its provision is recorded,
- (c) individuals are given an opportunity to ask questions and receive further advice and guidance by clinical staff,
- (d) people seeking treatment or storage, or considering donation, confirm that information they have provided is true to the best of their knowledge.

G.5.2.1 Information provision: informed consent

G.6 Obtaining consent from fertility patients

Related Information

Directive 2004/23/EC, Annex
Directive 2004/23/EC, Art.13
Directive 2006/17/EC, Annex IV, para.1.1
Directive 2006/17/EC, Art.2(5)(b)
HFE Act 1990, s.12(1)(c) (as amended)
HFE Act 1990, Sched.3



Related Sections

- S.7.5.4 Consent to storage and use of gametes and embryos** — The Centre shall establish Documented Procedures for obtaining consent to the storage or use of gametes to ensure that:
- (a) before people give consent they are given a suitable opportunity to receive proper counselling, from an independent counsellor, about the implications of giving consent to treatment, or to the storage or donation of gametes or embryos.
 - (b) before people give consent they are informed that they may place conditions upon their consent and that they may vary or withdraw their consent at any point until their gametes or embryos are transferred to a woman or used in a project of research, and the procedure for doing so,
 - (c) the consent given is recorded in writing and in accordance with relevant Directions issued by the HFEA.

G.5.2 Proper information: consent

G.6.1 Consent: general information

G.7.2 The offer of counselling

G.8.1 Consent requirements: use

Requirement (Scheme A)

Related Information

Directions D.2006/5
HFE Act 1990, s.12(1)(c) (as amended)
HFE Act 1990, s.13(6)
HFE Act 1990, Sched.3

- S.7.5.5** The Documented Procedures for obtaining consent to the storage or use of gametes shall include measures to ensure that a copy of the signed consent form is available for those who have given consent.

G.5.10 Proper information: storage

Requirement (Scheme B)

Related Information

Directive 2006/17/EC, Annex IV para.1.4

G.6.6.1 Consent to storage: requirements

G.8.1 Consent requirements: use

- S.7.5.6** The Documented Procedures for obtaining consent to the storage or use of gametes shall also include measures to ensure that:
- (a) people seeking treatment or storage, or considering donation are given sufficient time to reflect upon their decisions before giving their consent,
 - (b) the consent given is effective in accordance with the relevant legislation.

G.6.6.1 Consent to storage: requirements

G.8.1 Consent requirements: use

Related Information

Directive 2004/23/EC, Art.13
Directive 2006/17/EC, Annex IV, para.1.1

S.7.6 Clinical processes

S.7.6.1 Consultation — The Centre shall ensure that advice and recommendations for treatment are in accordance with the current guidelines on treatment.

G.8 Use of gametes and embryos in treatment

S.7.6.2 Counselling — Centres shall ensure that people seeking treatment or storage, or donating gametes or embryos are given a suitable opportunity to participate in counselling about the implications of the proposed action before they consent to treatment or to the use or storage of gametes or embryos.

G.7 Counselling services

Requirement (Scheme A)

Related Information

HFE Act 1990, s.13(6)

S.7.6.3 Centres shall ensure that:

- (a) current professional guidelines on counselling are complied with, and that when required counselling is provided by one or more counsellors it is independent of the clinical decision making Process,
- (b) implications counselling, support counselling and therapeutic counselling are each made available as appropriate,
- (c) potential users have written information about the service available and its benefits,
- (d) all practicable steps are taken to provide opportunities for counselling throughout the treatment, donation or storage Processes and afterwards if requested,
- (e) arrangements are in place for the provision of, or referral for, specialist counselling where this is appropriate, including genetic counselling, support counselling, therapeutic counselling and counselling appropriate for oncology Patients or others requiring the long term storage of gametes or embryos,

G.7 Counselling services

- (f) where a couple or individual is proposing to undergo fertility treatment and the possibility of donation arises, donor implications counselling shall be made available as in (a) above.

S.7.6.4 Welfare of the Child — Centres shall have Documented Procedures to ensure that proper account is taken of the welfare of any child that may be born as a result of treatment services.

Requirement (Schemes A and B)

Related Information

Directive 2006/17/EC, Annex III, para.2.1
HFE Act 1990, s.13(5) (as amended)

G.3.4 Welfare of the child: assessment process

G.7.1.2 Use of independent counselling organisations

G.7.1.3 Counselling: types available

S.7.6.5 Centres shall have Documented Procedures to ensure that proper account is also taken of the welfare of any other child who may be affected by the birth.

Requirement (Scheme A)

Related Information

HFE Act 1990, s.13(5) (as amended)

G.3.4 Welfare of the child: assessment process

G.7.1.2 Use of independent counselling organisations

G.7.1.3 Counselling: types available

S.7.6.6 Evaluation and screening of potential Donors — Where individuals are considering donation, Centres shall ensure that those individuals:

- (a) have received all the required information,
(b) understand that the donation of gametes is voluntary and unpaid, compensation being restricted to expenses and inconveniences.

Requirement (Schemes A and B)

G.4.11 Donation: expenses and compensation

G.4.4 Donation: information provision

Related Sections

Related Information

Directive 2004/23/EC, Art.13
 Directive 2004/23/EC, Arts 12(1)
 Explanatory and supplementary information for D2006/1
 HFE Act 1990, s.12(1)(e) (as amended)
 HFE Act 1990, s.13(6)
 HFE Act 1990, Sched.3, para.3

G.5.11.1
 Information provision:
 donating gametes for treatment

G.5.5 Proper information: egg sharing

S.7.6.7 Where individuals are considering donation, Centres shall ensure

- (a) that appropriate screening tests have been performed and are recorded,
- (b) that appropriate consideration has been given to the suitability of the Donor, including an assessment of any risks associated with using gametes or embryos from that Donor to the health or welfare of recipients or resulting children.

G.4.8 Donating for treatment: suitability

G.4.9 Donating for treatment: tests

Requirement (Scheme B)

Related Information

Directive 2004/23/EC, Art.15
 Directive 2004/23/EC, Art.19
 Directive 2004/23/EC, Art.28
 Directive 2006/17/EC, Annex III, para.2

S.7.6.8 Where individuals are considering donation, Centres shall ensure:

- (a) that no pressure or undue influence is applied to donate sperm, eggs or embryos by clinic staff, friends or relatives,
- (b) that the Donor is given the opportunity to participate in counselling to explore the implications of donation for all concerned,
- (c) that an authorised person collects and records the Donors' relevant medical information.

G.4.4.1 Donation: information provision

G.4.5 Donation: counselling

G.4.6 Donating for treatment: general

S.7.7.4 Donor registration

S.7.7.5 Procurement of gametes: records



Related Sections

S.7.6.9 Surrogacy — The Centre shall ensure that consideration is only given to the use of assisted conception techniques to produce a surrogate pregnancy where none of the persons commissioning the surrogacy arrangement is able to carry a child or, where any of the persons commissioning the arrangement is able to carry a child but her health may be seriously impaired by doing so.

G.3.3.4 Welfare of the child assessment: surrogacy

G.5.12 Proper information: surrogacy

Related Information

Surrogacy Arrangements Act 1985

S.7.6.10 Clinical treatment — The Centre shall, where appropriate, have documented clinical guidelines that include but are not limited to:

- (a) superovulation regimes,
- (b) oocyte retrieval,
- (c) sedation procedures,
- (d) resuscitation procedures,
- (e) sperm aspiration,
- (f) gamete and embryo transfer,
- (g) insemination procedures
- (h) follow up after treatment, including management of complications,
- (i) management of ovarian hyper-stimulation syndrome.

G.9 Procurement, processing, storage and handling of gametes and embryos

S.5.2 Documentation requirements

Requirement (Scheme B)

Related Information

Directions D.2004/2
Directive 2006/86/EC, Annex I, Part E, para.1
Directive 2006/86/EC, Annex I, Part E, para.2

S.7.7 Procurement, distribution and receipt of gametes and embryos

S.7.7.1 General — The Centre shall establish Documented Procedures for Procurement, packaging, Distribution and recall, and receipt of gametes and embryos that ensure:

- (a) that appropriate information has been provided,

G.13.7 Patient and donor identification



Related Sections

- (b) that, where appropriate, valid consent to examination and treatment has been obtained and that effective consent has been obtained to the storage and use of those gametes or embryos,
- (c) Patient, Patient Partner and Donor identification,
- (d) that any Adverse Incident that might result in harm to the Patient, Patient Partner or Donor is recorded and reviewed.

G.9.1
Procurement:
general

S.7.4 Information
for service users

S.7.5 Consent

S.9.4 Adverse
incidents

Requirement (Schemes A and B)

Related Information

Directions D.2007/3
Directive 2004/23/EC, Annex
Directive 2004/23/EC, Art.13
Directive 2004/23/EC, Art.18
Directive 2004/23/EC, Art.5
Directive 2006/17/EC, Annex IV
Directive 2006/17/EC, Art.2
Directive 2006/86/EC, Annex I, Part B, para.3
HFE Act 1990, s.12(1)(c) (as amended)
HFE Act 1990, s.13(6)
HFE Act 1990, Sched.3, para.3

- S.7.7.2** The Procurement of gametes shall be carried out by personnel who have successfully completed a training programme specified by a clinical team engaged in the Procurement of gametes. The Competence of the trained personnel shall be recorded.

The Centre shall establish Documented Procedures for Procurement, packaging, Distribution and recall, and receipt of gametes and embryos that ensure:

- (a) Donor evaluation and assessment,
- (b) the safety of the Patient/Patient Partner/Donor,
- (c) the quality and safety of the gametes and minimise the risk of bacterial or other contamination,
- (d) Patient/Patient Partner/Donor registration, third party Procurement documentation, home Procurement documentation, packaging and Distribution labelling of packages containing procured gametes, transportation, labelling of shipping container and recall and receipt of gametes meet the Requirements or expectations of these Standards.

G.4 Donation

G.4.6 Donating
for treatment:
general

G.4.7 Donating
for treatment:
family and other
relevant history

G.4.8 Donating
for treatment:
suitability

G.4.9 Donating
for treatment:
tests



Related Sections

NOTE: Cryopreserved gametes should be accompanied by documentation describing the minimum expectations for their post-thaw quality.

Requirement (Scheme B)

Related Information

Directive 2004/23/EC, Art.28
Directive 2006/17/EC, Annex III, para.2
Directive 2006/17/EC, Annex IV
Directive 2006/17/EC, Art.2

G.9 Procurement, processing, storage and handling of gametes and embryos

S.7.6.6 Evaluation and screening of potential donors (1)

S.7.7.13 Labelling of packages containing procured gametes

S.7.7.4 Donor registration

S.7.7.8 Third party procurement: documentation (3)

S.7.7.3 The Centre shall establish Documented Procedures that ensure that Procurement conforms with appropriate age limits for gamete providers.

G.4.2 Age of donors

G.9.2 Procurement of gametes: age restrictions

S.7.7.4 Patient / Patient Partner / Donor registration — For each Patient/Patient Partner/Donor registered at the Centre there shall be a record containing

G.6.6 Consent to storage

- (a) the Patient/Patient Partner/Donor identification (first name, family name, date of birth and sex),
- (b) consent, including the purpose for which the gametes and embryos may be used and any specific instructions for disposal if not used for the purpose for which consent was obtained.

G.6.7 Consent to use

Requirement (Schemes A and B)

Related Information

Directions D.2004/3
 Directions D.2007/7
 Directive 2006/17/EC, Annex IV para.1.4
 Directive 2006/17/EC, Art.2
 HFE Act 1990, s.12(1)(d) (as amended)
 HFE Act 1990, s.13(3)

S.7.7.5 The record relating to each Patient Partner (except for direct use) / Donor registered at the Centre shall also contain:

- (a) medical history, including presence of risk factors,
- (b) clinical and laboratory assessment data.

Requirement (Scheme B)

Related Information

Directive 2006/17/EC, Annex IV para.1.4
 Directive 2006/17/EC, Art.2

G.4.8 Donating for treatment: suitability

G.4.9 Donating for treatment: tests

S.7.6.7 Evaluation and screening of potential donors (2)

S.7.6.8 Evaluation and screening of potential donors (3)

S.7.7.1 Procurement, distribution and receipt: general

S.7.7.6 Third party Procurement documentation — Where the Procurement of gametes and embryos has taken place in a centre with which the Centre has a third party contract, that centre shall produce a procurement report that shall include, but not be limited to, the following:

- (a) identification, name and address of the Centre to receive the gametes,
- (b) Patient, Patient Partner or Donor identification.

Requirement (Schemes A and B)

G.2.1 Use of unlicensed facilities and services: general

S.4.2.10 Third party contracts

S.4.2.11 Transport of gametes and embryos



Related Information

Directions D.2000/3
Directive 2006/17/EC, Annex IV para.1.4
Directive 2006/86/EC Art.9
Directive 2006/86/EC, Annex VI
HFE Act 1990, s.12(1)(f) (as amended)

S.7.7.7 Third party Procurement documentation shall also include:

- (a) identification of the procured gametes and embryos,
- (b) identification of the person responsible for the procurement session,
- (c) date and time of Procurement,
- (d) a Record of any procedures undertaken on the gametes.

S.7.3.1
Traceability

S.7.3.2
Traceability:
procedures

Requirement (Scheme B)

Related Information

Directive 2006/17/EC, Annex IV para.1.4
Directive 2006/86/EC Art.9
Directive 2006/86/EC, Annex VI

S.7.7.8 Third party procurement documentation shall also include:

- (a) a Record of any Adverse Incidents,
- (b) where appropriate, identification/batch numbers of any reagents and transport media used.

G.14 Adverse
incidents

S.7.7.9 Home Procurement documentation — Where the Procurement of sperm has taken place at home, the Record shall contain:

- (a) the identification, name and address of the Centre to receive the sperm,
- (b) the Donor/Patient Partner identification.

G.2.3 Patients
producing sperm
samples at home

Requirement (Schemes A and B)

Related Information

Directions D.2000/3
Directive 2006/17/EC, Annex IV para.1.4



Related Sections

S.7.7.10 The home procurement documentation shall also contain a record of the date and time of Procurement.

G.2.3 Patients producing sperm samples at home

S.7.7.11 Packaging — Following procurement all gametes shall be packaged in a manner that minimises the risk of contamination and under conditions that ensure their safety and quality.

S.7.7.13 Labelling of packages containing procured gametes

Requirement (Scheme B)

Related Information

Directive 2006/17/EC, Annex IV, para.1.5.1

S.7.7.12 Distribution — When gametes or embryos are distributed from one Centre to another, the transportation and shipping container used shall ensure the safety and quality of the gametes or embryos, be suitable for the transport of biological materials, and comply with relevant legislation and regulations.

Requirement (Scheme B)

Related Information

Directive 2006/17/EC, Annex IV, para.1.5.1

Directive 2006/17/EC, Annex IV, para.1.5.2

Directive 2006/86/EC, Annex II, Part D, para.2

S.7.7.13 Labelling of packages containing procured gametes — At the time of Procurement each package containing gametes or embryos shall be labelled in a way that is not susceptible to unauthorised or undetectable alteration. Primary containers must indicate the unique code, and split number if applicable, of the donation and the type of gamete. When the size of packaging permits the following information shall also be provided:

G.13.7 Patient and donor identification

S.7.3.3 Coding

- (a) date (and time where possible) of donation,
- (b) identity of the Patient/Patient Partner/Donor,
- (c) in the case of known donations, the identity of the intended recipient.

If the information under points (a) – (c) above cannot be provided on the primary package label, it shall be provided on a separate sheet accompanying the primary package.

Requirement (Scheme B)



Related Information

Directive 2006/17/EC, Annex IV, para.1.6

S.7.7.14 Transportation, labelling of shipping container and recall — The transportation of gametes and embryos shall be under conditions that ensure their safety and quality. When transportation is by a Third Party, the Third Party shall be subject to a third party contract, and a documented agreement in place to ensure the required conditions are fulfilled. The transport conditions, including temperature and time limit, shall be specified and the labelling of every shipping container shall include:

- (a) the identification of the Centre from which the package is being transported (address and telephone number) and contact person in the event of problems,
- (b) the identification of the centre to which the package is to be delivered (address and telephone number) and person to be contacted to take delivery,
- (c) the date and time of the start of transportation,
- (d) specifications concerning the conditions of transport relevant to the safety and quality of the gametes,
- (e) specifications concerning the storage conditions (such as DO NOT FREEZE),
- (f) warnings as follows: TISSUES AND CELLS, HANDLE WITH CARE and DO NOT IRRADIATE and
- (g) in the case of autologous procurement, FOR AUTOLOGOUS USE ONLY.

NOTE: Where the container has not been validated by the manufacturer/supplier for specified transport conditions then the conditions need to be monitored during transport or validated by the Centre or Third Party undertaking the transportation.

The Centre originating the Distribution shall have a recall procedure that defines the responsibilities and actions required when a Distribution is recalled. Such a recall would be investigated using the procedure for investigation of Adverse Incidents. There shall be a procedure for handling returned gametes and embryos that include their reacceptance into the inventory, if applicable.

Requirement (Scheme B)

G.13.1
Witnessing
clinical and
laboratory
procedures:
general

G.9.8 Transport of
gametes and
embryos

S.4.2.10 Third
party contracts

S.4.2.11
Transport of
gametes and
embryos

S.9.4 Adverse
incidents

Related Information

Directive 2006/17/EC, Annex IV, para.1.6

Directive 2006/17/EC, Annex IV, para.1.7

Directive 2006/86/EC, Annex II, Part D

S.7.7.15 Receipt of gametes — Where appropriate, the Centre shall establish a procedure for the receipt of gametes or embryos from another centre to ensure that:

- (a) documented specifications are established against which each consignment of gametes or embryos is verified. These shall include the Requirements for Patient/Patient Partner/Donor documentation, packaging and transportation, labelling of containers for procured gametes, labelling of shipping containers and any associated documentation,
- (b) Verification is undertaken by authorised personnel,
- (c) quarantined consignments are not released until (b) is met.

In the case of gametes intended for partner treatment, in addition to the documentation required and the labelling of procured gametes, partner identification shall be recorded.

Requirement (Scheme B)

Related Information

Directive 2006/17/EC, Annex IV, para.2

S.7.7.16 The procedure for the receipt of gametes or embryos from another centre shall also ensure that:

- (a) Records are kept to demonstrate that before gametes or embryos are released all appropriate specifications have been met,
- (b) consignments not meeting the specifications are segregated and quarantined.

NOTE: Receipt and recording of sperm procured at home is, where appropriate, subject to the Requirements for receipt from another centre.

S.7.8 Laboratory processes

S.7.8.1 General — The Centre's laboratories shall comply with current professional guidelines, legislation and regulations (Appendix B).

G.13.1
Witnessing
clinical and
laboratory
procedures:
general

G.9.8 Transport of
gametes and
embryos

S.7.7.6 Third
party procurement
documentation (1)

G.9.8 Transport of
gametes and
embryos



NOTE: The provisions of this section relate to those laboratory Processes used in the handling, manipulation, storage and release of gametes and embryos.

- S.7.8.2** If the Centre has laboratories or contracts Third Party laboratories or practitioners to undertake the diagnosis and investigation of Patients, Patient Partners or Donors, or their gametes, embryos or any material removed from them, these laboratories shall obtain suitable accreditation.

G.2.1 Use of unlicensed facilities and services: general

NOTE 1: 'suitable accreditation' means accreditation by CPA(UK) Ltd or another body accrediting to an equivalent standard.

NOTE 2: The pathology disciplines involved in diagnosis and investigation include Andrology, Clinical Genetics, (Cytogenetics and Molecular genetics) and Clinical Biochemistry.

NOTE 3: If a laboratory computer is used to release results from the Centre's or a Third Party laboratory, an audit trail should indicate who was responsible for their release.

Documented laboratory procedures shall include information concerning their scope and purpose, hazards to laboratory personnel and precautions, the equipment/reagents required, and the instructions to be followed. The laboratory shall ensure that personnel are competent to perform the required procedures and work to current versions of the procedures and all referenced documentation.

Requirement (Scheme B)

Related Information

Directive 2004/23/EC, Art.24(2)
Directive 2006/86/EC, Annex I, Part A, para.5
Directive 2006/86/EC, Annex I, Part A, para.6.
Directive 2006/86/EC, Annex I, Part E, para.2
Directive 2006/86/EC, Annex II, Part C, para.4

- S.7.8.3 Selection and Validation of laboratory procedures** — The laboratory shall use procedures that meet the needs of Patients, ensure the safety and quality of gametes and embryos and are appropriate to the treatment plan concerned. These should be in conformity with existing professional guidance for good practice and published evidence, where available.

G.13 Witnessing clinical and laboratory procedures

S.9.2 Evaluation

Procedures shall be validated in accordance with professional guidelines and operate within legal and regulatory constraints. Validations should be based on previously published studies, or retrospective Evaluation of the Centre's own data. Records of all Validations shall be kept.

Significant changes in procedure shall result in the Validation being repeated, and the Documented Procedure being revised.

Procedures shall be evaluated for hazards to laboratory staff and precautions put in place to minimise potential hazards.

Requirement (Schemes A and B)

Related Information

Directive 2006/86/EC, Annex II, Part B
HFE Act 1990, s.17(1)

- S.7.8.4 Handling and manipulation of gametes and embryos** — The laboratory shall establish Documented Procedures to ensure that no activity involving gametes or embryos is carried out without ensuring the appropriate consents are in place.

G.8.1 Consent requirements: use

Requirement (Schemes A and B)

Related Information

Directive 2004/23/EC, Art.13
Directive 2006/17/EC, Art.2(5)(b)
HFE Act 1990, s.12(1)(c) (as amended)
HFE Act 1990, Sched.3

- S.7.8.5** The laboratory's Documented Procedures shall also be established to ensure that:

- (a) Processing of cells and embryos is performed using sterile technique and under conditions of appropriate air quality,
- (b) gametes or embryos are handled in a manner which protects those properties that are required for their ultimate clinical use, while minimising the risk of bacterial or other contamination,
- (c) Records are kept indicating each and every occasion when gametes and embryos are handled and manipulated, and by whom.

G.13.2
Witnessing procedures

G.8.3
Management of iatrogenic risk

G.9.4 Air quality

Requirement (Scheme B)



Related Information

Directive 2006/17/EC, Annex IV, paras 1.3
Directive 2006/86/EC, Annex I, Part D, para.2
Directive 2006/86/EC, Annex I, Part E, para.2
Directive 2006/86/EC, Annex II, Part B
Directive 2006/86/EC, Art.2

S.7.8.6 The laboratory's Documented Procedures shall also be established to ensure that:

- (a) micromanipulation procedures such as ICSI or blastomere biopsy are carried out only by a person who is authorised to carry out the procedure in question and for a purpose authorised by the Centre's licence,
- (b) where permitted, the mixture of gametes or embryos which have been subject to different laboratory procedures prior to transfer is recorded and the reasons for this clearly set out.

Requirement (Scheme A)

Related Information

HFE Act 1990, Sched.2, para.1(2)

G.1.5.6 ICSI practitioners: competence

G.1.5.7 Biopsy practitioners: competence

G.8.3.1 Iatrogenic risk

G.8.4.1 ICSI: mixed transfer

G.9.5
Micromanipulation of gametes and embryos

S.7.8.7 The laboratory's Documented Procedures shall also be established to ensure that appropriate measures are in place for the handling of contaminated samples.

G.9.7 Prevention of cross contamination

S.7.8.8 The laboratory shall establish Documented Procedures to ensure that all blood products, other than those of the woman receiving treatment, with which gametes or embryos might come into contact, are pre-tested for HIV, Hepatitis B and Hepatitis C.

G.8.3.1 Iatrogenic risk

G.9.7.2 Storage: tissue

Requirement (Schemes A and B)

Related Information

HFE Act 1990, s.17(1)(d)
HFE Act 1990, s.25(1)

Related Sections

S.7.8.9 Storage and release of gametes and embryos — The laboratory shall establish Documented Procedures to ensure that all storage and handling of gametes and embryos is in accordance with licence conditions, regulations, and with relevant Patient consent.

Requirement (Scheme B)

Related Information

Directive 2004/23/EC, Art.13
HFE Act 1990, s.12(1)(c) (as amended)
HFE Act 1990, s.14
HFE Act 1990, s.17(1)(c)

G.6.6 Consent to storage

G.6.7 Consent to use

G.8.1 Consent requirements: use

G.9.1 Procurement: general

S.7.8.10 The laboratory's Documented Procedures shall also be established to ensure that:

- (a) all storage of gametes and embryos is carried out under controlled conditions that are validated and monitored,
- (b) gametes and embryos are packaged for storage in such a way as to prevent adverse effect on the material, as well as to minimise the risk of contamination,
- (c) Records are kept indicating each and every occasion when gametes and embryos are handled during storage and release, and by whom,
- (d) Records are kept indicating that gametes and embryos meet documented specifications for safety and quality prior to release,
- (e) risk assessments (approved by Person Responsible) are undertaken, to determine the fate of all stored material, following introduction of any new Donor selection criterion or Donor/Patient Partner/Patient testing criterion or new Processing step enhancing safety and/or quality,
- (f) the disposal of discarded gametes and embryos is appropriate.

G.13 Witnessing clinical and laboratory procedures

G.9.10 Termination and disposal of gametes and embryos

G.9.7 Prevention of cross contamination

S.7.5 Consent

Requirement (Scheme A)

Related Information

Directive 2004/23/EC, Art.21
Directive 2006/17/EC, Annex IV, para.1.5.1
Directive 2006/86/EC, Annex I, Part E, para.2
Directive 2006/86/EC, Annex II, Part B, para.8
Directive 2006/86/EC, Annex II, Part C, para.4
Directive 2006/86/EC, Annex II, Part C, para.5

Related Sections

S.7.8.11 The laboratory's Documented Procedures shall also be established to ensure that gametes and embryos are not stored beyond the maximum period as laid down in statute, or the storage period consented to by the Patient(s) if less than the former.

Requirement (Scheme A)

Related Information

HFE Act 1990, s.14(1)(c)

G.6.6.1 Consent to storage: requirements

G.6.6.4 Consent to storage: extending storage of gametes

G.6.6.5 Consent to storage: extending storage of embryos

G.9.1.2 Storage: sperm donated pre-1991

G.9.9 Storage review

S.7.8.12 The laboratory's Documented Procedures shall also be established to ensure that:

- (a) no gametes or embryos are placed in storage unless those people who provided the gametes have been screened in accordance with current recommended guidance,
- (b) storage Centres shall carry out reviews of stored gametes and embryos at least once every two years, in order:
 - (i) to reconcile the Centre's Records with material in storage; and
 - (ii) to review the purpose and duration of storage; and
 - (iii) to identify any action that needs to be taken,
- (c) donated gametes (or embryos created using gametes) from a particular Donor are not used or distributed for the purpose of treatment where the number of families having children as a result of the use of gametes (or embryos created using gametes) from that Donor has reached 10,

G.8.6 Limitations on use of gametes

G.9.7 Prevention of cross contamination

G.9.9 Storage review

- (d) conditions are outlined for an exceptional release of material that does not conform to the Requirements or expectations of these Standards.

NOTE: Exceptional release should be based on criteria that include an assessment of the urgency of the request, the availability of test results, the importance of information that is not yet available and the availability of cells and gametes for the recipient. Documentation of exceptional release should include a statement by the recipient's clinician confirming agreement to the use of tissues and cells despite the documented Nonconformity. The clinician must be provided with information that becomes available after exceptional release that is relevant to the Quality of the gametes and embryos.

S.7.8.13 Assuring the Quality of procedures — The laboratory shall establish Documented Procedures to ensure:

- (a) that internal Quality control procedures are in place and that there is regular critical Evaluation of all Processes to ensure that they continue to achieve the intended results,
- (b) that Records of the results of Quality control/assessment activities, non-conformities detected and action taken are kept.

S.9.2 Evaluation

S.9.5
Improvement

Requirement (Scheme B)

Related Information

Directive 2006/86/EC, Annex I, Part F
Directive 2006/86/EC, Annex I, Part E, para.1

S.7.8.14 The laboratory's Documented Procedures shall also be established to ensure:

- (a) the maintenance of control charts for critical outcome parameters, in order to determine alert conditions/significant deviation from intended/expected outcome,
- (b) that the laboratory participates in all relevant inter-laboratory (external Quality assessment) schemes, Any serious Adverse Incidents that are potentially associated with Nonconformity of a laboratory procedure shall be investigated in accordance with these Standards.

G.14 Adverse incidents

S.9.2.6
Inter-center and inter-laboratory comparisons

S.9.4 Adverse incidents



Related Sections

S.7.8.15 Centres shall have witnessing protocols in place to double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process.

These checks shall be completed and recorded at the time the clinical or laboratory process/procedure takes place.

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

Use of electronic systems (such as bar coding and radio frequency identification) shall be suitable for use in the context of assisted conception.

G.13 Witnessing clinical and laboratory procedures

Related Information

Directive 2004/23/EC, Art. 8(2)

Directive 2006/17/EC, Art.2(5)

Directive 2006/17EC, Art.2(11)

Directive 2006/86/EC, Annex I, Part A, para.9

S.8.1 General

S.8.1.1 Where embryos are to be used for research the research Centre shall record, before the commencement of the project:

- (a) the proposed duration of the culture period; and
- (b) the procedure to be used to ensure that embryos do not develop after 14 days or (if earlier) the appearance of the primitive streak; and
- (c) the method to be used to terminate development.

Related Information
HFE Act 1990, s.3(4)

S.8.1.2 The Centre shall have written procedures to ensure that embryos are used only within the maximum period of storage permitted by law or within any period of storage specified in the Donor's consent if shorter than the maximum statutory storage period.

Requirement (Scheme A)

Related Information
HFE Act 1990, Sched.3

S.8.1.3 The Centre shall also have written procedures:

- (a) to ensure that embryos are only used in accordance with the Donors' consent,
- (b) for the appropriation of embryos to be used in research projects.

The Centre shall uniquely label each embryo donated to the research project in accordance with any Directions and / or guidance issued by the Authority.

Related Information
HFE Act 1990, s.15(4)

S.8.1.4 The person named as the Person Responsible on a research licence shall not also be named as the Person Responsible on a treatment licence.

G.5.13 Proper information: donation for research

S.8.2 Disclosure of interests

S.8.2.1 The Centre shall ensure that Donors are given information about how the research is funded, including any direct payments or benefits which would accrue to researchers and/or their departments, and any financial interests in the research project or its sponsoring organisations.

G.5.13 Proper information: donation for research

Requirement (Scheme A)

Related Information

HFE Act 1990, Sched.2, para.3(7)

HFE Act 1990, Sched.3

S.8.2.2 Staff involved in research shall follow relevant guidelines produced by the respective professional bodies. The Centre shall ensure that:

G.5.13 Proper information: donation for research

- (a) all financial interests and sums of money known or estimated to be paid for the research are disclosed to a research ethics committee,
- (b) all members of the research team, including nurses and non-medical staff, are informed about the way in which the research is being financed and managed.

S.8.3 Information provided to research donors

S.8.3.1 Where embryos are used for research, the Centre shall ensure that before Donors give their consent to the use of their gametes and/or embryos in a research project, they are informed that they may withdraw their consent, or vary the terms of their consent, until the embryos are used in the project of research.

G.5.13 Proper information: donation for research

NOTE: Embryos will be regarded as having been used for research as soon as they are under the control of the researchers and are being cultured/grown for use in research.

S.7.4.1 Information for users

Requirement (Scheme A)

Related Information

HFE Act 1990, s.12(1)(c) (as amended)

HFE Act 1990, Sched.3

Related Sections

S.8.3.2 The Centre shall also ensure that before Donors give their consent to the use of their gametes and/or embryos in a research project, they are given oral information, supported by relevant written material, which confirms:

- (a) the specific research project, including any tests that may be performed on embryos or cells derived from the embryos as part of the licensed research project;
- (b) that the decision whether to donate will not affect their treatment in any way,
- (c) whether the embryos will be reversibly or irreversibly anonymised, and the implications of this,
- (d) whether any information will be fed back to the Donors.

G.5.13 Proper information: donation for research

S.7.4.1 Information for users

S.8.4 Consent to research

S.8.4.1 Where donated material is used for research, the Centre shall ensure that clinical and research roles are separated, so that individuals involved in advising Patients regarding clinical decisions about their licensed treatment are not involved in the research project to which Patients are considering donating embryos or gametes.

Requirement (Scheme A)

Related Information

HFE Act 1990, Sched.2, para.3(7)

S.8.4.2 Where embryos or gametes are used for licensed research, the Centre shall ensure that:

- (a) a designated individual who is not directly involved in the Donor's treatment is available to discuss the project of research and the possibility of donating material to the project with the Donor(s),
- (b) the individual obtaining consent is suitably trained and qualified and has sufficient knowledge of the proposed research, and understands the risks involved; this person should also act in accordance with professional guidelines and not be directly involved with the research project,
- (c) the person(s) donating gametes and / or embryos to research is given sufficient time to consider the implications of their donation before the donated material is used in any research project.

G.5.13 Proper information: donation for research

S.7.4.1 Information for users



- S.8.4.3** The person taking consent should take extra care if the donor is in a dependent relationship with someone involved in the research project or who may be consenting under duress.

S.9.1 General

S.9.1.1 The Centre shall plan and implement Evaluation and improvement Processes to:

- (a) demonstrate that the assisted conception Processes are being conducted in a manner that meets the needs and Requirements of users,
- (b) ensure conformity of the Quality Management System,
- (c) continually improve the effectiveness of the Quality Management System.

Requirement (Scheme B)

Related Information

Directive 2006/86/EC, Annex I, Part F
Directive 2006/86/EC, Annex II, Part B, para.7

S.9.1.2 Evaluation activities shall include, but not be limited to, Evaluation of User Satisfaction, monitoring and resolution of users' complaints, encouraging staff suggestions, conducting internal audits of the Quality Management System, participation in inter-Centre Evaluations and external reviews.

The results of Evaluation and improvement activities shall be included in the input to the management review.

S.4.2.9 Quality management system: review

S.4.2.8 Management review

S.4.2.9 Quality management system: review

S.9.2 Evaluation

S.9.3 External reviews

S.9.2 Evaluation

S.9.2.1 Assessment of User Satisfaction — As a measure of the performance of the Quality Management System, the Centre shall monitor information relating to user perception as to whether the service has met their needs and requirements. Records shall be kept of the information collected and actions taken.

User complaints can be seen as the reverse of User Satisfaction and the provisions relating to their monitoring and resolution are given in these Standards.

NOTE: Centres are encouraged to obtain both positive and negative feedback from the users of their services, preferably in a systematic way. Methods should include user surveys regarding all aspects of the service.

Related Information

Directive 2006/86/EC, Annex I, Part F, para.4

S.9.2.2 Monitoring and resolution of complaints — The Centre shall establish Documented Procedures for the resolution of complaints or other feedback received from users. The user can be a Patient, Patient Partner or Donor, clinicians or purchasers of services and other relevant parties.

G.11 Complaints procedures

S.9.5.4 Corrective action

Records shall be kept of the complaints and their investigation together with the corrective action.

S.9.2.3 Staff suggestions — The Centre Management shall encourage staff to make suggestions for the improvement of any aspect of the Centre's service. Suggestions will be evaluated, implemented as appropriate and feedback provided to the staff. Records of suggestions and action taken by the management shall be maintained.

S.4.2.9 Quality management system: review

Related Information

Directive 2006/86/EC, Annex I, Part F, para.4

S.9.2.4 Internal audit — The Centre shall establish an internal audit Process to determine whether the Quality Management System:

S.4.2.9 Quality management system: review

(a) conforms to the planned arrangements for assisted conception Processes, to the Requirements and expectations of these Standards and to the Quality Management System Requirements (including Quality indicators) established by the Centre, and

(b) is effectively implemented and maintained.

Related Information

Directive 2006/86/EC, Annex I, Part F, para.4

S.9.2.5 The Centre shall establish a Documented Procedure to ensure that:

S.4.2.7 Quality manager

(a) the responsibilities for the planning and conduct of audits are defined,



Related Sections

- (b) the audit criteria, scope, frequency and methods are defined,
- (c) audits are carried out by trained personnel,
- (d) action is taken promptly to instigate corrective action,
- (e) the effectiveness of the action taken is verified in a subsequent audit,
- (f) Records of audits are kept that include:
 - (i) the Processes, areas or items audited
 - (ii) any non conformities found
 - (iii) recommendations and time scale for action
 - (iv) Record of action taken and subsequent Verification of effectiveness.

S.4.2.8
Management
review

S.9.5
Improvement

NOTE 1: The audit programme shall be planned by the Quality Manager. It shall take into account the importance of the Processes and areas to be audited and the results of previous audits. Auditors should not audit their own areas of responsibility.

NOTE 2: The main elements of the Quality Management System should be subject to internal audit once every twenty-four months.

NOTE 3: Quality indicators established for systematically monitoring and evaluating the Centre's assisted conception Processes should be a particular focus for audit.

Requirement (Scheme B)

Related Information

Directive 2006/86/EC, Annex I, Part F

Directive 2006/86/EC, Annex I, Part E, para.1

- S.9.2.6 Participation in inter-Centre comparisons and inter-laboratory comparisons** — The Centre shall participate in inter-Centre comparisons such as those organised by professional bodies and inter-laboratory comparisons (e.g. external Quality assessment schemes) and by other external bodies.

S.9.5.4 Corrective
action

The results of these comparisons should be evaluated and documented and relevant findings be used to improve the service.

In the case of inter-laboratory comparisons, the laboratory shall establish Documented Procedures to define the responsibilities and requirements for participation to ensure that:

- (a) a Record of participation is maintained that includes any reasons for failure to participate,
- (b) supervisory staff, together with the personnel undertaking the examinations, evaluate the returned results against agreed performance criteria and when nonconformities are identified, participate in the implementation and recording of corrective actions,
- (c) the effectiveness of corrective action is verified.

When a formal inter-laboratory comparison programme is not available, the laboratory shall develop a mechanism for determining the acceptability of procedures not otherwise evaluated. Whenever possible, this mechanism shall utilise externally derived challenge materials such as exchange of samples with other laboratories.

Related Information

Directive 2006/86/EC, Annex I, Part F

S.9.3 External reviews

External reviews — External reviews indicating nonconformities or potential nonconformities shall be reviewed and appropriate corrective or preventive action taken to ensure continuing compliance with the Requirements and expectations of these Standards. A Record shall be kept of corrective and preventative actions taken.

S.9.4 Identification, investigation, control, recording and notification of adverse incidents

S.9.4.1 Identification, investigation, control and recording — The Centre shall have a Documented Procedure for the identification, investigation, control and recording of Adverse Incidents (including Serious Adverse Events and Reactions) which ensures:

- (a) that Adverse Incidents are identified and investigated,
- (b) that relevant information is reported to:
 - all personnel within the Centre involved in assisted conception Processes

G.14.1 Adverse incidents: general

- other Centres engaged in the donation, Procurement, testing, Processing, storage and Distribution of gametes or embryos, to facilitate Traceability and ensure quality and safety control.

NOTE: The investigation of Adverse Incidents should include Evaluation of all assisted conception Processes directly related to the Adverse Incident and all Processes involving the management of resources, training and Competence of personnel, equipment, materials, information systems and control of environment.

Requirement (Scheme B)

Related Information

Directions D.2007/3
Directive 2004/23/EC, Art.11
Directive 2006/86/EC, Art.5
Directive 2006/86/EC, Art.6

S.9.4.2 The Centre's Documented Procedure relating to adverse incidents shall also ensure:

- (a) the recording of Adverse Incidents, including analysis of cause, corrective action taken and ensuing outcome,
- (b) the retention of all Records in association with the Adverse Incident including those of gametes and embryos procured or materials applied,
- (c) notification of the HFEA, by the Person Responsible, of Adverse Incidents and the subsequent provision of a confirmation/conclusion report.

NOTE: Centres must report all Adverse Incidents to the HFEA by telephone within 12 working hours of the identification of the Adverse Incident and submit an adverse Incident Report form within 24 working hours.

Requirement (Schemes A and B)

Related Information

Directions D.2007/3
Directive 2004/23/EC, Art.11
Directive 2006/86/EC, Art.5
Directive 2006/86/EC, Art.6

G.14.1 Adverse incidents: general

Related Sections

S.9.4.3 The Centre's Documented Procedure relating to Adverse Incidents shall also ensure:

- (a) the responsibilities and authorities for personnel responsible for the management of Adverse Incidents are defined,
- (b) proactive identification through risk assessment and internal audit,
- (c) the cessation of assisted conception Processes as required,
- (d) the identification of any Patient/Patient Partner/Donor who might have contributed to the Adverse Incident,
- (e) the control and verifiable recall of any gametes or embryos procured or applied in association with the particular Adverse Incident, within a predefined time,
- (f) the identification and notification of any consignee and recipients of gametes from the same Donor/Patient Partner in the event that they may be put at risk,
- (g) the control and verifiable recall of any material, and the investigation of any equipment used in association with the Adverse Incident.

G.14.1 Adverse incidents: general

Related Information

Directions D.2007/3
Directive 2004/23/EC, Art.11
Directive 2006/86/EC, Art.5
Directive 2006/86/EC, Art.6

S.9.4.4 Notification of Serious Adverse Reactions — The initial notification/report of a Serious Adverse Reaction to the HFEA shall include:

- (a) identification of the Centre,
- (b) report identification,
- (c) date of initial notification/report,
- (d) individual affected (Patient or Donor),
- (e) date of suspected Serious Adverse Reaction,
- (f) details of gametes or embryos involved in the Serious Adverse Reaction,

G.14.1 Adverse incidents: general

- (g) type of suspected Serious Adverse Reaction(s) including the transmission of infectious agents.

To be followed by a confirmation report including, items (a) – (c) above and:

- (i) date of confirmation report,
- (ii) confirmation of the type of reaction(s) or a change in type of reaction(s),
- (iii) outcome of investigation and final conclusions.

Related Information

Directions D.2007/3
Directive 2004/23/EC, Art.11
Directive 2006/86/EC, Art.5
HFE Act 1990, s.15B (as amended)

- S.9.4.5** The initial notification/report of a Serious Adverse Reaction to the HFEA shall also include:

G.14.1 Adverse incidents: general

- date and place of Procurement of gametes or application of gametes or embryos.

The subsequent confirmation report shall also include:

- clinical outcome, if known, and classified:
 - complete recovery
 - minor sequelae
 - serious sequelae
 - death

Requirement (Scheme B)

Related Information

Directive 2004/23/EC, Art.11
Directive 2006/86/EC, Art.5

- S.9.4.6 Notification of Serious Adverse Events** — The initial notification/report of a Serious Adverse Event to the HFEA shall include:

- (a) identification of the Centre,

- (b) report identification,
- (c) date of initial notification/report,
- (d) date of Serious Adverse Event, and
- (e) Evaluation of the event by activity, (Procurement, testing, transport, Processing, storage, Distribution or other) and specification of the source of error, (defect in gametes or embryos, equipment or material failure or defect), human error or other) to identify preventable causes.

To be followed by a conclusion report including, items (a) – (d) above and:

- (i) date of conclusion report,
- (ii) final analysis of cause and corrective action taken.

NOTE: The EU Directives specifically identify ‘any type of gamete or embryo misidentification or mix up’ as a Serious Adverse Event.

Requirement (Schemes A and B)

Related Information

Directions D.2007/3
Directive 2004/23/EC, Art.11
Directive 2006/86/EC, Annex IV
Directive 2006/86/EC, Art.6
HFE Act 1990, s.15A (as amended)

S.9.5 Improvement

S.9.5.1 Continual improvement — The Centre shall continually improve the effectiveness of the Quality Management System through the use of the Quality Policy, quality objectives, its Evaluation activities, corrective and preventive actions and management review. Action plans for improvement shall be developed, documented and implemented as appropriate. The effectiveness of the actions shall be monitored through a focused review or audit of the area concerned.

S.4.2.8
Management
review

Related Information

Directive 2006/86/EC, Annex I, Part F, para.3
Directive 2006/86/EC, Annex I, Part F, para.4



Related Sections

S.9.5.2 The Centre shall establish Quality indicators for systematically monitoring and evaluating the Centre's contribution to Patient care. When this programme identifies opportunities for improvement, Centre Management shall address them regardless of where they occur.

S.4.2.8
Management
review

S.9.5.3 The Centre shall establish an effective system for monitoring and assessing laboratory, clinical and counselling practice, and are expected to be able to demonstrate that procedures and outcomes are satisfactory judged by the highest standards of professional colleagues in relevant disciplines elsewhere. This monitoring system is expected to include an opportunity for feedback from people seeking treatment, people considering donation and people seeking storage of gametes and embryos.

S.9.2.1
Evaluation:
general

Requirement (Scheme B)

S.9.5.4 Corrective action — The Centre shall establish a Documented Procedure to eliminate the cause of nonconformities that includes:

- (a) reviewing nonconformities,
- (b) determining the causes of nonconformities,
- (c) evaluating the need for action to ensure that nonconformities do not recur,
- (d) promptly determining and implementing action needed,
- (e) recording the results of corrective action taken, and
- (f) reviewing the corrective action taken.

G.14.1.4 Adverse
incident:
procedure

S.4.2.4 Quality
objectives and
plans

Requirement (Scheme B)

Related Information

Directive 2006/86/EC, Annex I, Part F, para.2

Directive 2006/86/EC, Annex I, Part F, para.3

S.9.5.5 Preventive action — The Centre shall establish a Documented Procedure to eliminate the causes of potential nonconformities in order to prevent their occurrence that includes:

- (a) determining potential nonconformities and their causes,
- (b) evaluating the need for action to prevent occurrence of nonconformities,

S.4.2.4 Quality
objectives and
plans



- (c) promptly determining and implementing action needed,
- (d) recording the results of preventive action taken, and
- (e) reviewing preventive action taken.

NOTE: Preventive action is a pro-active Process for identifying opportunities for improvement rather than a reaction to the identification of problems or complaints. In addition to review of the operational procedures, preventive action might involve analysis of data, including trend- and risk-analyses and external quality assurance.

Requirement (Scheme B)

Related Information

Directive 2006/86/EC, Annex I, Part F, para.2

Directive 2006/86/EC, Annex I, Part F, para.3



G.1.1 The Person Responsible

G.1.1.1 The Person Responsible may be a medical doctor, nurse or a scientist. They should have sufficient insight into the scientific, medical, legal, social, ethical and other aspects of the centre's work to be able to supervise its activities properly. The qualities of integrity, responsibility, managerial authority and capability are more important than the attainment of any particular professional qualification. The HFEA expects the Person Responsible to take whatever specialist advice is necessary to allow them to continue to run the centre professionally.

S.4.1.4
Qualifications for
the role of Person
Responsible

G.1.2 Medical Staff

G.1.2.1 The individual with overall clinical responsibility for treatment services involving in vitro fertilisation should:

S.6.2 Personnel

- (a) be on the General Medical Council Specialist Register; and
- (b) have completed training recognised by the Royal College of Obstetricians and Gynaecologists; and
- (c) participate in a recognised programme of continuing medical education and professional development.

G.1.2.2 Where the centre is licensed to provide insemination services only, the individual with overall clinical responsibility should:

S.6.2.2
Personnel:
management

- (a) be a registered medical practitioner; and
- (b) have sufficient experience in an established infertility clinic to be qualified to take full charge of the centre's treatment services.

G.1.2.3 Other medical staff involved in the provision of treatment services should be registered medical practitioners with sufficient experience under supervision to qualify them to take part in providing treatment. Medical staff who carry out laparoscopies should be Fellows or Members of the Royal College of Obstetricians and Gynaecologists. Medical staff in training should follow relevant training programmes under appropriate supervision.

S.6.2.2
Personnel:
management

S.6.2.7
Personnel:
training (1)

G.1.3 Nursing Staff



G.1.3.1 All nursing staff should be appropriately qualified and registered by the Nursing and Midwifery Council, be experienced in women's reproductive health and:

S.6.2 Personnel

- (a) be working towards national and/or locally set competencies to ensure appropriate standards of clinical competence, and
- (b) be able to provide evidence of competency in the duties performed either by certification of a recognised qualification or by written testimonial by another suitable qualified and competent person in that discipline/function (e.g. ultrasound, embryo transfer, IUI, egg collection, etc.)

Related Information

Criminal Justice and Public Order Act 1994
Department of Health - Confidentiality: NHS Code of Practice
Department of Health - HIV Infected Health Care Workers: A Consultation Paper on Management and Patient Notification
Department of Health - Standards for Better Health

G.1.4 Counselling staff: general

G.1.4.1 The centre should designate a responsible individual who will ensure that the counselling facilities accord with the expectations of counselling services outlined in this Code of Practice.

S.6.2.2
Personnel:
management

G.1.4.2 Treatment centres should ensure that at least one member of staff is appointed to fulfil the role of counsellor for service users. This person should:

S.6.2 Personnel

- (a) hold either a recognised counselling, clinical psychology, counselling psychology or psychotherapy qualification to diploma of higher education level or above; or
- (b) hold an Infertility Counselling Award; or
- (c) hold a professional social work qualification recognised by one of the UK social care councils; or
- (d) be able to provide evidence of working towards accreditation through the British Infertility Counselling Association/ British Fertility Society Infertility Counselling Award.

Related Information

BICA Guidelines for Good Practice in Infertility Counselling (2006)



Related Sections

G.1.4.3 A member of staff appointed to fulfil the role of counsellor should be able to provide evidence of membership of a recognised professional counselling body with a complaints/disciplinary procedure and have agreed to abide by an appropriate code of conduct or ethics.

S.6.2 Personnel

G.1.4.4 Where the centre offers treatment within the context of an egg sharing arrangement a member of staff appointed to fulfill the role of counsellor for couples participating in such arrangements is expected to be aware of the medical processes and the legal and social issues relevant to egg sharing arrangements.

G.15 Egg sharing agreements

S.6.2 Personnel

G.1.5 Staff Engaged in Scientific Services

G.1.5.1 All healthcare scientists working in HFEA licensed centres should be registered or show evidence of working towards registration with the Health Professions Council where applicable.

S.6.2 Personnel

G.1.5.2 The individual with responsibility for a seminology laboratory should:

S.6.2 Personnel

- (a) possess a degree or higher national diploma in a relevant discipline, and
- (b) have acquired sufficient experience in a seminology laboratory to supervise and be responsible for such a laboratory.

G.1.5.3 The individual with responsibility for the clinical embryology laboratory should:

S.6.2 Personnel

- (a) possess an appropriate scientific or medical degree, and
- (b) have had a sufficient period of experience in a clinical embryology laboratory consistent with the ability to supervise and be responsible for such a laboratory.

Related Information

Association of Biomedical Andrologists - Guidelines for Good Practice

G.1.5.4 Where the centre offers a preimplantation testing service, staff with responsibility for a preimplantation genetic testing laboratory should:

S.6.2 Personnel

- (a) possess an appropriate scientific or medical degree, and
- (b) have acquired sufficient experience in an appropriately accredited medical genetics diagnostic laboratory to supervise and to be responsible for such a laboratory.



Related Information

Association of Clinical Embryologists - Accreditation Standards And Guidelines For IVF Laboratories

G.1.5.5 Where genetic testing of those seeking treatment or considering donation is carried out, the centre should ensure that an individual is available who understands:

- (a) the nature of the tests conducted; and
- (b) the scope and limitations of the tests; and
- (c) the accuracy and implications of the tests; and
- (d) the meaning of the test results.

S.6.2 Personnel

G.1.5.6 The assessment of the competence of a new ICSI practitioner should be carried out initially by the Senior Embryologist or equivalent and approved by the Person Responsible and appropriately documented. When a new ICSI practitioner is approved in this way, the HFEA should be informed in writing and ICSI data for the first three months of practice should be submitted.

S.6.2.9
Competence
assessment

G.1.5.7 The assessment of the competence of a new blastomere/ polar body biopsy practitioner should be carried out initially by either an HFEA external advisor or by a practitioner within the centre who has already been approved by the HFEA. The assessor's report should be sent to the HFEA for approval of the practitioner. Where information submitted to the HFEA subsequently indicates a significant break in practice, the Authority may require re-examination of a practitioner's competence in the relevant technique.

S.6.2.9
Competence
assessment

S.7.8.6 Handling
and manipulation
of gametes and
embryos (3)

Related Information

CH (06) 03, Annex A



G.2.1 General

G.2.1.1 Where facilities or services provided by a third party are used in the course of a treatment process, the Person Responsible should be satisfied that the procedures of the provider are capable of integrating with the centre's own quality system. In particular, a third party provider's procedures should:

- (a) allow for audit of the entire service and for full traceability of samples; and
- (b) include an emphasis on minimising cross contamination (where relevant); and
- (c) follow relevant professional guidelines; and
- (d) ensure that adverse incidents are reported and any gametes and embryos affected are capable of being effectively recalled.

G.14.1 Adverse incidents: general

S.7.3.2 Traceability: procedures

S.7.7.6 Third party procurement documentation (1)

Related Information

HFEA Third party guidance note

G.2.1.2 A third party agreement should be made in accordance with any licence conditions imposed by the Authority. Specifically, the documentation for third party agreements should include:

- (a) the full name and address, and other relevant contact details, of the third party; and
- (b) a full and accurate description of the nature of the service to be provided; and
- (c) the details of the person who is responsible for managing the arrangement between the centre and the third party; and
- (d) information about how often the agreement will be reviewed and by whom;
- (e) a summary of the responsibilities of the third party and detailed procedures which specify the activities to be carried out and by whom they are to be carried out; and
- (f) specific criteria that the service provided by the third party must meet, particularly in relation to quality and safety; and
- (g) the procedure for communicating any test /diagnostic results to the commissioning centre, including procedures for sign off and confirmation that the result applies to the correct sample.

S.4.2.10 Third party contracts

S.7.7.6 Third party procurement documentation (1)



Related Information

HFEA Third party guidance note

G.2.2 Transport and satellite arrangements

G.2.2.1 Where any part of treatment takes place in a satellite or transport centre, the licensed centre providing the licensable treatment must ensure that the treatment process complies with the requirements of the HFE Act, the HFEA Code of Practice and Directions made by the HFEA. Particular attention should be given to requirements covering information, counselling, the welfare of the child and confidentiality. The licensed centre should put in place effective procedures to ensure that that relevant information about these requirements, and any changes to these requirements, is communicated to satellite or transport centres in a clear and timely manner. The requirements should form the basis of a third party agreement.

S.4.2.10 Third party contracts

S.7.7.6 Third party procurement documentation (1)

Related Information

HFEA Third party guidance note

G.2.2.2 All centres with satellite or transport arrangements should also hold third party agreements.

Related Information

HFEA Third party guidance note

G.2.3 Patients producing sperm samples at home

G.2.3.1 Centres should normally only store or use sperm which has been obtained directly from the provider, from another licensed clinic, from a centre with which the licensed centre has a transport arrangement, or imported pursuant to Directions from the HFEA. In exceptional circumstances the centre may use sperm produced by a man at home. In these circumstances, the centre should:

G.13 Witnessing clinical and laboratory procedures

- (a) take all reasonable steps to satisfy itself that the sperm has been produced by that man; and
- (b) take all reasonable steps to satisfy itself that the sperm has been produced not more than two hours previously; and
- (c) take all reasonable steps to satisfy itself that the sperm has not been subject to subsequent interference; and
- (d) formally record these matters in the patient records.

S.7.7.9 Home procurement: documentation (1)



G.2.4 Supplying sperm for home insemination

G.2.4.1 Centres should supply sperm for home insemination only in exceptional circumstances which make it impractical or undesirable for the patient to be inseminated at the centre. When sperm is supplied for home insemination, the treatment centre should record this fact in the patient notes and explain the relevant exceptional circumstances. Where it is decided to offer home insemination the centre should ensure that relevant legal and licensing requirements, and provisions Code of Practice, are complied with.

S.7.8.12
Laboratory
processes:
storage (3)

S.7.8.9 Storage
and release of
gametes and
embryos

G.2.4.2 The centre may not supply cryopreserved sperm to a person not covered by a licence. Sperm supplied for home insemination must therefore be thawed or in the process of thawing. Provided that the woman has attended the treatment centre for the purpose of assessment, the sperm may be provided to her either by handing it to her in person or by sending it to her by courier. The use of a dry shipper or any other container which would preserve the sperm in a frozen or preserved state upon leaving the treatment centre is prohibited.

G.9.6 Coding and
traceability

G.2.4.3 Where sperm is supplied for home insemination the centre should complete the relevant DI Treatment Form in the usual way except that the date of supply or posting should be entered as the date of insemination and a note should be made that the sperm was supplied for home insemination.

G.5.3.1
Information
provision:
treatment

G.9.6 Coding and
traceability

S.7.8.12
Laboratory
processes:
storage (3)

G.3. Welfare of the child and the assessment of those seeking treatment



Guidance

Related Sections

G.3.1 Scope of the welfare of the child provision

G.3.1.1 The centre should take into account the welfare of any child who may be born as a result of treatment and of any other child who may be affected by the birth before providing any treatment service. Treatment services include any treatment (such as surgery or the administration of drugs) which is provided for the purpose of assisting women to carry children. In order to take the welfare of the child into account, the centre should consider any relevant information they receive in reaching their decision whether or not to provide treatment services.

S.7.1.2 Welfare of the child assessment (1)

S.7.1.3 Welfare of the child assessment (2)

G.3.2 Welfare of the child risk assessments

G.3.2.1 The centre should carry out an assessment of risk of harm to the welfare of the child before providing any licensed treatment or any unlicensed treatments which involve the handling or manipulation of gametes outside of the body. This does not include the donation of gametes or embryos (except in surrogacy arrangements) or the storage of gametes for later use.

S.7.1.2 Welfare of the child assessment (1)

S.7.1.3 Welfare of the child assessment (2)

G.3.2.2 The centre should carry out a risk assessment in relation to each patient and their partner (if applicable) before any treatment is provided. The assessment should be carried out in a non-discriminatory way. In particular, patients should not be unfairly discriminated against on grounds of gender, race, disability, sexual orientation, religious belief or age.

G.15 Egg sharing agreements

G.3.3 Welfare of the child assessment: relevant risk factors

S.7.1.2 Welfare of the child assessment (1)

S.7.1.3 Welfare of the child assessment (2)

G.3.2.3 Where the child will not be raised by the carrying mother (i.e. in a surrogacy arrangement) the centre should carry out an assessment both in relation to those commissioning the surrogacy arrangement and the surrogate (and her partner, if she has one).

G.3.3.4 Welfare of the child assessment: surrogacy

G.3. Welfare of the child and the assessment of those seeking treatment



Guidance

Related Sections

S.7.6.9 Surrogacy

G.3.2.4 The centre should repeat the welfare of the child risk assessment where:

- (a) there has been a gap of two years or more in contact between the clinic and the patient(s); or
- (b) there has been a change of partner; or
- (c) a child has been born to the patient(s) since the previous assessment; or
- (d) where the centre has reason to believe that there has been a significant change in the patient's medical or social circumstances.

G.3.3 Welfare of the child assessment: relevant risk factors

S.7.1 Assisted conception processes: general

G.3.3 Relevant risk factors to take into account

G.3.3.1 Those seeking treatment are entitled to a fair assessment. The centre is expected to conduct the assessment with skill and care, and have regard to the wishes of all those involved.

G.6 Obtaining consent from fertility patients

S.7.6.4 Welfare of the child (1)

S.7.6.5 Welfare of the child (2)

G.3.3.2 In order to take into account the welfare of the child, the centre should consider factors which are likely to cause serious physical, psychological or medical harm, either to the child to be born or to any existing child of the family. These factors include:

S.7.1.2 Welfare of the child assessment (1)

S.7.1.3 Welfare of the child assessment (2)

- (a) any aspect of the patient's (or, where applicable, their partner's) past or current circumstances which means that either the child to be born or any existing child of the family is likely to experience serious physical or psychological harm or neglect. Such aspects might include:
 - (i) previous convictions relating to harming children, or
 - (ii) child protection measures taken regarding existing children, or
 - (iii) serious violence or discord within the family environment;

G.3. Welfare of the child and the assessment of those seeking treatment



Guidance

Related Sections

- (b) any aspect of the patient's (or, where applicable, their partner's) past or current circumstances which is likely to lead to an inability to care for the child to be born throughout its childhood or which are already seriously impairing the care of any existing child of the family. Such aspects might include:
 - (i) mental or physical conditions, or
 - (ii) drug or alcohol abuse;
- (c) any aspect of the patient's (or, where applicable, their partner's) medical history which means that the child to be born is likely to suffer from a serious medical condition;
- (d) any other aspects of the patient's (or, where applicable, their partner's) circumstances which treatment centres consider to be likely to cause serious harm to the child to be born or any existing child of the family.

G.3.3.3 Where the child will have no legal father, the centre should assess the prospective mother's ability to meet the child's/children's needs and the ability of other persons within the family or social circle willing to share responsibility for those needs.

S.7.1.2 Welfare of the child assessment (1)

S.7.1.3 Welfare of the child assessment (2)

G.3.3.4 Where the child will not be raised by the carrying mother, the centre should take into account the possibility of a breakdown in the surrogacy arrangement and whether this is likely to cause serious harm to the child to be born or any existing children in the surrogate's family.

G.3.2.4 Welfare of the child assessment: repeating assessment

S.7.6.9 Surrogacy

G.3.4 The assessment process

G.3.4.1 Where patients have referred themselves for treatment, the centre should take all reasonable steps to verify the identity of those seeking treatment by appropriate evidence (e.g. passport, photocard driving licence, etc.).

S.7.5.2 Consent: documented procedures (1)

Related Information

CH (99) 07 on Verification of Identity of Patients, Donors and Partners

G.3. Welfare of the child and the assessment of those seeking treatment



Guidance

Related Sections

G.3.4.2 The centre should take reasonable steps to determine who will have parental responsibility for any child or children who may be born as a result of treatment and take reasonable steps to determine who will be the person or persons responsible for raising such child or children.

S.7.6.4 Welfare of the child (1)

S.7.6.5 Welfare of the child (2)

G.3.4.3 The centre should take a medical and social history from each patient and see each couple together and, where appropriate, separately. The information gathered from the patient(s) should relate to the relevant risk factors to be taken into account.

G.3.3.2 Welfare of the child assessment: risk factors (2)

G.3.4.4 Where the centre considers that the information gathered from the patient(s) suggests that serious harm may be caused, the centre should obtain the consent from the prospective patient(s) to approach any individuals, agencies or authorities for such further factual information as the centre deems to be required to investigate the matter further. Further information should be sought where:

G.10.5 Disclosure with consent

G.6.11 Consent to disclosure of identifying information

- (a) information provided by the patient suggests that serious harm may be caused to the child; or
- (b) prospective patient(s) have failed to provide any information requested; or
- (c) the information is inconsistent; or
- (d) there is evidence of deception.

Refusal by the patient(s) to give such consent is a factor to be taken into consideration in the decision about whether to provide treatment. The refusal should not, itself, be grounds for denying treatment, although the centre should discuss with the patient(s) the reason for the refusal.

Related Information

HFEA Consent form - disclosure of identifying information

G.3.4.5 In circumstances in which further information has been collected, treatment should be refused if the centre concludes that either the child to be born or any existing child of the family is likely to experience serious physical, psychological or medical harm or where the treatment centre is unable to obtain sufficient further information to conclude that there is no significant risk.

G.3.3.2 Welfare of the child assessment: risk factors (2)

G.3. Welfare of the child and the assessment of those seeking treatment



Guidance

Related Sections

G.3.4.6 In deciding whether to refuse treatment, the centre should take into account views from all staff who have been involved with the care of the patient(s). The patient(s) should be given the opportunity to respond to adverse information and objections before a final decision is made.

G.3.3.2 Welfare of the child assessment: risk factors (2)

G.3.4.7 Where adverse information has been provided in confidence to a member of staff, consent is expected to be sought from the information provider to discuss it with other members of staff. Where such consent is refused but the member of staff considers the matter to be crucial to the decision to be taken, the member of staff should use his or her discretion, based upon good professional practice, before breaking that confidence. In line with professional guidance, patients should normally be informed of the decision to break confidence and the reasons for it, before information is shared with other members of staff.

G.3.4.8 Where treatment is refused, the centre should:

- (a) explain the reasons for the refusal to the woman and, where appropriate, her partner, together with any circumstances which may cause the centre to reconsider its decision; and
- (b) explain any remaining options; and
- (c) explain opportunities for obtaining appropriate counselling.

G.3.5 Written records

G.3.5.1 In all cases the centre should record in writing information that has been considered in respect of the welfare of the child. Where further information has been sought or discussion taken place, the record is expected to reflect the views of those who were consulted in reaching the decision and the views of those seeking treatment.

G.10.1 Confidentiality: general



G.4.1 Advertising

G.4.1.1 Advertising and publicity materials should conform to the general principles set out in the guidelines of the General Medical Council and the Code of Professional Conduct of the Nursing and Midwifery Council. Any such materials should be designed and written with regard to the particularly sensitive issues involved in recruiting donors and to conform to the requirements of the British Advertising Standards Authority.

G.4.1.2 Advertising or publicity aimed at recruiting gamete or embryo donors or encouraging donation should not include any reference to the possibility of financial gain or comparable advantage, although reference may be made to reimbursements or compensations permitted under relevant HFEA Directions.

G.4.11 Donation: expenses and compensation

S.7.7.6 Third party procurement documentation (1)

G.4.2 Age of prospective donors

G.4.2.1 Unless there are exceptional reasons for doing so, sperm should not be taken for the treatment of others from donors aged 46 or over. If there are exceptional reasons, the centre should record these in the patient records.

G.9.2 Procurement of gametes: age restrictions

S.7.7.3 Procurement of gametes: age limits

G.4.2.2 Unless there are exceptional reasons for doing so, eggs should not be taken for the treatment of others from donors aged 36 or over. If there are exceptional reasons, the centre should record these in the patient records.

G.9.2 Procurement of gametes: age restrictions

S.7.7.3 Procurement of gametes: age limits



Related Sections

G.4.2.3 Gametes should not be taken from anyone under the age of 18 for the treatment of others.

G.9.2
Procurement of gametes: age restrictions

S.7.7.3
Procurement of gametes: age limits

G.4.2.4 Where gametes are used to produce embryos specifically for donation, or embryos are donated following licensed fertility treatment, the centre should follow the age limits for gamete donors (35 for egg donors and 45 for sperm donors) unless there are exceptional reasons for not doing so. If there are exceptional reasons, the centre should record these in the patient records.

G.9.2
Procurement of gametes: age restrictions

S.7.7.3
Procurement of gametes: age limits

G.4.3 Fertility patients as potential donors

G.4.3.1 Where relevant, the possibility of donating gametes should be raised before a potential donor's treatment cycle begins and not during the cycle itself. Patients should not be subject to any pressure or undue influence to donate gametes or supernumerary embryos. Counselling must be offered in all cases in which donation is to take place.

G.15.1 Egg sharing agreements: general

G.4.3.2 The centre should, in all relevant respects, treat egg providers involved in egg sharing arrangements in the same way as other potential gamete donors.

G.5.11 Proper information: donation for treatment

G.5.5 Proper information: egg sharing

G.4.3.3 The centre should ensure that:

(a) care is taken in the selection of egg providers in egg sharing arrangements; and

S.7.6.1
Consultation

(b) egg providers are fully assessed and medically suitable; and

S.7.6.10 Clinical treatment

G.4. Recruiting, assessing and screening donors



Guidance

Related Sections

- (c) the treatment offered is the most suitable available to satisfy the needs of the egg provider and recipient(s).

S.7.6.7 Evaluation and screening of potential donors (2)

- G.4.3.4** Where embryos have been created using partner sperm produced at home and donation is being considered, the centre should take the fact that the sperm was not produced at a licensed treatment centre into account and inform prospective recipients of this fact if appropriate.

G.2.3 Patients producing sperm samples at home

S.7.7.10 Home procurement: documentation (2)

S.7.7.9 Home procurement: documentation (1)

G.4.4 Information for prospective donors

- G.4.4.1** Before any information, consents or samples are obtained from any prospective donor, or any screening tests are carried out, the recruiting centre should:

G.5.11 Proper information: donation for treatment

- (a) ensure that the prospective donor understands what medical and laboratory tests are to be carried out and why they are necessary; and
- (b) inform the prospective donor that the tests may reveal previously unsuspected conditions (e.g. low sperm count, genetic anomalies or HIV infection); and
- (c) inform the prospective donor that no further use will be made of their gametes, or any embryos produced using their gametes, if they withdraw their consent at any time until those gametes or embryos have been transferred to a woman in the course of treatment services; and
- (d) give the prospective donor full, up-to-date advice on nature and extent of information that is held about donors by the clinic and the HFEA and the circumstances in which this information, both identifying and non-identifying may be, or must be, disclosed.

S.7.6.6 Evaluation and screening of potential donors (1)



G.4.5 Provision of counselling to those considering donation

G.4.5.1 All prospective donors must be given a suitable opportunity to receive proper counselling. Where embryos are to be donated the recruiting centre should offer counselling to each person whose gametes were used to bring about the creation of the embryos.

G.7.2 The offer of counselling

S.7.6.2
Counselling (1)

S.7.6.8 Evaluation and screening of potential donors (3)

G.4.6 Donating for treatment: general enquiries to be made

G.4.6.1 Before any information, consents or samples are obtained from any prospective donor or any screening tests are carried out, the recruiting centre should ask the prospective donor whether they have previously provided gametes or embryos at a different centre and, if so, establish that the limit of 10 families per donor will not be exceeded.

G.8.6 Limitations on use of gametes

G.9.1.3
Procurement:
general

S.7.8.12
Laboratory
processes:
storage (3)

G.4.6.2 The recruiting centre should take reasonable steps to verify the identity of the prospective donor, either by contacting the person's GP or, where consent to approach the GP is refused, by asking for appropriate proof of identification (e.g. passport or photocard driving licence). Failure to obtain satisfactory evidence of identity should be taken into account in deciding whether or not to accept gametes or embryos for treatment.

G.6.1.1 Consent:
proof of identity

S.7.7
Procurement,
distribution and
receipt of
gametes and
embryos



G.4.7 Donating for treatment: family and other relevant history

G.4.7.1 Before gametes are provided, the recruiting centre should take medical and family histories and details of previous donations. The centre should encourage prospective donors to provide as much other non-identifying biographical information as possible, so that it may be available to prospective parents and resulting children. If a prospective donor cannot give a full and accurate family history, the centre should record this fact and take it into account in deciding whether or not to accept gametes or embryos for treatment.

S.7.6.7 Evaluation and screening of potential donors (2)

G.4.7.2 Wherever possible, and particularly where the centre considers that the information gathered from the prospective donor suggests that they may be unsuitable to donate, the centre should seek the prospective donor's consent to approach their GP for such further factual information as the centre deems to be required. Further information should always be sought where:

G.4.10 Donating for treatment: people considered unsuitable as donors

- (a) information provided by the patient suggests the presence of risk factors that may affect any person treated using the donor's gametes or any child born as a result; or
- (b) the prospective donor has failed to provide any information requested; or
- (c) the information provided by the prospective donor is inconsistent; or
- (d) there is evidence of deception.

S.7.6.7 Evaluation and screening of potential donors (2)

Refusal by the prospective donor to give such consent should to be taken into consideration in the decision about whether to accept the prospective donor. The refusal should not, itself, be grounds for not accepting the donor, although the centre should discuss with the prospective donor the reason for the refusal.

Related Information

HFEA Consent form - disclosure of identifying information



G.4.8 Donating for treatment: suitability as a donor

G.4.8.1 Before accepting gametes for the treatment of others, the recruiting centre should consider the suitability of the prospective donor. The views of all centre personnel involved with the prospective donor should be taken into account. In particular, the centre should consider:

- (a) personal or family history of heritable disorders; and
- (b) personal history of transmissible infection; and
- (c) the level of potential fertility indicated by semen analysis (where appropriate); and
- (d) the implications of the donation for the prospective donor and their family, especially for any children they may have at the time of donation or in the future; and
- (e) the implications for any offspring born as a result of the donation, in both the short and long term.

G.4.10 Donating for treatment: people considered unsuitable as donors

G.4.9 Donating for treatment: medical and laboratory tests

G.4.9.1 In addition to the requirements set out in Appendix A, donors of gametes and embryos should be screened in accordance with current professional guidance produced by the relevant professional bodies.

Related Information

British Andrology Society - Guidelines for the Screening of Semen Donors for Donor Insemination
Recommendations for good practice on the screening of egg and embryo donors, British Fertility Society, 2000

S.7.6.7 Evaluation and screening of potential donors (2)

G.4.9.2 Gamete providers in surrogacy arrangements are expected to be screened in accordance with screening requirements for donors of gametes for treatment.

S.7.6.7 Evaluation and screening of potential donors (2)

S.7.6.9 Surrogacy



G.4.10 Donating for treatment: people considered unsuitable as donors

G.4.10.1 A prospective donor should not be accepted if the centre concludes that either a recipient or any child that may be born as a result of treatment using the donor's gametes is likely to experience serious physical, psychological or medical harm, or where the treatment centre is unable to obtain sufficient further information to conclude that there is no significant risk.

G.4.8 Donating for treatment: suitability

S.7.6.7 Evaluation and screening of potential donors (2)

G.4.10.2 Where the centre decides that a prospective donor is unsuitable to donate, it should record the reasons and also explain these to the person concerned. The centre should present the reasons for the decision sensitively and answer any questions in a straightforward and comprehensive manner.

G.4.8 Donating for treatment: suitability

G.4.10.3 The centre should offer counselling to all prospective donors who are deemed to be unsuitable for any reason. Where the centre refuses to accept a prospective gamete donor because of physical or psychological problems that require separate treatment or specialist counselling, the centre should provide reasonable assistance to the individual to obtain relevant treatment or counselling.

G.7.2 The offer of counselling

S.7.7 Procurement, distribution and receipt of gametes and embryos

G.4.10.4 Where information affecting the suitability of a prospective donor becomes known after the selection process is complete, the centre should review the prospective donor's suitability and take appropriate action.

G.4.8 Donating for treatment: suitability

G.4.10.5 Where the centre learns (e.g. through the birth of an affected child) that a gamete donor has a previously unsuspected genetic disease or is the carrier of a deleterious recessively inherited condition, the centre should:

G.14.1 Adverse incidents: general

- (a) notify the supplying centre and the HFEA immediately. (The supplying centre should immediately notify other centres who have received gametes obtained from that donor); and

G.4.8 Donating for treatment: suitability

G.7.2 The offer of counselling



- (b) consider notifying the gamete donor of their condition and, where the gamete donor has been informed of their condition, offer counselling and testing; and
- (c) inform patients who have received treatment using gametes from that donor where that treatment has resulted in a live birth and to offer these patients appropriate counselling; and
- (d) where a woman is pregnant as a result of treatment with gametes from that donor, consider carefully when and how the woman should be given this information.

G.4.10.6 The centre should advise gamete donors that where, subsequent to a donation being made, the donor discovers they are affected by a previously unsuspected genetic disease or finds they are a carrier of a deleterious recessively inherited condition (e.g. through the birth of an affected child), they should inform the centre to which they supplied their gametes as soon as possible. The centre should then proceed as indicated above.

G.4.10.5
Donation: genetic information (1)

G.5.11 Proper information: donation for treatment

G.4.11 Expenses and compensation

G.4.11.1 Individual donors of gametes or embryos may receive reimbursement of expenses and compensation in accordance with relevant HFEA Directions. Centres procuring gametes or embryos from donors should maintain a central log of all expenses and compensation paid to donors containing information about the date, amount, recipient and reasons for each payment.

S.7.6.6 Evaluation and screening of potential donors (1)

Related Information

CH (06) 01 Implementation of the outcomes of the SEED review

G.4.11.2 The centre should assure itself that no payments or benefits have been made or promised to the donor by any other agency or intermediary, except insofar as these are in accordance with relevant HFEA Directions.

S.7.6.6 Evaluation and screening of potential donors (1)

Related Information

CH (06) 01 Implementation of the outcomes of the SEED review

G.4. Recruiting, assessing and screening donors



Guidance

Related Sections

G.4.11.3 Reasonable expenses incurred by an egg donor who becomes ill as a direct result of donating, may also be reimbursed by the treatment centre.

S.7.6.6 Evaluation and screening of potential donors (1)

Related Information

CH (06) 01 Implementation of the outcomes of the SEED review



G.5.1 General Information

G.5.1.1 The provision of proper information should be clearly distinguished from the offer of counselling, which people who are seeking treatment, providing gametes/embryos for donation or wishing to store their gametes/embryos need not accept.

G.7 Counselling services

G.5.1.2 The centre should provide a clearly identified member of staff who can provide supplementary information and answer further questions. This person should have been given appropriate guidance and training. The centre should keep a written record of all relevant information provided to patients and donors.

G.5.2 Informed consent

G.5.2.1 Before any person gives consent to:

- the storage or use of their gametes; or
- the creation of embryos using their gametes; or
- the storage or use of embryos created using their gametes,

G.6.6 Consent to storage

G.6.7 Consent to use

the person seeking their consent should give them information about the following:

S.7.4 Information for service users

- (a) the availability of counselling; and
- (b) the right to vary or withdraw the terms of consent at any time up to the point where the gametes or embryos have been transferred to a patient in the course of fertility treatment or used in a project of research; and
- (c) the procedure for varying or withdrawing consent; and
- (d) in the case of embryos, the consequences of a variation or withdrawal of consent by either gamete provider where the wishes of gamete providers, or where she is not one of these people, those of either gamete provider and the woman to be treated, do not coincide; and
- (e) costs, fees or reimbursements relevant to treatment, counselling, donation or storage of gametes or embryos; and
- (f) options available in the event of death or mental incapacity including, in the case of embryos, the death or mental incapacity of the other gamete provider, and the requirements for consent necessary to fulfil the individual's wishes; and



- (g) if applicable, the possibility of registering a deceased man as the father of a child resulting from treatment provided after his death and the conditions that must be met for such registration to take place.

Related Information

CE (03) 02 on Deceased fathers - how to register a man as the father of a child conceived after his death

CH (03) 06 on Posthumous Conception - Consent Requirements for Birth Registration

G.5.3 Information for those seeking fertility treatment

G.5.3.1 Before the centre provides treatment to any woman, the centre should give the woman who is to receive treatment and her partner, if applicable, information about:

S.7.4 Information for service users

- (a) the centre's policy on selecting patients; and
- (b) the expected waiting time for treatment and the possible disruption of the individual's domestic, personal and/or professional life which may be caused by treatment; and
- (c) the centre's statutory duty to take account of the welfare of any resulting or affected child; and
- (d) other fertility treatments available, including those for which a licence is not required; and
- (e) possible variations, outcomes and limitations of the proposed treatment (data provided in all relevant patient resources should include the centre's own most recent live birth rate per treatment cycle as verified by the HFEA, and the national live birth rate per treatment cycle); and
- (f) any charges to be made to the patient in connection with the treatment strategy proposed and the likelihood, and likely variation, of foreseeable changes to those charges as treatment progresses; and
- (g) where appropriate, the procedure used to collect gametes, including a description of possible discomfort, pain and risk to the individual related to this procedure; and
- (h) the possible side effects and risks of treatment to the woman to be treated and any resulting child, including ovarian hyperstimulation syndrome (OHSS); and

G.5. Providing proper information



Guidance

Related Sections

- (i) the fact that a possible association between ovulation induction therapy and ovarian cancer remains uncertain; and
- (j) the advantages and disadvantages of continued treatment after failed attempts; and
- (k) the importance of informing the treatment centre about the eventual outcome of the treatment (including outcomes in which no live birth results); and
- (l) the centre's complaints procedure.

Related Information

National Institute for Clinical Excellence - Fertility: Assessment and treatment for people with fertility problems

G.5.3.2 Where the treatment involves the use of superovulatory drugs or the transfer of multiple embryos in any one cycle (whether fresh or previously cryopreserved) the centre should give people seeking treatment information about the risks to the woman, fetus and any resulting child associated with multiple pregnancy, including:

- (a) the level of increased risk of miscarriage and complications such as raised blood pressure; and
- (b) the higher incidence of premature birth that is associated with multiple pregnancies, including reference to the problems of low birth weight, increased still birth and perinatal mortality; and
- (c) the increased incidence of disability and other health problems associated with multiple pregnancy, as well as the potential need for extended stays in hospital both before and after birth; and
- (d) the possible practical, financial and emotional impact of a multiple birth on the family unit and the individual children.

G.8.5 Multiple embryo transfer: risks

S.7.4 Information for service users

G.5.3.3 Where the treatment involves the creation of embryos outside the body the centre should give people seeking treatment information about the availability of embryo cryopreservation facilities and the implications of storage and subsequent use of stored embryos.

S.7.4 Information for service users



G.5.4 Additional information for those seeking treatment with donated gametes or embryos

G.5.4.1 The centre should give people seeking treatment with donated gametes or embryos:

- (a) relevant non-identifying information about donors whose gametes are made available to them for treatment, including any non-identifying information that may be disclosed to a donor-conceived person born as a result of treatment using that donor's gametes when they reach the age of 18; and
- (b) relevant information about genetic inheritance and, in particular, the likelihood of inheriting physical characteristics from the donor.

S.7.4 Information for service users

G.5.4.2 The centre should give people seeking treatment with donated gametes or embryos information about genetic and other screening which people providing gametes undergo. This information should include details about:

- (a) the sensitivity of the tests to be carried out; and
- (b) the possibility that a screened provider of gametes may be a carrier of a genetic disease or infection; and
- (c) the availability of genetic screening (especially if the people providing gametes at the centre are not screened for cystic fibrosis).

G.4.7 Donating for treatment: family and other relevant history

G.4.8 Donating for treatment: suitability

G.4.9 Donating for treatment: tests

S.7.4 Information for service users

G.5.4.3 The centre should provide information to people seeking treatment with donated gametes or embryos which explains the limitations of testing procedures and the risks associated with treatment. If any concerns are raised appropriate counselling should be made available.

G.4.9 Donating for treatment: tests

S.7.4 Information for service users

G.5.4.4 Where a woman is to receive donor insemination treatment, the centre should discuss with the woman the number of treatment cycles to be attempted in the event of a failure to conceive, before further investigation takes place and thereafter, and review this situation at regular intervals.

S.7.4 Information for service users

G.5. Providing proper information



Guidance

Related Sections

S.7.6.1
Consultation

G.5.11 Proper
information:
donation for
treatment

G.6.9 Consent:
husband or male
partner

G.5.4.5 The centre should provide information to people seeking treatment with donated gametes or embryos about legal parentage and the collection and provision of information, specifically:

- (a) who will be the child's legal parent(s) under the HFE Act 1990 and other relevant legislation (Nationals or residents of other countries, or individuals treated with gametes obtained from foreign donors, are expected to be informed that the law in other countries may be different from that in the United Kingdom); and
- (b) information which centres must collect and register with the HFEA in respect of the donors and the extent to which that information may be disclosed to people born as a result of donation; and
- (c) a child's potential need to know about its origins; and
- (d) a child's right to seek information about its origins upon reaching the age of 18 years or to seek information about the possibility of being related to someone they intend to marry if intending to marry before the age of 18.

Related Information

Directions D.2004/3

G.5.4.6 There is evidence that finding out suddenly, later in life, about donor origins can be emotionally damaging to children and to family relations. Therefore, it should be made clear to individuals seeking treatment with donated gametes or embryos that telling their child/children about their origins early in childhood is in their welfare interests. The centre should encourage and prepare patients to be open with their children from an early age about the circumstances of their conception. Counselling should be offered as a matter of course and the centre should give people seeking treatment with donated gametes and embryos information about:

- (a) the importance of sharing information with the child/children about their donor origins from an early age; and
- (b) the value that counselling may provide for patients to explore the implications of treatment and particularly how information may be shared with their child/children.

G.7.2.3
Implications
counselling: using
donated material



G.5.5 Additional information for those participating in an egg sharing arrangement

G.5.5.1 The centre should make egg providers and recipients aware, prior to their consent being sought, of the screening that will be undertaken before treatment is begun.

G.4.4.1 Donation: information provision

G.4.9 Donating for treatment: tests

G.5.4.2 Information provision: donor screening

G.5.5.2 The centre should provide women receiving eggs with same information as other people seeking treatment with donated gametes. In addition, before the egg sharing cycle begins, the centres should provide egg providers and recipients with separate written information which should include:

G.15 Egg sharing agreements

G.5.4 Proper information: treatment with donated gametes or embryos

S.7.4 Information for service users

- (a) a description of the criteria used for the selection of women providing and receiving eggs in egg sharing arrangements; and
- (b) a description of how the centre proposes to determine the allocation of eggs between provider and recipient(s); and
- (c) a description of the screening that a woman providing eggs in an egg sharing arrangement will undergo; and
- (d) a description of the terms of the agreement to be entered into; and
- (e) a description of the law relating to consent, in particular the rights of a woman providing eggs to vary or withdraw her consent and the implications of her doing so; and
- (f) a description of available alternative treatment options.



G.5.6 Additional information for those seeking ICSI treatment

G.5.6.1 The patient information about ICSI should include the following:

- (a) the risk of damage to eggs when ICSI is used; and
- (b) the risk of possible inheritance of genetic and chromosomal abnormalities including cystic fibrosis gene mutations, sex chromosome defects and heritable sub-fertility; and
- (c) the risk of ICSI resulting in embryos with abnormal numbers or structures of chromosomes
- (d) the risk of ICSI resulting in embryos with novel chromosomal abnormalities; and
- (e) the risk of children conceived following ICSI having developmental and birth defects; and
- (f) the risk to the woman during pregnancy, including the risk of miscarriage.

G.12
Preimplantation
testing services

S.7.4 Information
for service users

G.5.7 Additional information for those seeking PGD treatment

G.5.7.1 Patient information for PGD should include reference to the process, procedures and risks involved in undertaking IVF and biopsy procedures in the context of the provision of a sophisticated genetic test. Information should also be provided about the experience of the clinic in carrying out the procedure.

G.12.3
Preimplantation
diagnosis of
heritable
conditions

S.7.4 Information
for service users

G.5.7.2 The centre should provide information to those seeking treatment to assist them in making decisions about their treatment. This information should include:

- (a) genetic and clinical information about the specific condition; and
- (b) its likely impact on those affected and their families; and
- (c) information about treatment and social support available; and

G.12.2 Genetic
consultation

G.12.3
Preimplantation
diagnosis of
heritable
conditions

G.5. Providing proper information



Guidance

Related Sections

- (d) where the family has no direct experience of the condition, the testimony of families and individuals about the full range of their experiences of living with the condition.

S.7.4 Information for service users

- G.5.7.3** Where information about the particular genetic disorder has already been provided, for example by a regional genetics centre, the centre need not provide this information again. If this is the case, the centre should satisfy itself that this information has already been provided to a satisfactory standard.

S.7.4 Information for service users

- G.5.7.4** Before PGD treatment is provided the centre should ensure that those seeking treatment have had a sufficient opportunity and assistance to consider fully the possible outcomes of genetic testing and their implications.

G.12.2 Genetic consultation

S.7.4 Information for service users

G.5.8 Additional information for those seeking PGS for aneuploidy

- G.5.8.1** In addition to relevant information that should be given when PGD is offered, patients considering PGS for aneuploidy should also be informed in writing:

G.12.2 Genetic consultation

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

G.12.4 Preimplantation genetic screening for aneuploidy

S.7.4 Information for service users

G.5. Providing proper information



Guidance

Related Sections

G.5.8.2 The centre should inform patients considering PGS for aneuploidy that genetic counselling is available and make arrangements to provide such counselling if required.

G.12.2 Genetic consultation

G.5.9 Additional information for those seeking preimplantation tissue typing

G.5.9.1 In addition to relevant information that should be given when PGD is offered, information given to patients considering preimplantation tissue typing should include:

G.12.2 Genetic consultation

- (a) information about the specific tissue typing tests to be carried out;
- (b) an explanation of the latest evidence relating to any possibility of risk associated with the biopsy procedure for any child who may be born;
- (c) the overall likelihood of a successful outcome for the affected child, including:
 - the likelihood of an embryo with appropriate tissue type being available for transfer following the IVF, biopsy and genetic testing,
 - the likelihood of a child being born as a result, taking into account the circumstances of the people seeking treatment and their previous reproductive experience,
 - the likelihood of tissue from that child providing a successful treatment for the affected child,
 - the limitations of the treatment for the affected child;
- (d) the likely impact of the proposed procedure on all family members involved; and
- (e) information about other sources of treatment, counselling and social support available.

G.12.5 Preimplantation testing for histocompatibility (tissue typing)

S.7.4 Information for service users

G.5.9.2 Where information relating to the disorder affecting the existing child has already been provided, for example by a regional genetics centre or by the clinical team responsible for the care of the affected child, it will not be necessary to provide this information again. If this is the case, the centre should satisfy itself that this information has already been provided to a satisfactory standard and obtain a statement to that effect from those who have provided it.

G.12.2 Genetic consultation



G.5.10 Information for those seeking storage of gametes or embryos

G.5.10.1 Where there is an intention to store gametes or embryos, or where this possibility arises in the course of treatment, in addition to relevant information relating to treatment and donation, the centre should give those providing the gametes or embryos relevant information about:

S.7.4 Information for service users

- (a) the possible deterioration or loss of viability of gametes or embryos as a consequence of storage and the potential risk of cross contamination between samples; and
- (b) regulations relating to statutory storage periods for gametes and embryos, and regulations relating to extension of storage periods including, in the case of embryos, the requirement for the consent of both gamete providers to any extension of storage; and
- (c) the likelihood of a live birth resulting from previously cryopreserved embryos; and
- (d) screening tests to be carried out, the reason for these tests and the implications of the tests for the gamete providers.

Related Information

HFE (Statutory Storage Period for Embryos) Regulations 1996
HFE (Statutory Storage Period) Regulations 1991

G.5.10.2 The centre should provide specific information tailored to the needs and circumstances of oncology patients and other patients requiring long-term storage, including specific information appropriate to minors, in addition to the relevant information set out above.

S.7.4 Information for service users

Related Information

HFEA Consent forms

G.5.10.3 The centre should inform those storing sperm or embryos that the HFE Act provides that where the sperm of a man is used for insemination or where embryos created using his sperm are transferred after his death, he is not to be treated as the father of any child that may result, except for the purpose of being recorded on a register of births as the father of the child subject to the requirements of the Human Fertilisation and Embryology (Deceased Fathers) Act 2003 being fulfilled. That Act also provides for a man, in certain circumstances, to be recorded as the father of a child resulting from treatment services provided to his wife or partner after his death using embryos created using donor sperm before his death, provided he has consented in writing to being so recorded.

G.6.10 Consent to be recorded as the father of a child after death



G.5.11 Information for those donating gametes for the treatment of others

G.5.11.1 In addition to relevant information relating to treatment and storage, the centre should give those donating gametes for the treatment of others information about:

- (a) the screening to be undertaken including the practical implications of an HIV antibody test and other tests; and
- (b) the scope and limitations of genetic testing which will be carried out together with the implications for the potential donor and his or her family; and
- (c) the importance of informing the recruiting centre of any medical information that may come to light after donation has taken place which may have health implications for any woman who receives treatment with the donor's gametes or for any child who may be born as a result of such treatment;
- (d) the procedure used to collect gametes including description of possible discomfort, pain and risk to the individual in this procedure, including, for example, use of superovulatory drugs; and
- (e) whether or not they will be regarded in law as a parent of any child born as a result of their donation; and
- (f) the restriction on the use of gametes and embryos from an individual donor when the number of families that have already had children as a result of treatment using gametes or embryos from that donor has reached 10 (or such lower figure as may be specified by the donor); and
- (g) the information about donors that must be collected by the centre and held on the HFEA Register; and
- (h) the extent to which the centre or and the HFEA may disclose non-identifying information about donors, for example to prospective recipients or to the parents of donor-conceived children;
- (i) the obligation on the HFEA to disclose both non-identifying and identifying information about a donor who registers after 1 April 2005, to someone who applies for such information if the applicant is over 18 and appears to have been conceived using gametes, or embryos created using gametes, from that donor; and

G.4.4 Donation: information provision

G.6.8 Consent: egg sharing

G.6.9 Consent: husband or male partner

S.7.4 Information for service users

G.5. Providing proper information



Guidance

Related Sections

- (j) the importance to the donor of supplying up-to-date contact information so that they may be advised if and when such a disclosure is to be made;
- (k) the possibility that a donor-conceived person who is disabled as a result of an inherited condition about which the donor knew, or ought reasonably to have known, but failed to disclose, may be able to sue the donor for damages; and
- (l) where the donor is a non-patient egg donor, her freedom to withdraw from the donation process after preparation for egg recovery has begun and without incurring any financial or other penalty.

Related Information

Directions D.2004/3

G.5.12 Information for those involved in surrogacy arrangements

G.5.12.1 In addition to relevant information about gamete donation, the centre should give those participating in a surrogacy arrangement information about the effect of the Parental Orders (Human Fertilisation and Embryology) Regulations 1994 and (in Scotland) the Parental Orders (Human Fertilisation and Embryology) (Scotland) Regulations 1994, which provide that parental rights and obligations in respect of surrogacy arrangements may, provided certain conditions are met, be transferred from the birth parents to those who commissioned the surrogacy arrangement.

S.7.6.9 Surrogacy

Related Information

Parental Orders (HFE) (Scotland) Regulations 1994
Parental Orders (HFE) Regulations 1994

G.5.13 Information for those donating gametes or embryos for research

G.5.13.1 The centre should give people considering the donation of gametes or embryos for the purposes of research the following information:

- (a) that research is experimental and any gametes and embryos used and created for the purposes of any project of research may not be transferred for treatment; and

S.8.2 Disclosure of interests

S.8.3.1 Information provided to research donors: consent

G.5. Providing proper information



Guidance

Related Sections

- (b) where patients are undergoing fertility treatment for their own benefit then only those fresh or frozen gametes and embryos that are not required for treatment can be used for research; and
- (c) that research will not affect the treatment cycle; and
- (d) where gametes or embryos are being donated to research in the course of treatment services, that this will not compromise the treatment cycle; and
- (e) that they are under no obligation to donate gametes and embryos for research and their decision to do so will have no repercussions for any treatment they may receive; and
- (f) that they may specify conditions subject to which the gametes or embryos may be used; and
- (g) that they have the right to vary or withdraw their consent to the use of their gametes or embryos in any project of research at any time up until the gametes and embryos are used for the purposes of the research project; and
- (h) that they are expected to have an opportunity to ask questions and discuss the research project; and
- (i) that after the research has been completed, all donated gametes and embryos will be allowed to perish; and
- (j) details of the research project, including likely outcomes and how any individual donation will impact on the overall project.

G.5.13.2 If there is a possibility that donated gametes or embryos could be used in secondary research the centre should inform those considering donation of this possibility and give them the following further information:

S.8.3 Information provided to research donors

- (a) that gametes and embryos, or embryo cell samples, may be fixed for future studies and that such research is called secondary research; and
- (b) that secondary research could include genetic research (and the resulting implications); and
- (c) that as a means of protecting confidentiality, gametes and embryos for secondary research may be anonymised but that this may be reversible; and



- (d) that if gametes and embryos were to be reversibly anonymised and if genetic research were to be proposed, those considering donation should be offered counselling about the implications and given the opportunity to reconsider the terms of their consent; and
- (e) that if gametes and embryos were to be irreversibly anonymised, those considering donation should be fully informed of the implications, that is to say, that no information or results from the research, including clinically relevant information, could be fed back to them; and
- (f) that if embryos are to be used for stem cell research, those considering donation will be given thorough and appropriate information about the nature of this kind of research and its implications, including the information that any stem cells lines created may continue indefinitely and may be used in different research projects.

G.5.13.3 Where any genetic research is to be carried out on identifiable samples, or those capable of being identified, the centre should obtain the explicit consent of those considering donation. This should be preceded by information about the research project and what, if any, information may be fed back to the donor.

S.8.3 Information provided to research donors

G.5.14 Additional information for those seeking treatment with in vitro matured eggs

Patient information about in vitro maturation of eggs is expected to include reference to the process, procedures and risks involved in undertaking IVF/ICSI with in vitro matured eggs. Reference is expected to be made to the experience of the clinic in carrying out the procedure and information about potential long term risks.



G.6.1 General information

G.6.1.1 Treatment centres have an obligation to take all reasonable steps to ensure the valid identity of all persons accepted for treatment, including partners who might not often be seen in the centre during treatment. Where there is doubt about a patient's identity, the centre should take steps to verify their identity including the examination of photographic identification evidence such as a photocard driving licence or passport. The centre should record this evidence in the patient records.

G.13.7 Patient and donor identification

G.4.6.2 Donation: verification of identity

S.7.5.2 Consent: documented procedures (1)

G.6.1.2 To avoid the possibility of misrepresentation or mistake (e.g. where patients present for treatment with new partners) the centre should check the identities of patients (and their partners, if applicable) against identifying information held in the patient records at each consultation and on each occasion when examination, treatment or donation takes place.

S.7.5.2 Consent: documented procedures (1)

G.6.1.3 The centre is expected to allow individuals seeking treatment, or considering donation or storage sufficient time to reflect upon their decisions before obtaining their consent.

G.6.2.3 Consent: treatment with donated gametes or embryos

S.7.5.3 Consent: documented procedures (2)

G.6.1.4 The centre should assure people providing gametes that they may specify additional conditions subject to which their gametes (or embryos created using them) may be stored or used. Consent may be varied or withdrawn at any time providing that the gametes and embryos have not already been transferred to a woman in the course of treatment services or used in research.

S.7.5.4 Consent to storage and use of gametes and embryos

G.6.1.5 The centre should obtain a written record of consent from each person receiving treatment or providing gametes for use in treatment, storage or research.

G.8.2.4 Record of written consent (2)

Related Information
HFEA Consent forms



S.7.5.4 Consent to storage and use of gametes and embryos

G.6.2 Consent to examination and treatment

G.6.2.1 All people generally have the right to withhold or give consent to examination and treatment. Unless there are exceptional circumstances, the centre may not examine or treat people without first obtaining their consent. The only exceptional circumstances which are likely to arise in the course of fertility treatment services are:

S.7.5 Consent

- (a) where the procedure is necessary to save the patient's life; and
- (b) the treatment cannot be postponed; and
- (c) the patient is unconscious or mentally incapacitated and cannot indicate their wishes.

Related Information

Department of Health - Reference Guide to Consent for Examination or Treatment

General Medical Council - Seeking Patients' Consent: The Ethical Considerations

Gynaecological Examinations: Guidelines for Specialist Practice (RCOG 2002)

Human Tissue Authority - Human Tissue Authority Code of Practice 1: Consent

G.6.2.2 For consent to be valid it must be:

S.7.5 Consent

- (a) given voluntarily (without pressure or undue influence being exerted to accept treatment); and
- (b) given by a person who has capacity to consent to such treatment; and
- (c) given only upon receipt of sufficient information to enable the person giving consent to understand the nature, purpose and implications of the treatment.

G.6. Obtaining consent from fertility patients



Guidance

Related Sections

G.6.2.3 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 person(s) seeking treatment before the beginning of their treatment. The centre should allow people sufficient time to consider the implications of using donated gametes or embryos and to receive counselling before giving consent.

G.6.1.3 Consent: considering implications

S.7.5 Consent

G.6.2.4 Where a woman is to undergo an egg or embryo transfer the centre should obtain her consent to the proposed number of eggs or embryos to be transferred, and place a record of her consent in the patient records.

G.8.2.2 Consent: number of eggs or embryos to transfer

S.7.5.3 Consent: documented procedures (2)

G.6.3 Consent to the presence of observers

G.6.3.1 If a member of the centre's team wishes an observer to be present when a patient is being examined, treated or counselled, they should explain beforehand who the observer is and why this is desirable. The centre should provide appropriate information and ask the patient whether or not there is an objection. If the patient objects, the observer should not attend.

S.7.5 Consent

G.6.4 Consent by children and young people

G.6.4.1 Parents may not consent on behalf of their children to the keeping or use of their gametes, or to the creation keeping or use of embryos created using their gametes (insofar as those gametes are mature gametes).

S.7.5 Consent

G.6.4.2 Only children who are competent to do so are capable of giving effective consent. In assessing the competence of children to consent to a proposed procedure, the centre should follow current guidance produced by the Department of Health, the General Medical Council and other professional bodies. The General Medical Council's guidelines state:

S.7.5 Consent

“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.”

G.6. Obtaining consent from fertility patients



Guidance

Related Sections

Related Information

General Medical Council - Seeking Patients' Consent: The Ethical Considerations

- G.6.4.3** The centre should have written information which is accessible to children and young people, given by a member of staff with the necessary skills in communicating with children.

S.7.5 Consent

G.6.5 Mental capacity

- G.6.5.1** Where there is any doubt regarding the mental capacity of a person to give consent to a proposed procedure, or to the storage or use of gametes or embryos, the centre should follow current guidelines produced by professional bodies. If they remain in any doubt, the centre should seek their own legal advice.

S.7.5 Consent

G.6.6 Consent to storage of gametes and embryos

- G.6.6.1** The centre should ensure that people who consent to the storage of gametes or embryos:

- (a) specify the maximum period of storage (the maximum initial storage periods permitted by law being 10 years for gametes and five years for embryos); and
- (b) state what is to be done with the stored gametes or embryos if, for reasons of death or mental incapacity, they become incapable of varying or revoking their consent.

G.9.9.1 Patient information: end of storage period (1)

S.7.5 Consent

S.7.8.11 Laboratory processes: storage (2)

- G.6.6.2** The centre should ensure that consent to the storage of gametes or embryos is given in writing and that before people give consent they have:

- (a) been given an opportunity to receive proper counselling about the implications of giving that consent; and
- (b) been provided with proper information; and
- (c) been informed that the consent they give may be varied or withdrawn at any time until the gametes or embryos have been transferred to a woman in the course of treatment or used in research by giving notice to the person keeping the gametes or embryos.

G.5.10 Proper information: storage

G.7.2 The offer of counselling

S.7.5.4 Consent to storage and use of gametes and embryos

G.6. Obtaining consent from fertility patients



Guidance

Related Sections

S.7.5.6 Consent to storage: documented procedures (2)

S.7.5.5 Consent to storage: documented procedures (1)

G.6.6.3 The centre should give a copy of the written record of consent to each person who gives consent to the storage of gametes or embryos.

G.6.6.4 Before consent is obtained from any person wishing to store gametes for more than 10 years, the centre should ensure that the person satisfies the conditions for extended storage.

Related Information

HFE (Statutory Storage Period) Regulations 1991

G.6.6.5 Before consent is obtained from any person wishing to store embryos for more than five years, the centre should ensure that the person satisfies the conditions for extended storage.

Related Information

HFE (Statutory Storage Period for Embryos) Regulations 1996

G.6.6.6 The centre should usually ask patients to give consent to the use of gametes and embryos at the same time as consent to storage. However the centre should accommodate those seeking long term storage of gametes who may wish to give consent to storage separately from consent to use.

Related Information

HFEA Consent forms

G.6.7 Consent to use of gametes and embryos

G.6.7.1 Where there is an intention to create an embryo outside the body, the person obtaining consent should ensure that each individual consenting to the use of the embryo produced from their gametes specifies one or more of the following purposes for which the embryo may be used:

- (a) providing treatment for that individual or that individual and a named partner;
- (b) providing treatment for others;

S.7.5 Consent

G.6. Obtaining consent from fertility patients



Guidance

Related Sections

(c) research.

G.6.7.2 The centre should ensure that consent to the use of gametes or embryos is given in writing and that before people give consent they have:

- (a) been given an opportunity to receive proper counselling about the implications of giving that consent; and
- (b) been provided with proper information; and
- (c) been informed that the consent they give may be varied or withdrawn at any time until the gametes or embryos have been transferred to a woman in the course of treatment or used in research by giving notice to the person keeping the gametes or embryos.

G.5.2.1
Information
provision:
informed consent

G.7.2 The offer of
counselling

S.7.5.4 Consent
to storage and
use of gametes
and embryos

G.6.7.3 The centre should give a copy of the written record of consent to each person who gives consent to the use of gametes or embryos.

S.7.5.5 Consent
to storage:
documented
procedures (1)

G.6.7.4 Where there is an intention to donate gametes for the treatment of others (including the creation of an embryo for that purpose), the centre should ensure that the written consent of the donor(s) is obtained. The centre is not required to obtain the consent of the donor's partner or spouse but where the donor is married or in a long-term relationship the centre should nonetheless encourage the donor to seek their partner's support for the donation of their gametes.

S.7.5.3 Consent:
documented
procedures (2)

S.7.7.4 Donor
registration

G.6.7.5 Where a woman withdraws her consent to the use of her eggs for the treatment of others after preparation has begun, the centre is expected to accept any financial loss which it sustains as a result of the withdrawal of either the woman providing or receiving the eggs.

G.6.8 Additional consent considerations for those participating in an egg sharing arrangement

G.6.8.1 The person obtaining consent should ensure that an egg provider's consent is recorded in such a way as to allow different conditions to be placed on the use of eggs and the use and storage of embryos created for the egg provider's own treatment, on the one hand, from

G.15 Egg sharing
agreements

G.6. Obtaining consent from fertility patients



Guidance

Related Sections

conditions placed on the use of eggs and the use and storage of embryos created for the treatment of the recipient(s), on the other hand, and to allow those conditions to be varied independently.

Related Information

HFEA Consent forms

S.7.5.4 Consent to storage and use of gametes and embryos

- G.6.8.2** The person obtaining consent should emphasise to both the egg provider and recipient(s) that the egg provider may withdraw or vary her consent up to the time that an egg, or embryo created using her eggs, is transferred to a woman, used in a project of research or allowed to perish. The possible consequences of this should be made clear to both the egg provider and the recipient(s) before the egg sharing cycle begins and should be set out in the written patient information included with the egg sharing agreement.

G.15 Egg sharing agreements

G.6.7.5 Consent to use: withdrawal of consent

S.7.5.4 Consent to storage and use of gametes and embryos

G.6.9 Consent of the husband or male partner and legal fatherhood

- G.6.9.1** The centre should explain that there is a difference in law between the legal status of 'father' and having 'parental responsibility' for a child and, where applicable, that when a child is born to an unmarried couple, the male partner will only automatically have parental responsibility for that child if he is recorded as the child's father in the register of births. The centre should adopt the procedures set out in this guidance to assist in the prevention or resolution of later disputes about legal fatherhood. In any case in which people seeking treatment have doubts or concerns about legal parenthood or parental responsibility for a child born as a result of treatment services, they should be advised to seek their own legal advice.

G.5.4.5 Information provision: legal parenthood

S.7.5 Consent

- G.6.9.2** Where a married woman is seeking treatment using sperm, or embryos created using sperm, other than the sperm of her husband, the centre should advise those seeking treatment that the woman's husband will be the father of any resulting child unless, at the time of placing the embryo or sperm and eggs in the woman, or her insemination:

S.7.5 Consent

- (a) the woman and her husband were judicially separated; or
- (b) it is shown that the husband did not consent to the licensed treatment that resulted in the birth.

G.6. Obtaining consent from fertility patients



Guidance

Related Sections

G.6.9.3 Where a married woman is seeking treatment using sperm, or embryos created using sperm, other than the sperm of her husband, the centre should take all practicable steps to ascertain whether the husband consents to the treatment (taking into account the duty of confidentiality to the woman, where applicable) and to obtain a written record of the husband's consent. Where the husband does not consent the centre should take all practicable steps to obtain written evidence that he does not consent. Where the centre is unable to obtain a written record of the husband's consent or refusal to consent, a record of the steps taken to establish whether he consents to the treatment should be recorded in the patient notes.

G.5.4.5
Information
provision: legal
parenthood

G.6.9.4 Where an unmarried woman (or a woman who is judicially separated from her husband or whose husband does not consent to the treatment) is to be treated together with a male partner using donated sperm, or using embryos created with sperm other than that of her male partner, the centre should advise those seeking treatment that the male partner will be the father of any resulting child.

G.5.4.5
Information
provision: legal
parenthood

G.6.9.5 Where an unmarried woman is to be treated together with a male partner using donated sperm, or using embryos created with sperm other than that of her male partner, the centre should record at each appointment whether the man was present. The centre should take all practicable steps to obtain the written acknowledgment of the male partner that he is being treated together with the woman and that donated sperm, or embryos created using another man's sperm, are to be used. If the male partner does not attend at the time of embryo transfer, the centre should ensure that the written acknowledgement is updated immediately before embryo transfer.

G.5.4.5
Information
provision: legal
parenthood

S.7.4.1
Information for
users

G.6.10 Consent to be recorded as the father of a child after death

G.6.10.1 Where a man gives consent for his gametes, or embryos created using his gametes, to be used after his death in the treatment of his wife or partner, the centre should ensure that he is given the opportunity to give separate written consent to be recorded as the father of any child born as a result of such treatment.

G.5.10.3
Information
provision:
posthumous use

G.6.10.2 Where a man and a woman are to receive treatment together using donated sperm, and where that treatment might result in embryos being placed in storage which could be transferred after the man's death, the centre should ensure that the man is given the opportunity to give separate written consent to be recorded as the father of any child born as a result of such treatment.

G.5.10.3
Information
provision:
posthumous use



Related Information

CH (03) 06 on Posthumous Conception - Consent Requirements for Birth Registration

G.6.11 Consent to disclosure of identifying information

G.6.11.1 The provision of relevant information to clinicians and others involved in treatment or diagnosis is usually in the interests of the individual concerned. However, patients do have the right to decide if any information is to be disclosed and to whom. Therefore the centre should seek each person's written consent for disclosure of information which relates to the provision of treatment services to them.

G.10.5 Disclosure with consent

S.7.2 Confidentiality and access to health records

Related Information

HFEA Consent form - disclosure of identifying information

G.6.11.2 Before consent to disclosure is obtained the person seeking consent should provide with person whose consent is sought with sufficient information to allow them to make a properly informed decision, including:

G.10.5 Disclosure with consent

S.7.2 Confidentiality and access to health records

- (a) precisely what information is to be disclosed; and
- (b) the reasons for disclosure (e.g. so that a GP can be kept informed about the fertility treatment); and
- (c) the implications of disclosure, in particular the fact that, once it is disclosed, the information will no longer be subject to the special provisions of the HFE Act 1990 but only by the general law of confidentiality; and
- (d) the specific individual to whom the information is to be disclosed or (where the disclosure is required in connection with either the provision of treatment services, or any other medical, surgical obstetric services for the individual giving consent, the audit of clinical practice or the audit of accounts) the organisation to whom the information is to be disclosed.



G.7.1 General

- G.7.1.1** Counselling should be provided only by qualified counsellors. The centre should ensure that provision of counselling is clearly distinguished from the clinical assessment of a person's suitability for treatment, storage or donation, the provision of information prior to obtaining consent or providing treatment, and the normal relationship between clinical staff and patients or donors.

G.1.4.2
Counsellors:
qualifications

Related Information

BICA Guidelines for Good Practice in Infertility Counselling (2006)

- G.7.1.2** The centre should endeavour to maintain good relationships with independent counselling organisations so that those considering donation or seeking treatment may be given the maximum assistance in obtaining appropriate counselling in addition to, or as an alternative to, the resources available at the centre itself.

S.7.6.3
Counselling (2)

- G.7.1.3** The centre should maintain up-to-date lists of different types of locally available and accessible counselling and local and national organisations that can provide relevant information, and make those lists available to those seeking counselling outside the treatment centre.

G.1.4 Counselling
Staff: general

S.7.6.3
Counselling (2)

G.7.2 The offer of counselling

- G.7.2.1** The centre should make implications counselling available to all people seeking treatment services or consenting to the storage or use of gametes or embryos. This should normally be provided by a counsellor attached to the centre. Centres should also, where appropriate, refer people to sources of more specialised counselling outside the centre, taking account of their duty of confidentiality under the HFE Act 1990.

G.10.1
Confidentiality:
general

S.7.6.2
Counselling (1)

- G.7.2.2** The centre should normally make the offer of counselling after the person seeking treatment, storage or donation has received oral and written information about the services to be provided and has had an opportunity to reflect on the implications, and before they give consent to treatment or to storage or use of gametes or embryos. Discussion may then focus on the meaning and consequences of the decision rather than just practical aspects of any given treatment. However, the timing and frequency of counselling sessions is primarily a matter to be agreed between the counsellor and the person or couple concerned.

G.6.6.2 Consent
to storage:
information
provision

S.7.6.2
Counselling (1)

G.7. Provision of proper counselling services



Guidance

Related Sections

S.7.6.3
Counselling (2)

G.7.2.3 Where the possibility of treatment with donated gametes or embryos arises in connection with the provision of fertility treatment the centre should offer counselling about the implications of treatment with donated material separately from counselling about the implications of treatment. Treatment involving the use of donated material should not proceed unless the woman and, where applicable, her partner, have been given a suitable opportunity to receive counselling about the implications of using donated material.

S.7.6.3
Counselling (2)

G.7.2.4 Where the possibility of donating gametes or embryos arises in connection with the provision of fertility treatment, the centre should offer counselling about the implications of donation separately from counselling about the implications of treatment. Where the possibility of donation arises after a cycle of fertility treatment has already begun, treatment should not proceed unless the woman and, where applicable, her partner, have been given a suitable opportunity to receive counselling about the implications of donation.

S.7.6.2
Counselling (1)

G.7.2.5 The centre should encourage those who intend to participate in an egg sharing arrangement to use counselling provided in accordance with professional guidance given by the British Infertility Counselling Association.

G.15 Egg sharing agreements

S.7.6.3
Counselling (2)

Related Information

BICA Guidelines for Good Practice in Infertility Counselling (2006)

G.7.2.6 The centre should ensure that patients are made aware that the offer of counselling is routine. The offer should include written information giving the name(s) of the qualified counsellor, explaining the counsellor's role, when the counsellor is available and how to access the service. There should be no pressure to accept the offer of counselling but the centre should allow sufficient time for consideration of the offer and the information supplied.

G.5.1.1 Providing proper information: general

S.7.6.2
Counselling (1)

G.7.2.7 People should be able to seek counselling at any stage of their investigation or treatment, i.e. before, during and after treatment. If a person who has previously donated gametes or embryos, or received treatment requests further counselling at any point, the centre is expected to take all practicable steps to help them to obtain it. This will be particularly important, for example, in a case in which a person wishes to vary a consent they have previously given.

S.7.6.2
Counselling (1)

G.7. Provision of proper counselling services



Guidance

Related Sections

- G.7.2.8** The centre should offer people the opportunity to be counselled with a partner, if they have one, or individually. It is not acceptable for the centre to offer only group counselling sessions; group sessions may, however, be offered in addition to individual/couple sessions.

S.7.6.3
Counselling (2)

G.7.3 Conduct of counselling

- G.7.3.1** Counsellors should follow current professional guidance on good practice in infertility counselling.

S.7.6.3
Counselling (2)

Related Information

BICA Guidelines for Good Practice in Infertility Counselling (2006)

G.7.4 Counselling records and confidentiality

- G.7.4.1** The centre should record each offer of counselling and the person's decision to accept or reject such offers in the patient notes.

S.7.6.2
Counselling (1)

- G.7.4.2** Information obtained in the course of counselling is expected to be confidential (although it may be disclosed in certain circumstances, for example, where information provided in confidence gives a team member cause for concern about the suitability of a person to donate gametes or to receive treatment). The written records of the professional counsellor are expected to be kept in a secure place.

G.10.1
Confidentiality:
general

S.7.2
Confidentiality
and access to
health records



G.8.1 Before use: consent requirements relating to use of gametes and embryos

G.8.1.1 Where gametes or embryos are to be used in treatment the centre should ensure that an effective consent exists from each person who provided the gametes.

G.6 Obtaining consent from fertility patients

G.6.6 Consent to storage

S.7.5.4 Consent to storage and use of gametes and embryos

S.7.8.4 Handling and manipulation of gametes and embryos (1)

G.8.1.2 Where consent to the use of sperm was given before 1 August 1991, the centre may not use that sperm unless the consent was given in writing and has not been subsequently withdrawn. If consent has not been obtained either before or after 1 August 1991, the sperm may not be used unless and until such consent is obtained.

G.8.1.3 Where a gamete provider has died, the gametes and any embryos created using these gametes may not be used unless the gamete provider has given written consent to use after his or her death. Where such consent has been given, the gametes or embryos may only be used in accordance with that consent, for the purposes specified.

S.7.5.4 Consent to storage and use of gametes and embryos

G.8.1.4 Where embryos are to be used, the terms of the consent of the woman who produced the eggs must be compatible with the consent of the man who provided the sperm for the use in question.

G.8.2 Before use: consent requirements relating to treatment

G.8.2.1 No licensed treatment should be given to any woman without her written consent to that specific treatment. The written document on which the consent is recorded is expected to explain the nature of the treatment, the steps to be taken and indicate that the woman has

G.5.3 Proper information: patients

G.8. Use of gametes and embryos in treatment



Guidance

Related Sections

been given proper information about the implications of taking the proposed steps. The woman is expected to be given the opportunity to decide if she wishes to consent to all stages of her treatment before it begins, or whether she would prefer to consider the number of eggs or embryos to be replaced after egg collection.

G.6 Obtaining consent from fertility patients

S.7.5.3 Consent: documented procedures (2)

G.8.2.2 Where a woman is to undergo an egg or embryo transfer the centre should discuss with her the appropriate number of eggs or embryos to be transferred, and the reasons for this (including the risk of multiple births), obtain her consent to the proposed number of eggs or embryos to be transferred, and place a record of her consent in the patient records.

G.6.2.4 Consent: number of eggs or embryos to be transferred

G.8.5 Multiple embryo transfer: risks

S.7.5.3 Consent: documented procedures (2)

Related Information

HFEA Patient Fact Sheet - Multiple pregnancies and births: considering the risks

G.8.2.3 If the woman is to undergo a transfer of previously cryopreserved eggs or embryos, the centre should ask her before beginning the cycle to consider the number of eggs or embryos to be transferred.

G.6.2.4 Consent: number of eggs or embryos to be transferred

G.8.5 Multiple embryo transfer: risks

S.7.5.5 Consent to storage: documented procedures (1)

G.8.2.4 The centre should give a copy of the signed consent form to the woman giving consent.

S.7.5.5 Consent to storage: documented procedures (1)



G.8.2.5 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 before the beginning of their treatment cycle.

G.6.2.3 Consent: treatment with donated gametes or embryos

S.7.6.1 Consultation

G.8.3 Management of iatrogenic risk

G.8.3.1 The centre should not use gametes or embryos in treatment where those gametes or embryos have been exposed to a material risk of contamination or damage which might cause harm to recipients or to resulting children. If in any doubt about these risks, the centre should to seek expert advice.

S.7.6.10 Clinical treatment

G.8.4 Use of embryos created using intracytoplasmic sperm injection (ICSI)

G.8.4.1 The centre should not transfer to a woman embryos created by ICSI along with embryos created by any other method of insemination unless there are exceptional reasons for doing so and then only in accordance with the conditions of the centre's licence. Where a mixed transfer takes place the centre should explain the exceptional circumstances in the patient notes and record it in accordance with the relevant Directions.

S.7.6.10 Clinical treatment

G.8.5 Management of risks arising from multiple embryo transfers

G.8.5.1 Where a woman is to receive treatment using her own eggs, or embryos created using her own eggs, whether fresh or previously cryopreserved:

G.6.2.4 Consent: number of eggs or embryos to be transferred

- (a) where the woman is aged under 40 at the time of transfer the centre should not transfer more than two eggs or two embryos in any treatment cycle, regardless of the procedure used;
- (b) where the woman is aged 40 or over at the time of transfer the centre should not transfer more than three eggs or three embryos in any treatment cycle, regardless of the procedure used.

S.7.6.10 Clinical treatment

G.8. Use of gametes and embryos in treatment



Guidance

Related Sections

G.8.5.2 Where a woman is to receive treatment using donated eggs or embryos, or using embryos created with donated eggs, the centre should not transfer more than two eggs or two embryos in any treatment cycle, regardless of the woman's age at the time of transfer and regardless of the procedure used.

S.7.6.10 Clinical treatment

G.8.5.3 Where a woman is to receive treatment using her eggs or embryos that have been screened for aneuploidy, the centre should not transfer more than two embryos in any treatment cycle, regardless of the woman's age at the time of transfer.

S.7.6.10 Clinical treatment

G.8.6 Ensuring the limitations on the use of gametes from an individual donor are not exceeded

G.8.6.1 All centres using gametes (or embryos created using gametes) from a particular donor that were not obtained directly from the donor by that centre should notify the primary centre for that donor each time a new patient has either:

G.9.1.3 Procurement: general

- (a) a live birth as a result of treatment using that donor's gametes; or
- (b) embryos created using that donor's gametes which are placed in storage and available for subsequent transfer.

S.7.8.12 Laboratory processes: storage (3)

G.8.6.2 When a primary centre for a particular donor becomes aware that six families have had either:

S.7.8.12 Laboratory processes: storage (3)

- (a) a live birth as a result of treatment using that donor's gametes; or

- (b) embryos created using that donor's gametes which are placed in storage and available for subsequent transfer;

the primary centre should notify all other centres having or using gametes (or embryos created using gametes) from that donor within two working days. Thereafter, unless they are used to treat a family who has an existing child using that donor, secondary centres should only use the gametes (or embryos created using gametes) from that donor subject to specific authorisation from the primary centre. Treatment cycles in which recipients have already begun or undertaken any form of medical, surgical or obstetric treatment (such as ovarian stimulation or egg collection) when the notification is given should be allowed to continue.

G.8. Use of gametes and embryos in treatment



Guidance

Related Sections

G.8.6.3 When using gametes (or embryos created using gametes) from a particular donor subject to specific authorisation from a primary centre, a secondary centre should notify the primary centre each time a woman enters or leaves a relevant treatment situation. Relevant treatment situations are:

S.7.8.12
Laboratory
processes:
storage (3)

- (a) having begun, but not complete, a treatment cycle (e.g. begun ovarian stimulation); or
- (b) having received treatment (insemination or embryo transfer) and awaiting confirmation of pregnancy; or
- (c) having a confirmed ongoing pregnancy; or
- (d) having embryos created and not yet transferred (e.g. placed in storage); or
- (e) having received treatment but being lost to follow-up.

G.8.6.4 A primary centre should ensure, when giving specific authorisation to a secondary centre for the use of gametes (or embryos created using gametes) from a particular donor, that no more than 10 women at any one time:

S.7.8.12
Laboratory
processes:
storage (3)

- (a) have had a live birth as a result of treatment using that donor's gametes; or
- (b) have embryos created using that donor's gametes which are placed in storage and available for subsequent transfer; or
- (c) are in an ongoing relevant treatment situation as a result of treatment using gametes (or embryos created using gametes) from that donor.

G.8.7 Sex selection for social reasons

G.8.7.1 The centre should not, for social reasons:

- (a) select embryos of a particular sex, or
- (b) separate sperm samples, or use sperm samples which have been separated, for the purpose of sex selection.

G.8.7.2 Due to concerns about the reliability of the technique, sperm that has been subject to gradient methods of sperm sorting for sex selection should not be used for medical reasons.



G.8.8 Mixing of gametes and embryos

- G.8.8.1** It is expected that women will not be treated with gametes, or with embryos derived from gametes, of more than one man or woman during any treatment cycle.



G.9.1 Procurement: general

G.9.1.1 Except in very exceptional circumstances, gametes may not be taken from anyone who is incapable of giving consent, or has not given a valid consent to examination and treatment. Gametes may not be stored or used unless there exists an effective consent to the use or storage of those gametes.

G.6.2 Consent: examination and treatment

G.6.4 Consent: children and young people

G.6.5 Consent: mental capacity

S.7.5 Consent

G.9.1.2 Where sperm was in storage on 1 August 1991, storage may legally continue without the written consent of the individual who provided the sperm. However, there is no obligation upon a centre to continue to store sperm in the absence of a written agreement to do so.

G.9.1.3 When obtaining gametes or embryos for the treatment of others, whether direct from a donor, from another licensed centre or from a foreign supplier, the centre should take appropriate steps to discover whether gametes from that donor have been obtained for use in licensed treatment before and, if so:

G.4.6.1 Donation: 10 families limit

G.8.6 Limitations on use of gametes

- (a) to establish which centre is the primary centre for that donor; and
- (b) to notify that centre that they propose to use that donor's gametes; and
- (c) if appropriate, to seek authorisation to do so.

G.9.2 Procurement of gametes: age restrictions

G.9.2.1 The centre should not take gametes from persons under the age of 18 for purposes of treatment unless:

- (a) it is the intention to use the gametes for the patient's own treatment or that of the patient's partner; and
- (b) the centre is able to satisfy itself that the patient is capable of giving, effective consent to the use of the gametes for that purpose; and

G.6.4 Consent: children and young people

S.7.7.3 Procurement of gametes: age limits

G.9. Procurement, processing, storage and handling of gametes and embryos



Guidance

Related Sections

- (c) the patient has given effective consent to the use of the gametes for that purpose.

G.9.2.2 The centre should not take gametes from persons under the age of 18 for purposes of storage or research unless it is able to satisfy itself that the donor is capable of giving, and actually gives, effective consent to such storage or research.

G.6.4 Consent: children and young people

S.7.7.3 Procurement of gametes: age limits

G.9.2.3 The centre should not take eggs from persons under the age of 18 for purposes of research unless the HFEA has been specifically informed in each case.

G.6.4 Consent: children and young people

S.7.5.3 Consent: documented procedures (2)

G.9.3 Safety of equipment used to store cryopreserved gametes and embryos

G.9.3.1 All centres storing patients' gametes and embryos (including donated gametes stored for 'sibling use') should have effective alarms and monitoring systems in place to ensure the safety of cryopreserved gametes and embryos. These systems should have the following specifications:

S.6.3.8 Storage facilities: security

- (a) local alarms (i.e. on individual dewars for either temperature or liquid nitrogen level); and
- (b) auto-dial (or similar, e.g. link to fire alarm board) facility to contact staff outside normal working hours; and
- (c) adequate staffing and funding to allow the implementation of formal emergency procedures including 'on-call'; and
- (d) adequate spare storage space and/or vessels to enable transfer of samples in the event of a vessel failure.

G.9.3.2 Centres storing gametes and/or embryos for patients whose fertility may be impaired by medical treatment should divide individual patients' samples into separate storage vessels.

S.6.3.8 Storage facilities: security



G.9.4 Processing of gametes and embryos: air quality

G.9.4.1 Procedures involving the manipulation of gametes or embryos (for example, sperm preparation, separation of eggs from cumulus cells, and fertilisation of eggs), should be performed within a controlled environment.

S.7.8.5 Handling and manipulation of gametes and embryos (2)

Related Information

HFEA Summary of air quality information, 2006

G.9.4.2 Section deleted. Repetition of G.9.4.1

S.7.8.5 Handling and manipulation of gametes and embryos (2)

S.7.8.7 Handling of contaminated samples

G.9.4.3 Wherever practical, the centre should carry out procedures involving the processing of gametes or embryos in an environment with air quality of at least Grade C in the critical work area. The centre should strive to maintain a background environment of Grade D air quality in laboratories in which gametes or embryos are processed.

S.7.8.5 Handling and manipulation of gametes and embryos (2)

Related Information

HFEA Summary of air quality information, 2006
Rules and Guidance for Pharmaceutical Manufacturers and Distributors (MCA 2002)

G.9.4.4 Where it is not practical to carry out a procedure involving the manipulation of gametes or embryos (for example, ICSI or blastomere biopsy) in a Grade C environment, the procedure should be carried out in an environment of at least Grade D air quality.

S.7.8.5 Handling and manipulation of gametes and embryos (2)

Related Information

HFEA Summary of air quality information, 2006
Rules and Guidance for Pharmaceutical Manufacturers and Distributors (MCA 2002)

G.9.4.5 Where the environmental air quality has dropped below Grade D in the course of a procedure involving the manipulation of gametes or embryos, those gametes or embryos should only be used in treatment if the centre can assure itself that no additional risk to the woman to be treated or to any resulting child is entailed as a result.

S.7.8.5 Handling and manipulation of gametes and embryos (2)

G.9. Procurement, processing, storage and handling of gametes and embryos



Guidance

Related Sections

Related Information

HFEA Summary of air quality information, 2006
Rules and Guidance for Pharmaceutical Manufacturers and Distributors (MCA 2002)

G.9.4.6 Air quality monitoring should be used as a routine measure of quality assurance (for example, through particle counts or the use of settle plates, keeping a record of any cultures observed).

S.7.8.5 Handling and manipulation of gametes and embryos (2)

G.9.4.7 The air quality validation process should include documentation of culture conditions, temperature mapping and use of control charts to predict effects of any change in procedures.

S.7.8.5 Handling and manipulation of gametes and embryos (2)

G.9.5 Micromanipulation of gametes and embryos

G.9.5.1 Micromanipulation procedures such as ICSI or blastomere biopsy should be carried out only by practitioners who have been appropriately approved. Information about micromanipulation cycles should be recorded and, where required, submitted to the HFEA in accordance with the relevant Directions.

S.7.8.6 Handling and manipulation of gametes and embryos (3)

Related Information

Association of Clinical Embryologists - Accreditation Standards And Guidelines For IVF Laboratories

G.9.5.2 The centre's clinical protocols should describe the indications for the use of ICSI. The reasons for using ICSI in any particular case should be explained in the patient notes. Circumstances in which ICSI may be appropriate include:

S.7.6.10 Clinical treatment

- (a) where the man has very few live sperm (oligozoospermia) or no sperm (azoospermia) in their semen; or
- (b) where the sperm do not move properly, are in other ways abnormal or are otherwise unlikely to fertilise an egg; or
- (c) where sperm has been retrieved directly from the epididymis or the testes, from the urine, or by electro-ejaculation; or
- (d) where there are high levels of antibodies in the semen; or
- (e) where there have been previous fertilisation failures.

G.9. Procurement, processing, storage and handling of gametes and embryos



Guidance

Related Sections

G.9.5.3 Where eggs have failed to fertilise, regardless of the insemination procedure used, the centre should not attempt to re-inseminate those eggs for use in treatment.

S.7.6.10 Clinical treatment

G.9.6 Coding and traceability

G.9.6.1 The centre's traceability procedures should encompass all materials or equipment that could have an impact on the quality or safety of the gametes and embryos, for example:

- (a) culture media; and
- (b) serial numbers / batch numbers of equipment and materials coming into direct contact with gametes and embryos; and
- (c) records relating to monitoring and maintaining the required conditions in incubators and storage tanks.

G.13 Witnessing clinical and laboratory procedures

S.6.4.3 Equipment and materials: documented procedures (1)

S.7.3.1 Traceability

G.9.6.2 Where gametes have been kept in storage at the centre (for example, for oncology or pre-vasectomy patients) and are subsequently supplied to another centre (for example, for continued storage or use in treatment) the centre will not be expected to hold traceability data for the subsequent parts of the process that take place outside the centre. However, the storing centre should have record keeping procedures that allow a link to be made to the centre to which the gametes are supplied so that the complete process from procurement to use or disposal may be traced if required.

S.7.3.1 Traceability

G.9.7 Segregation of samples to prevent cross contamination

G.9.7.1 As a minimum, the following categories of sample are stored separately in order to minimise the risk of cross contamination:

- (a) samples from patients who have screened negative,
- (b) samples from unscreened patients (including samples in temporary storage whilst awaiting the results of screening tests and samples stored before comprehensive screening was introduced and where the patients have not subsequently been screened),
- (c) samples from patients who have screened positive.

S.6.3.7 Storage facilities: general

S.7.8.8 Laboratory procedures: screening

G.9. Procurement, processing, storage and handling of gametes and embryos



Guidance

Related Sections

- G.9.7.2** The centre should ensure that storage of tissue that does not require a licence from the HFEA fulfils the requirements and expectations of the relevant, current guidance.

Related Information

Department of Health - A Code of Practice for Tissue Banks Providing Tissues of Human Origin For Therapeutic Purposes
Department of Health - Guidance on the Microbiological Safety of Human Organs

S.7.8.5 Handling and manipulation of gametes and embryos (2)

S.7.8.8 Laboratory procedures: screening

G.9.8 Transport of gametes and embryos

- G.9.8.1** The centre may only supply gametes or embryos to another licensed centre or third party in accordance with Directions made by the HFEA. The centre may only import or export gametes or embryos in accordance with Directions made by the HFEA.

S.4.2.11 Transport of gametes and embryos

S.7.7.14 Transportation, labelling of shipping container and recall

S.7.7.15 Receipt of gametes (1)

S.7.7.16 Receipt of gametes (2)

- G.9.8.2** The Person Responsible receiving gametes or embryos transferred from an EEA country or Gibraltar is responsible for ensuring the following:

- (a) the member state from which the transfer is being made has implemented the EUTCD,
- (b) the centre from which the transfer is being made is licensed or accredited under the laws and measures of the member state,
- (c) the gametes/embryos transferred meet UK requirements on screening, as set out in licence conditions and the 7th edition of the Code of Practice,

S.4.2.11 Transport of gametes and embryos

G.9. Procurement, processing, storage and handling of gametes and embryos



Guidance

Related Sections

- (d) the donor of the gametes/embryos is identifiable, has consented to the transfer of their gametes/embryos to the UK and has been made aware of the legal position in the UK on identifying donors (including the implications for the donor),
- (e) the donor of the gametes/embryos must have only received reasonable expenses or reimbursement for loss of earnings. No inconvenience payments should have been made to the donor.

Related Information

Directive 2004/23/EC, Art.9

G.9.8.3 When importing gametes/embryos into the UK the form 'Notification of the transfer of gametes/embryos from within Gibraltar or the European Economic Area (EEA) into the UK (Imports)' should be filled in. In this form the PR will be required to make a declaration that they are assured that the centre from which the transfer is being made meets the requirements listed above.

Related Information

HFEA Import/export notification forms, 2007

G.9.8.4 When exporting gametes/embryos from the UK to Gibraltar or within the EEA the form 'Notification of the transfer of gametes/embryos to Gibraltar or the European Economic Area (EEA) from the UK (Exports)' should be filled in.

G.9.8.5 Completed forms should be returned to the HFEA no later than five working days after the transfer has taken place.

G.9.8.6 The PR is also responsible for ensuring that the donor is registered with the Authority. Records to be kept in respect of the gametes and donors of embryos being transferred are detailed in Directions 2007/04.

Related Information

Directions D.2007/4

G.9.8.7 Before a patient considers obtaining gametes or embryos from Gibraltar or the EEA the centre should inform them that the donation/s must meet specified criteria, relating to UK standards.

G.5.4 Proper information: treatment with donated gametes or embryos



G.9.9 Storage review

G.9.9.1 The centre should operate a bring-forward system in order to ensure sufficient advance notice of the end of the statutory storage period (or such shorter period as specified by a person who provided the gametes) for gametes or embryos in storage.

G.6.6.1 Consent to storage: requirements

G.6.6.4 Consent to storage: extending storage of gametes

G.6.6.5 Consent to storage: extending storage of embryos

S.7.8.11 Laboratory processes: storage (2)

S.7.8.12 Laboratory processes: storage (3)

G.9.9.2 The centre should endeavour to maintain contact with patients who have gametes or embryos in storage for their own treatment, and with any woman to be treated with stored gametes or embryos (where she is not a gamete provider), and inform them when the end of the permitted storage period is approaching. Gamete providers (or a woman to be treated and her partner, as appropriate) should be given sufficient notice to enable them to consider the available options and have access to appropriate information and advice. The centre should explain to gamete providers and current fertility patients the importance of informing the centre of any change of contact details for this purpose.

S.7.8.11 Laboratory processes: storage (2)

S.7.8.12 Laboratory processes: storage (3)

G.9. Procurement, processing, storage and handling of gametes and embryos



Guidance

Related Sections

G.9.10 Termination and disposal of gametes and embryos

G.9.10.1 The centre should take account of the special status of the human embryo when the development of an embryo is to be brought to an end and should ensure that it approaches the termination of the development of embryos and the disposal of the remaining material with appropriate delicacy and sensitivity, having regard to the interests of the gamete providers and/or any persons for whose treatment the embryos were being kept.

S.7.8.10
Laboratory
processes:
storage (1)

G.9.10.2 Where consent to continued storage has been withdrawn by only one gamete provider, the centre should take steps to ensure that the other gamete provider (unless that person is a donor) is informed of the centre's obligation to dispose of the embryos. Where the woman to be treated is not one of the gamete providers, the centre should take similar steps to ensure that she is informed of the obligation to dispose of the embryos.

G.5.10.1
Information
provision: storage

G.5.5.2
Information
provision: egg
sharing



G.10.1 General obligations

G.10.1.1 The centre should ensure that information provided in confidence, including all information relating to donors, patients and children born as a result of treatment, is kept confidential and only disclosed in the circumstances permitted by law. The centre should ensure that service users do not have access to any other person's records (including those of that person's spouse or partner) without that other person's prior consent.

S.7.2
Confidentiality
and access to
health records

Related Information

Healthcare Commission - Code of Practice on Confidential Personal Information

NHS Code of Practice on Confidentiality (2003)

NHS Code of Practice on Records Management (2006)

G.10.1.2 Where the centre is in doubt about whether a proposed disclosure is lawful, it should seek independent legal advice.

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health records

G.10.2 Confidentiality

G.10.2.1 The centre should have clear security procedures to 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). The security procedures should be appropriate for the type of record keeping system, including where information is held on paper, electronically or in any other type of system.

S.6.5 Information
management

S.7.2
Confidentiality
and access to
health records

G.10.2.2 In addition to standard procedures to protect the confidentiality of patients and donors, the centre should take care to keep all notes, facilities and procedures for the egg provider separate from those for the recipient(s) in an egg sharing arrangement. Care should be taken to ensure that confidentiality is not compromised, for example, where the woman providing eggs and the woman receiving them are treated at the same centre at the same time.

G.15 Egg sharing
agreements

S.7.2
Confidentiality
and access to
health records



G.10.3 Disclosure of non-identifying information

G.10.3.1 The centre may disclose information insofar as it does not identify, or could not reasonably be expected to lead to the identification of, a person to whom the centre owes a duty of confidentiality. Where the centre is in doubt about whether information it proposes to disclose is actually or potentially identifying, it should seek independent legal advice.

S.7.2
Confidentiality
and access to
health records

Related Information

CH (04) 07 Disclosure of information relating to gamete donation

G.10.4 Disclosures authorised by statute

G.10.4.1 Information held by the centre that relates to:

- (a) the keeping or use of gametes or any identifiable person; or
- (b) the provision of treatment services for any identifiable woman; or
- (c) the keeping or use of an embryo taken from any identifiable woman; or
- (d) the birth of a child as a result of treatment services

S.7.2
Confidentiality
and access to
health records

should, in general, be disclosed only to the HFEA or to another licensed clinic which needs to know for the purpose of continuing care. This includes not only information that directly concerns the matters set out above but also any information held by the centre that could connect them with a person whose identity is known.

G.10.4.2 Exceptions to this general rule may apply in certain cases where the information is disclosed:

- (a) to the person to whom the information relates (or their partner, if the information relates to their treatment together); or
- (b) with the consent of the person or persons to whom the information relates; or
- (c) in connection with certain proceedings, including any formal procedure for dealing with complaints; or
- (d) incidentally, where this is unavoidable when making a permitted disclosure; or

S.7.2
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and access to
health records

G.10. Confidentiality and access to confidential information



Guidance

Related Sections

- (e) in an emergency, where disclosure is necessary to avert imminent danger to the health of a person to whom the information relates and it is not reasonably practicable to obtain the consent of that person; or
- (f) by order of a Court in certain specified circumstances; or
- (g) in certain circumstances and subject to certain specified safeguards, about a person who has died.

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

Related Information

Access to Health Records (Northern Ireland) Order 1993

Access to Health Records Act 1990

Data Protection Act 1998

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

G.10.4.3 Where the centre refers a person seeking treatment to another licensed centre, relevant information should be provided in accordance with the requirements and expectations of good clinical practice. Information relevant to the welfare of the child is expected always to be supplied.

S.7.2
Confidentiality
and access to
health records

G.10.5 Disclosure with consent

G.10.5.1 Information about the provision of treatment services to identifiable people may be disclosed with the consent of the person (or persons) to whom it relates only if:

- (a) the person obtaining consent has taken reasonable steps to explain the implications of disclosure to the person concerned before their consent is obtained, and
- (b) the person(s) to whom the information is to be disclosed is specified in the terms of the consent given (either by name or other unique description, such as the person's physician, solicitor or interpreter) or is someone who needs the information in connection with:
 - providing medical, surgical or obstetric services to the person giving consent; or
 - carrying out an audit of clinical practice; or
 - auditing accounts.

G.6.11.1 Consent:
disclosure of
identifying
information (1)

S.7.2
Confidentiality
and access to
health records

G.10. Confidentiality and access to confidential information



Guidance

Related Sections

G.10.5.2 Where consent to disclosure is given, the centre should obtain a record of the consent in writing wherever possible.

Related Information

HFEA consent form - disclosure of identifying information

G.6.1.5 Consent: written record

S.7.2 Confidentiality and access to health records

G.10.5.3 The centre should seek renewed consent to disclosure if the nature of the treatment changes after an initial consent has been given (e.g. where, in the course of treatment, it is proposed that donor gametes are used in place of the patient's own gametes, or where patients move from unlicensed to licensed fertility treatment).

Related Information

HFEA consent form - disclosure of identifying information

G.6.11 Consent to disclosure of identifying information

S.7.2 Confidentiality and access to health records

G.10.5.4 Where people have given consent to disclosure of information to an unspecified person who is providing medical, surgical or obstetric services, or carrying out a clinical or financial audit, the centre should take care to ensure that the information is only disclosed where the person to whom it is given has a genuine need for it in connection with one of those activities.

G.6.11 Consent to disclosure of identifying information

S.7.2 Confidentiality and access to health records

G.10.5.5 When a disclosure is made with the consent of the person to whom the information relates the centre should make clear to the recipients of the information the precise terms upon which it is disclosed and for which consent has been given.

G.6.11 Consent to disclosure of identifying information

S.7.2 Confidentiality and access to health records

G.10. Confidentiality and access to confidential information



Guidance

Related Sections

G.10.5.6 The centre 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 they disclose the information they have received, a child might learn in an inappropriate way that they were born as a result of treatment services.

G.6.11 Consent to disclosure of identifying information

S.7.2
Confidentiality and access to health records

G.10.6 Access to personal health records

G.10.6.1 A person whose health records are being held by the centre (known as the “data subject”) is normally entitled to receive a copy of their own health records, provided that their request is made in writing (which includes a request by electronic means) and any required fee is paid. The source of the information and an explanation of any recondite or technical terms should be given.

S.7.2
Confidentiality and access to health records

Related Information

Data Protection Act 1998
Guidance from the Information Commissioner

G.10.6.2 The centre should comply promptly with subject access requests made under the Data Protection Act 1998. Usually, such requests will be for copies of medical records. The centre must satisfy itself as to the identity of the person making the request and may also need to request written consent and proof of identity from the partners of applicants if information relating to them is contained in the medical record. The centre may also levy a fee of between £10 and £50 in order to fulfil requests for copies of medical records. Once proof of identity and payment has been received, centres have a total of 40 calendar days to respond to the request. (This differs from the 20 working days available under the Freedom of Information Act 2000 and the Environmental Information Regulations 2004.) The centre should be aware that some requests for information may fall under different information access regimes and will need to ensure that they comply within the appropriate timeframes.

G.10.7 Freedom of information legislation

S.7.2
Confidentiality and access to health records

Related Information

Guidance from the Information Commissioner

G.10. Confidentiality and access to confidential information



Guidance

Related Sections

G.10.6.3 The centre should take into account additional exceptions and modifications to the Data Protection Act 1998 before access is given.

Related Information

Access to Health Records Act 1990

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

G.10.7 Freedom of information legislation

S.7.2 Confidentiality and access to health records

G.10.7 Requests under freedom of information legislation

G.10.7.1 The Freedom of Information Act 2000 (FOIA) gives the public the right to access information held by central government, local government and other public organisations. The Act is intended to improve openness and accountability in the public sector. Consequently, any information in a recorded format (paper, computer file, email, disc, tape, microfiche, etc.) submitted to the HFEA is subject to disclosure under the FOIA, with the exception of that information covered by the confidentiality provisions of the Human Fertilisation and Embryology Act 1990 (as amended). The HFEA will take into consideration arguments for non-disclosure from information providers but such arguments may not be determinative in the Authority's final decision regarding disclosure.

Related Information

Freedom of Information Act 2000

S.7.2 Confidentiality and access to health records

G.10.7.2 Centres that operate within NHS Trusts will also be directly subject to the provisions of the Freedom of Information Act 2000, although information covered by the HFE Act will be subject to exemptions. As such they may be required to respond directly to requests for information addressed to them in line with the FOI policy of the Trust. Such centres will also be subject to the requirements of the Environmental Information Regulations 2004, which supply applicants with wide-ranging rights of access to information and include a provision that allows prohibitions on disclosure of information established in other statutes to be overridden.

Related Information

Environmental Information Regulations 2004 para 5(6)

S.7.2 Confidentiality and access to health records

G.10.7.3 In the case of both FOI and EIR requests, the centre should respond within 20 working days. FOI requests should be submitted in writing (mail, fax, email), include the name and contact details of the applicant, and identify the information required. EIR requests can be submitted either in writing or verbally.

S.7.2 Confidentiality and access to health records

G.10. Confidentiality and access to confidential information



Guidance

Related Sections

G.10.7.4 Centres covered by the provisions of the FOIA will be expected to fulfil a number of duties: the duty to confirm or deny whether the information requested is held, the duty to communicate information to the applicant, the duty to reply promptly, the duty to advise and assist, and the duty to give reasons for any refusal of a request. They will also be expected to comply with the Code of Practice on the Discharge of Public Authorities' Functions and the Code of Practice on the Management of Records issued under s.45 and s.46 of the Freedom of Information Act 2000 respectively, as well as the Code of Practice on the Discharge of the Obligations of Public Authorities under the Environmental Information Regulations 2004 issued under regulation 16 of the Regulations.

S.7.2
Confidentiality
and access to
health records

Related Information

Department of Health - Records Management: NHS Code of Practice, Parts 1 & 2

G.10.8 Breach of confidentiality

G.10.8.1 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. Where the centre is in any doubt about the implications of a breach of confidentiality it should consult the HFEA.

G.14.1.1 Adverse
incidents:
reporting

S.9.4 Adverse
incidents



G.11.1 General

G.11.1.1 The centre should ensure that all centre staff understand the right of service users to complain and the procedure to be followed when a complaint is made.

S.9.2.2 Monitoring and resolution of complaints

G.11.1.2 It may often be appropriate to deal with complaints as they arise without invoking a formal complaints procedure. In such cases, members of staff are expected to deal promptly and conscientiously with issues as they are raised. However staff should understand that whilst complaints may appear to be trivial to them, they may nonetheless be of great importance to the complainant. Staff should not deter service users from making formal complaints if they so wish to do so.

S.9.2.2 Monitoring and resolution of complaints

Related Information

The Private and Voluntary Care (England) Regulations 2001

G.11.2 Complaints procedure

G.11.2.1 The centre should ensure that written procedures are in place for acknowledging and investigating complaints, as well as collecting suggestions and compliments, and that staff who deal with complaints have received appropriate training.

S.9.2.2 Monitoring and resolution of complaints

G.11.3 Complaints officer and complaints register

G.11.3.1 The centre should nominate a member of staff to act as complaints officer. The complaints officer should be:

S.9.2.2 Monitoring and resolution of complaints

- (a) the first point of contact when a service user makes a complaint; and
- (b) responsible for the investigation of complaints and the effective operation of the complaints procedure.

G.11.3.2 The centre should display notices prominently in reception areas explaining the complaints procedure, and giving the name and contact information for the complaints officer. This information should also be given to patients. Someone of at least equivalent seniority to the complaints officer should also be available to deal with complaints in case a service user feels unable to raise their complaint with the nominated complaints officer.

G.5.3.1 Information provision: treatment

G.11. Complaints procedures



Guidance

Related Sections

G.11.3.3 The centre's complaints officer should maintain an accurate complaints register including, for each complaint:

- (a) an explanation of the steps taken; and
- (b) a record of all communications with the complainant (including oral communications); and
- (c) a record of the outcome and action taken.

S.9.2.2 Monitoring and resolution of complaints

G.11.3.4 The centre's complaints register should be made available to HFEA inspectors during inspections.

S.9.2.2 Monitoring and resolution of complaints

G.11.4 Investigation of complaints

G.11.4.1 Where appropriate, an independent element should be included in the investigation of a complaint.

S.9.2.2 Monitoring and resolution of complaints

G.11.4.2 If a service user remains dissatisfied with the result of the investigation of their complaint, they should be made aware of whatever further procedures might be available to them (e.g. the Health Commissioner in the NHS).

S.9.2.2 Monitoring and resolution of complaints

G.11.4.3 In NHS centres, the complaints procedure is expected to be in accordance with standards required of NHS services. In private centres the procedures are expected to be in accordance with the standards required by the Healthcare Commission in England or the Care Commission in Scotland or the Care Standards Inspectorate Wales in Wales or the relevant successor body and as set out in this Code of Practice.

S.9.2.2 Monitoring and resolution of complaints

Related Information

Department of Health - National Minimum Standards and Regulations for Independent Health Care
National Health Service (Complaints) Regulations 2004
The Private and Voluntary Care (England) Regulations 2001



G.12.1 Staff involved

G.12.1.1 The centre should ensure that a multidisciplinary team is involved in the provision of the PGD service, including reproductive specialists, embryologists, clinical geneticists, infertility counsellors, genetic counsellors, cytogeneticists and molecular geneticists. This team should maintain close contact with the primary care physician or the referring clinician, and treatment is expected to also encompass continued support of patients following PGD.

G.9.5.1
Micromanipulation
procedures:
general

S.6.2.1
Personnel:
general

G.12.2 Genetic Consultation

G.12.2.1 As well as ensuring that people seeking treatment have been provided with, and had an opportunity to consider proper information about the treatment being considered, the centre should ensure that people seeking treatment have access to both clinical geneticists and genetic counsellors.

G.5.7 Proper
information: PGD

S.7.6.3
Counselling (2)

G.12.2.2 Ideally, people seeking treatment are expected to be referred to the treating centre by a Regional Genetics Centre. However, all those seeking treatment should at least be known to an accredited clinical geneticist.

S.7.6.3
Counselling (2)

G.12.2.3 Centres are expected to work closely with the local genetics team of those seeking treatment.

G.12.2.4 In addition to genetic counselling the centre should ensure that those seeking treatment and their families have access to proper counselling about the implications of the procedure, including continued care following treatment. Counselling should be made available to all family members in a way appropriate to their age and circumstances.

S.7.6.2
Counselling (1)

S.7.6.3
Counselling (2)

G.12.3 Preimplantation diagnosis of heritable conditions

G.12.3.1 The decision to use PGD should be made in consideration of the unique circumstances of those seeking treatment, rather than the fact that they carry a particular genetic condition.

S.7.6.1
Consultation



Related Sections

G.12.3.2 The use of PGD should be considered only where there is a significant risk of a serious genetic condition being present in the embryo. The perception of the level of risk by those seeking treatment is an important factor in the decision making process. The seriousness of the condition should be a matter for discussion between the people seeking treatment and the clinical team.

S.7.6.1
Consultation

G.12.3.3 In any particular situation the following factors should be considered when deciding the appropriateness of PGD:

G.5.7 Proper
information: PGD

- (a) the view of the people seeking treatment of the condition to be avoided; and
- (b) their previous reproductive experience; and
- (c) the likely degree of suffering associated with the condition; and
- (d) the availability of effective therapy, now and in the future; and
- (e) the speed of degeneration in progressive disorders; and
- (f) the extent of any intellectual impairment; and
- (g) the extent of social support available; and
- (h) the family circumstances of the people seeking treatment.

S.7.6.1
Consultation

S.7.6.3
Counselling (2)

G.12.4 Preimplantation genetic screening for aneuploidy

G.12.4.1 The use of PGS for aneuploidy should be considered only in the treatment of the following categories of patient:

G.5.8 Proper
information: PGS
for aneuploidy

- (a) women over 35 years of age; or
- (b) women with a history of recurrent miscarriage not caused by translocations or other chromosomal rearrangements; or
- (c) women with several previous failed IVF attempts where embryos have been transferred; or
- (d) women with a family history of aneuploidy not caused by translocations or other chromosomal rearrangements; or
- (e) male partners whose sperm has higher than normal levels of aneuploidy.

S.7.6.1
Consultation



G.12.5 Preimplantation testing for histocompatibility (tissue typing)

G.12.5.1 Where preimplantation tissue typing is to be used in conjunction with preimplantation genetic diagnosis for heritable genetic disease, the requirements and expectations applicable to a PGD service should be followed.

G.12.3.1 PGD:
general

G.5.9.1
Information
provision:
histocompatibility
testing (1)

S.7.6.1
Consultation

G.12.5.2 Centres offering preimplantation tissue typing should be able to demonstrate that they have arrangements in place for contacting patients to invite them and their families to take part in long-term follow-up studies, including long-term medical and psychosocial follow up of children born as a result. Centres are expected strongly to encourage patients and their families to participate in follow-up studies.

S.9.2 Evaluation

G.12.5.3 The multidisciplinary team involved in providing the licensed treatment should maintain close contact with the referring clinician and, in addition, with the specialist responsible for the care of the affected child. Treatment is expected also to encompass continued support of patients and their families following the procedure.

S.7.6.3
Counselling (2)

G.12.5.4 The decision to use preimplantation tissue typing should be made in consideration of the particular circumstances of each case, rather than the fact that it is sought in order to provide tissue to treat a particular condition.

G.12.2.3 Genetic
consultation:
general (3)

S.7.6.1
Consultation

G.12.5.5 Preimplantation tissue typing is expected to be available only to select embryos which, when transferred to the woman, may result in a child who may provide histocompatible tissue for the treatment of an existing child who is affected by a serious or life-threatening condition. The seriousness of the condition should be a matter for discussion between the people seeking treatment and the clinical team.

S.7.6.1
Consultation



G.12.5.6 When deciding the appropriateness of preimplantation tissue typing in any particular situation consideration should be given to the condition of the affected child, including:

- (a) the degree of suffering associated with the condition of the affected child; and
- (b) the speed of degeneration in progressive disorders; and
- (c) the extent of any intellectual impairment; and
- (d) the prognosis for the affected child in relation to all treatment options available; and
- (e) the availability of alternative sources of tissue for the treatment of the affected child, now and in the future; and
- (f) the availability of effective therapy for the affected child, now and in the future.

G.12.3
Preimplantation
diagnosis of
heritable
conditions

S.7.6.1
Consultation

G.12.5.7 Consideration should also be given to the possible consequences for any child who may be born as a result, including:

- (a) any risks associated with embryo biopsy for the child who may be born; and
- (b) the likely long-term emotional and psychological implications for the child who may be born; and
- (c) whether the treatment of the affected child is likely to require intrusive surgery for the child to be born (and whether this is likely to be repeated); and
- (d) any complications or predispositions for the child who may be born associated with the tissue type to be selected.

G.3.1.1 Welfare of
the child: general

S.7.1.2 Welfare of
the child
assessment (1)

G.12.5.8 Consideration should also be given to the family circumstances of the people seeking treatment, including:

- (a) the previous reproductive experience of those seeking treatment; and
- (b) the views of the people seeking treatment and of the affected child about the condition of the affected child; and
- (c) the likelihood of a successful outcome, taking into account the reproductive circumstances of the patients (i.e. number of embryos likely to be available for testing in each treatment cycle, the number likely to be suitable for transfer, whether carrier

S.7.6.1
Consultation

G.12. Preimplantation testing services



Guidance

Related Sections

embryos may be transferred, the number of cycles likely to be undertaken) and the likely outcome of treatment for the affected child; and

- (d) the consequences of an unsuccessful outcome; and
- (e) the demands of IVF/preimplantation testing treatment on the family whilst caring for an affected child; and
- (f) the extent of social support available; and
- (g) the family circumstances of the people seeking treatment.



G.13.1 General

G.13.1.1 Centres should have witnessing protocols in place to double check the identification of samples and the patients or donors to whom they relate, at the time each of the following clinical or laboratory procedures take place, in line with guidance in this section and HFEA model protocols:

(a) egg collection:

- cross checking of identifying information provided by the egg provider against records and laboratory data sheet or cross checking of information entered into electronic system and allocation of barcode/RFID tag,
- cross checking of information marked on egg collection dishes and lids against patient documentation,

(b) sperm collection:

- cross checking of identifying information provided by the sperm provider against records, laboratory data sheet and sperm receptacle or cross checking of information entered into system and allocation of barcode/RFID tag,

(c) sperm preparation:

- cross checking of information on tubes to documentation and information on sperm receptacle (i.e. at the time the sperm sample is transferred onto a preparation column),

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

- verification of identifying information on the dishes and tubes and confirmation that the sperm and eggs should be mixed/sperm should be injected into eggs,

(e) transfer of gametes or embryos between tubes/dishes:

- cross checking of information marked on dishes and tubes to the patient's/donor's documentation and information marked on dishes and tubes which the gametes or embryos are being transferred from,

(f) transfer of embryos into a woman:

S.7.3 Traceability and coding

S.7.7.1 Procurement, distribution and receipt: general

S.7.7.2 Procurement of gametes: general

S.7.8.10 Laboratory processes: storage (1)

S.7.8.15 Witnessing the identification of samples

S.7.8.3 Selection and validation of laboratory procedures

S.7.8.5 Handling and manipulation of gametes and embryos (2)



- cross checking of identifying information provided by the patient against patient records/electronic system and laboratory data sheet and confirmation that these are the correct embryos to transfer,
- (g) insemination of a woman with sperm prepared in the laboratory
- cross checking of identifying information provided by the patient against patient records or cross checking of information entered into system and allocation of barcode/RFID tag,
 - verify the sperm provider's identifying information in the sperm provider's documentation/electronic system and on the sperm container and confirm that this is the correct sperm provider,
- (h) placing gametes or embryos into cryopreservation:
- cross checking of identifying information on the storage container to the patient's/donor's documentation and information on the tube/dish which the gametes/embryos are being transferred from,
 - the location which the gametes or embryos are placed in the dewar,
- (i) removal of gametes or embryos from cryopreservation:
- cross checking information on the storage container against information in the patient/donor records to confirm they are the correct gametes or embryos to remove,
 - cross referring information from the storage container and patient/donor documentation/information on the electronic system to the thaw dish/tube (and if applicable attaching a bar code/RFID tag to the thaw dish/tube),
- (j) disposal of gametes or embryos:
- cross checking information on the storage container against information in the patient/donor records to confirm they are the correct gametes or embryos to dispose,
- (k) transporting gametes or embryos:

G.13. Witnessing clinical and laboratory procedures



Guidance

Related Sections

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

NOTE 1 (applies to G.13.1.1 a [second bullet point only] and c): Step does not need to be manually witnessed if an electronic system (bar coding or RFID) is being used.

NOTE 2 (applies to G.13.1.1 e): As part of their risk assessment, centres may consider that during the process of sperm preparation witnessing the cross checking of information on tubes can be carried out on all tubes at the beginning and at the end of the procedure and not contemporaneously for every stage of the procedure.

If an electronic system (bar coding or RFID) is being used, as part of their risk assessment, centres may consider that manually witnessing transfer steps (other than those outlined in G.13.1.1 d., h. and i.) is not necessary (for example if the system has forcing functions).

Related Information

CH (07) 02 New witnessing Guidance

G.13.1.2 Each stage of the witnessing trail should check the patient's/donor's full name and a unique identifier. If at some stages (e.g. labelling donor sperm) it is not possible to label the dishes/tubes with the donor name then it should be ensured that the donor code used is uniquely identifying and the dishes/tubes should be labelled with the female patient's name and unique identifier as soon as possible.

Related Information

CH (07) 02 New witnessing Guidance

S.7.3 Traceability and coding

S.7.7.1 Procurement, distribution and receipt: general

S.7.7.2 Procurement of gametes: general

S.7.8.3 Selection and validation of laboratory procedures

S.7.8.5 Handling and manipulation of gametes and embryos (2)



S.9.2.4 Internal audit

G.13.2 Witnessing procedures

G.13.2.1 The checking of identification of samples and patients/donors, and witnessing of these checks, should be recorded at the time the clinical and laboratory procedures (outlined in section G.13.1) take place. This means that embryologists performing procedures which need to be witnessed can not work alone. This will ensure that the witnessing protocol has the maximum potential to identify possible errors in the treatment process at the time the procedures take place.

S.7.3 Traceability and coding

S.7.8.5 Handling and manipulation of gametes and embryos (2)

A record should be made in the patient/donor notes at the time the procedure takes place confirming:

- (a) the procedure undertaken; and
- (b) the date and time of the procedure; and
- (c) the signature of the person undertaking the procedure; and
- (d) the signature of the witness to the procedure.

(Or where electronic witnessing is performed a hard copy of the details generated should be produced).

G.13.2.2 There should be a separate record of the name, job title and signature of every person who carries out or is a witness to laboratory and clinical procedures.

S.7.3.1 Traceability

G.13.3 Risk assessment of witnessing system

G.13.3.1 Centres should conduct a risk assessment before introducing any new protocols for witnessing. Consideration needs to be given to integrating protocols into the whole laboratory and clinical process and risk reduction procedures. Centres may wish to identify and specify key points at which a mismatch is most likely to occur.

S.7.3.1 Traceability

S.7.3.2 Traceability: procedures

S.7.8.13 Assuring the quality of procedures (1)

G.13. Witnessing clinical and laboratory procedures



Guidance

Related Sections

S.7.8.14 Assuring the quality of procedures (2)

S.9.2.4 Internal audit

G.13.3.2 Centres should be aware of the concept of 'involuntary automaticity' particularly in relation to considering who the most appropriate person to witness procedures and the workload of laboratory and clinical staff. This concept is recognised to compromise the effectiveness of witnessing to prevent mismatches of gametes and embryos. Consideration should be given to the appropriate work load and working hours for laboratory and clinical staff. Staff should comply with the need to take regular breaks.

S.7.8.13 Assuring the quality of procedures (1)

S.7.8.14 Assuring the quality of procedures (2)

S.9.2.4 Internal audit

G.13.3.3 Centres should have in place witnessing protocols, relevant to their local systems and conditions, based on HFEA model protocols. Where appropriate clinics may adapt HFEA model protocols to take into account their local systems.

S.7.8.13 Assuring the quality of procedures (1)

S.7.8.14 Assuring the quality of procedures (2)

S.9.2.4 Internal audit

G.13.3.4 Centres should ensure that compliance with witnessing protocols is checked regularly, including at the time of the centre's quality management system audit.

S.7.8.13 Assuring the quality of procedures (1)

S.7.8.14 Assuring the quality of procedures (2)

S.9.2.4 Internal audit



G.13.4 Appropriate person to witness

G.13.4.1 Centres should give consideration to who is the most appropriate person to witness clinical and laboratory procedures. An appropriate person to witness is a person who has completed the centre's training programme for new staff, and refresher training (as appropriate), to ensure that the principles of witnessing procedures are fully understood and that the centre-specific protocols are followed.

S.6.2.7
Personnel:
training (1)

G.13.4.2 At egg collection and embryo transfer the appropriate person to witness is another embryologist or clinician.

G.13.4.3 At sperm collection centres may consider the patient/donor to be the appropriate person to witness the cross checking of their identifying information against their records, laboratory data sheet and/or sperm receptacle.

G.13.4.4 Insemination centres performing IUI may consider the patient to be the appropriate person to verify the sperm provider's details.

G.13.5 Interruptions and distractions in the clinic and laboratory

G.13.5.1 Consideration should be given to the implications of distractions in the clinic and laboratory e.g. from telephones. Centres should, wherever possible, ensure that distractions within the clinic and laboratory are minimised.

G.13.5.2 When considering the protocol used for witnessing procedures and the most appropriate person to carry out these checks centres may wish to take into account the implications of interruptions to the work of laboratory and clinical staff, particularly embryologists performing critical procedures. Interrupting and returning to a task is a common source of human error.

G.13.6 Training

G.13.6.1 Centres should ensure that there is an induction programme in place for new staff to ensure that the principles of witnessing are fully understood and that centre specific protocols are followed.

S.6.2.7
Personnel:
training (1)

G.13. Witnessing clinical and laboratory procedures



Guidance

Related Sections

G.13.6.2 Staff should receive appropriate training if a new system for witnessing is introduced.

S.6.2.7
Personnel:
training (1)

G.13.7 Patient and donor identification

G.13.7.1 Centres should establish procedures to ensure the accurate identification of patients and donors and their gametes and embryos.

G.3.4.1
Verification of
identity

G.4.6.2 Donation:
verification of
identity

G.13.7.2 At the patient/donor assessment stage, centres should take all reasonable steps to verify the identity of donors, and patients seeking treatment who have referred themselves, by appropriate evidence (e.g. passport or photocard driving licence).

G.3.4.1
Verification of
identity

G.4.6.2 Donation:
verification of
identity

G.13.7.3 Upon egg or sperm collection, embryo transfer and sperm insemination patients and donors should be asked to actively supply the identifying information (full name and date of birth) requested by verbally stating it, rather than confirming or rejecting information read out by a member of staff.

G.13.7.4 Centres should give consideration to how patients and donors with disabilities (e.g. sight impaired, hearing impaired, learning difficulties) and patients and donors whose first language is not English will be asked to identify themselves actively. In the case of patients and donors whose first language is not English, wherever possible an independent interpreter should be used.

G.13.8 Identification of samples

G.13.8.1 Centres should allocate a unique identifier to each sample of gametes or embryos, from patients/donors, to ensure they can be accurately identified at all stages of the laboratory and treatment process. This identifier could, for example, include the patient's/donor's date of birth and/or hospital/NHS number and/or donor code.

S.7.3 Traceability
and coding

G.13. Witnessing clinical and laboratory procedures



Guidance

Related Sections

G.13.8.2 All samples of gametes and embryos should be labelled with at least the patient's/donor's full name and a unique identifier. If at some stages (e.g. labelling donor sperm) it is not possible to label the dishes/tubes with the donor name then it should be ensured that the donor code used is uniquely identifying and the dishes/tubes should be labelled with the female patient's name and unique identifier as soon as possible.

S.7.3 Traceability and coding

G.13.8.3 Centres should give consideration to the most appropriate way to label dishes/tubes when it is possible that they will be in sight of the patient (e.g. at embryo transfer or insemination).

S.7.3 Traceability and coding

G.13.8.4 Consideration should be given to the most suitable stage for labelling to change from the donor's/male partner's identifying information to the female patient's identifying information. Centres may consider it appropriate to label all dishes and tubes with both partners' names and identifying codes throughout the entire laboratory and treatment process.

S.7.3 Traceability and coding

G.13.8.5 Once a check has taken place centres should ensure that gametes or embryos from other patients or donors are not introduced into the critical working area (e.g. the hood) until the procedure has been completed. In particular, during the process of sperm preparation no more than one sample should be processed under the hood at any one time. However, it is acceptable for centres to cryopreserve gametes or embryos from more than one patient at one time provided that procedures are in place to keep the samples separate.

S.7.3 Traceability and coding

G.13.8.6 When sperm samples are produced at home centres should ensure that protocols are in place to make sure the sperm receptacle is clearly labelled with the sperm providers full name and unique identifier, that the identity of the sperm provider is confirmed and the sperm provider confirms that the sample is his.

G.6.2.3 Consent: treatment with donated gametes or embryos

S.7.3 Traceability and coding

G.13.8.7 Centres should have formal risk control measures in place to minimise the risk of 'transcribing' incorrect or incomplete identifying data onto a patient's record sheet(s). A vulnerability exists when transcribing details from the patient notes to another record(s) - particularly if an individual record sheet becomes separated from the patient's notes and is relied on during a witnessed step (for example a laboratory record sheet).



G.13.8.8 As part of a quality control system, audits of the patient's notes must include checking for transcription errors (or omissions) involving patient identifiers such as, misspelling of names and the absence of a unique identifier on any individual record sheet, particularly laboratory records.

G.13.9 IUI/GIFT with partner sperm

G.13.9.1 Centres should follow witnessing protocols, in line with the model protocols suggested by the HFEA, for the relevant procedures.

S.7.8.4 Handling and manipulation of gametes and embryos (1)

G.13.10 Use of electronic witnessing systems (bar coding and radio frequency identification)

G.13.10.1 Centres should conduct a risk assessment before introducing any new system or protocols for witnessing which should cover the following:

- (a) centres should ensure that the supplier/manufacturer of the system demonstrates that it is fit for use in the context of assisted conception,
- (b) centres should be aware that reliability and safety of electronic systems may differ depending on the type of system,
- (c) centres should evaluate the evidence for the safety and reliability of the system based on data supplied by the system supplier/manufacturer (e.g. false positive and negative matches, equipment breakdown) and any relevant studies. The software used should be fully tested, quality assured and risk assessed,
- (d) centres should consider how the manufacturer is satisfied that the labels/tags used in the system will continue to be effective when placed in long term cryostorage,
- (e) centres should ensure that any new system implemented will not cause harm to gametes and embryos,
- (f) centres should consider how the supplier/manufacturer satisfies itself that the system will not cause harm to gametes and embryos (for example whether the manufacturer has commissioned any independent reports as part of their quality assurance or carried out irradiance readings).



This risk assessment should be conducted in the context of risk factors which are already present. Consideration needs to be given to integrating the system used into the whole laboratory and clinical process and risk reduction procedures.

- G.13.10.2** Centres should be aware that the potential for human error to be unintentionally introduced into an electronic witnessing system can never be totally eliminated. However, effective risk assessment should reduce or mitigate this risk.
- G.13.10.3** Centres should give consideration to any potential loopholes in the system which could allow users to circumvent key steps, thus negating error safeguards. Centres should give consideration to implementing a system that allows the allocation of a unique identifier (e.g. a fingerprint) to each system user which allows them to log onto the system.
- G.13.10.4** Centres should not solely rely on the use of electronic systems to check the identification of patients, donors and samples. Centres should follow protocols for witnessing in line with HFEA model protocols; these include a number of manual witnessing steps.
- G.13.10.5** Centres should have procedures in place to ensure that all witnessing steps can be completed in the event of electronic system failure. Consideration should be given to the most effective way for staff to maintain their manual witnessing skills for all critical steps to ensure that checks can still be carried out, at all critical steps, in the possible event of electronic system failure.
- G.13.10.6** In addition to the electronic system of identification (information stored on bar codes or RFID tags) centres should continue to manually label all culture dishes/tubes (plus lids) and straws with the patient's full name and unique identifier. In any event of electronic identification failure (for example loss of a bar code label or RFID tag from a sample) centres should revert to methods of manual identification.
- G.13.10.7** Centres will need to consider whether the barcodes or RFID tags used are suitable for use on storage containers (i.e. able to withstand long periods of cryopreservation).



G.13.11 Bar coding systems

G.13.11.1 Centres considering installing a bar coding system should, as part of their risk assessment, consider the type and power of light used in the bar code equipment and the length of time which gametes and embryos are likely to be exposed to it. Centres should consider whether exposure to this light is likely to result in harm to gametes and embryos. Centres should conduct this risk assessment in the context of other risk factors in the centre and the environment (e.g. light used in microscopes).

G.13.11.2 While there is a substantial evidence base concerning the use of bar coding with human tissue, as far as the HFEA is aware no independent studies have yet been conducted on the effect of light on human gametes and embryos. Consequently there is not yet a compelling evidence base to enable the HFEA to categorically consider the use of bar coding systems to be risk free.

G.13.11.3 Bar coding equipment may use a range of light sources. The HFEA is aware of two types of bar coding systems which are marketed for use in an assisted conception setting: those which use white light emitting diodes and those which use laser light.

G.13.11.4 Taking into account that there is evidence of damage to human cells from some powers of laser light, centres will need to consider the degree of possible risk involved with using laser light bar coding systems. Centres should ensure that they only consider using class 1 or 2 lasers.

G.13.11.5 Bar code equipment which uses ultraviolet or infrared light should not be used as these sources of radiation are known to have heating, and therefore potentially damaging, effects on human cells.

G.13.12 Radio frequency identification systems (RFID)

G.13.12.1 Centres considering installing an RFID system should, as part of their risk assessment, consider the frequency of the radio waves used in the RFID system and whether exposure to them is likely to result in harm to gametes and embryos. Centres should be aware that detectable changes in temperature may result in DNA damage. Centres should conduct this risk assessment in the context of other risk factors in the centre and the environment (e.g. mobile phone signals).

G.13. Witnessing clinical and laboratory procedures



Guidance

Related Sections

G.13.12.2 While there is an evidence base for the use of RFID in a medical setting as far as the HFEA is aware no independent studies have yet been conducted on the effect of electromagnetic radiation on human gametes and embryos. Consequently there is not yet a compelling evidence base to enable the HFEA to categorically consider use of RFID systems to be risk free.



G.14.1 General

G.14.1.1 The centre should report all incidents and near misses occurring at that centre or, where the incident is in relation to a treatment process that involves a third party, at any centre with which it has a third party agreement to the HFEA within 24 hours of the discovery of the incident in accordance with HFEA Directions.

S.9.4 Adverse incidents

Related Information

Directions D.2007/3

G.14.1.2 All breaches of the HFE Act 1990 or failures to conform to specifications set out in the standards forming the first part of this Code must be reported as adverse incidents to the HFEA. The HFEA will also investigate patient complaints that relate to adverse incidents.

S.4.1.9 Person Responsible: notification of incidents

Related Information

Directions D.2007/3

S.9.4 Adverse incidents

G.14.1.3 The reporting of adverse incidents arising from the use of equipment and materials is encouraged. Reports should be sent to the 'competent authority', the Medicines and Healthcare products Regulatory Agency (MHRA). An 'adverse incident' in this context is defined as an incident which produces, or has the potential to produce, unwanted effects involving the safety of patients, users and others. This reporting is distinct but complementary to that required by the HFEA.

S.6.4.1 Equipment and materials: requirements

S.9.4.1 Identification, investigation, control and recording

G.14.1.4 Where an adverse incident has occurred, centres are expected to:

- (a) review relevant procedures in order to minimise the risk of any reoccurrence of the incident, and
- (b) inform the HFEA of the revised procedures.

S.9.4 Adverse incidents

G.15. Egg sharing agreements



Guidance

Related Sections

G.15.1 General

G.15.1.1 The centre should draw up separate agreements with the egg provider and with the egg recipient(s). The centre's agreements with an egg provider and with those receiving eggs from that provider should be consistent with each other. The centre should abide by the terms of egg sharing agreements it has made.

S.7.6.1
Consultation

G.15.1.2 Where benefits are offered to an egg provider those benefits should be given in connection with the cycle in which eggs are supplied for the treatment of a recipient unless there is a clinical reason to defer them. In these circumstances only, the egg provider may elect to donate all the eggs collected in the initial cycle and to take advantage of the benefits in a subsequent cycle.

S.7.6.1
Consultation

S.7.6.10 Clinical
treatment

Related Information

Directions D.2006/1

G.15.1.3 Eggs collected from an egg provider in a single cycle should not be shared among more than two other recipients.

S.7.6.6 Evaluation
and screening of
potential donors
(1)

G.15.2 Agreement between a licensed centre and an egg provider

G.15.2.1 The agreement between the centre and the egg provider should set out the terms of the arrangement in full. It should identify clearly the egg provider and the centre, and to be signed by both parties.

G.5.5 Proper
information: egg
sharing

S.7.4.1
Information for
users

G.15.2.2 The agreement should include a statement confirming:

(a) that any patient who has consented to providing eggs for the treatment of others in licensed treatment under the HFE Act 1990 will not be the legal parent of any child/children resulting from the donation; and

S.7.4.1
Information for
users

(b) what information will be available to the egg provider about the recipient and the outcome of her treatment, for example the number and sex of any children born as a result; and

S.7.5 Consent

G.15. Egg sharing agreements



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Related Sections

- (c) what information will be available to the egg recipient about the egg provider and the outcome of her treatment, for example the number and sex of any children born as a result.

G.15.2.3 The agreement should include a full description of what the treatment is expected to involve, including:

- (a) the number of cycles of treatment covered by the agreement; and
- (b) the date upon which treatment will begin.

G.5.5 Proper information: egg sharing

S.7.4.1 Information for users

G.15.2.4 The agreement should include a statement from the egg provider confirming that she has:

- (a) had an opportunity to discuss the treatment procedures involved in providing her eggs as part of an egg sharing arrangement with a qualified member of the treatment centre's staff; and
- (b) received both verbal and written information about the treatment to be provided; and
- (c) received all the appropriate information listed in the relevant parts of the HFEA's Code of Practice (written information should be attached to the agreement); and
- (d) been offered counselling about the implications of the treatment.

G.4.3 Patient donors

G.5.5 Proper information: egg sharing

G.7.2.5 Implications counselling: egg sharing

S.7.4.1 Information for users

S.7.6.2 Counselling (1)

G.15.2.5 The agreement should include a statement confirming:

- (a) that the patient's consent to the treatment has been obtained; and
- (b) that the egg provider's consent to the use of eggs/creation, use and storage of embryos has been recorded appropriately; and
- (c) that the agreement does not override the terms of paragraph 4 of Schedule 3 to the HFE Act 1990 (i.e. that the egg provider may withdraw or vary her consent in respect of any embryo

G.6.8 Consent: egg sharing

S.7.5 Consent

S.7.5.3 Consent: documented procedures (2)

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created using her egg at any time until that embryo is transferred to a woman, used in a project of research or allowed to perish); and

- (d) the consequences of any variation or withdrawal of consent, and the liability of the parties involved for any additional charges that may be applied.

G.15.2.6 The agreement should include a statement describing:

- (a) what charges (if any) are expected to be paid to the treatment centre by the egg provider; and
- (b) if the egg provider's treatment is provided at a discounted cost, the circumstances that would result in the egg provider being liable for the total cost of her treatment and the total sums she would have to pay (Where an insufficient number of eggs are collected for sharing the egg provider is expected to be given the option of using all the eggs at no additional cost to her.)

G.5.3.1
Information
provision:
treatment

G.5.5 Proper
information: egg
sharing

S.7.4.1
Information for
users

G.15.2.7 The agreement should include full details of the proposed arrangements for distributing the eggs between the provider and recipient(s), including:

- (a) the minimum number of eggs required for sharing; and
- (b) the number of recipients among whom eggs will be shared (this should not exceed two, excluding the egg provider); and
- (c) how these eggs will be allocated between the provider and recipient(s).

G.5.5 Proper
information: egg
sharing

S.7.4.1
Information for
users

G.15.3 Agreement between a licensed centre and an egg recipient

G.15.3.1 The agreement between the centre and the egg recipient should set out the terms of the arrangement in full. It should identify clearly the egg recipient and the centre, and to be signed by both parties.

S.7.4.1
Information for
users



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G.15.3.2 The agreement should include a statement confirming:

- (a) that any patient who has consented to providing eggs for the treatment of others in licensed treatment under the HFE Act 1990 will not be the legal parent of any child/children resulting from the donation; and
- (b) what information will be available to the egg provider about the recipient and the outcome of her treatment, for example the number and sex of any children born as a result; and
- (c) what information will be available to the egg recipient about the egg provider and the outcome of her treatment, for example the number and sex of any children born as a result; and
- (d) what information will be available to any offspring of the egg recipient about the egg provider, including information recorded on the HFEA Register which the offspring are entitled to receive and the circumstances under which they may receive it.

G.5.5 Proper information: egg sharing

S.7.4.1 Information for users

G.15.3.3 The agreement should include a full description of what the treatment is expected to involve, including:

- (a) the number of cycles of treatment involved; and
- (b) the date upon which treatment will begin; and
- (c) that a portion of the eggs collected from the egg provider will be used for the provider's own treatment.

S.7.4.1 Information for users

G.15.3.4 The agreement should include a statement from the recipient confirming that she has:

- (a) had an opportunity to discuss the treatment procedures involved in receiving eggs as part of an egg sharing arrangement with a qualified member of the centre's staff; and
- (b) received both verbal and written information about the treatment to be provided; and
- (c) received all the appropriate information listed in the relevant parts of the HFEA's Code of Practice (written information should be attached to the agreement); and
- (d) been offered counselling about the implications of the treatment; and

G.4.3 Patient donors

G.7.2.5 Implications counselling: egg sharing

S.7.4.1 Information for users

S.7.5 Consent

G.15. Egg sharing agreements



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Related Sections

- (e) been informed about the screening that the egg provider has undergone and the limitations of that screening in the avoidance of transmissible conditions.

G.15.3.5 The agreement should include a statement confirming that the agreement does not override the terms of paragraph 4 of Schedule 3 to the HFE Act 1990 (i.e. that the egg provider may withdraw or vary her consent in respect of any embryo created using her eggs at any time until that embryo is transferred to a woman, used in a project of research or allowed to perish).

G.6.8 Consent: egg sharing

S.7.5.4 Consent to storage and use of gametes and embryos

G.15.3.6 The agreement should include a statement describing:

- (a) what charges are expected to be paid to the centre by the egg recipient; and
- (b) what treatment services these charges will cover.

G.5.5.2 Information provision: egg sharing

S.7.4.1 Information for users

G.15.3.7 The agreement should include full details of the proposed arrangements for distributing the eggs between the provider and recipient(s), including:

- (a) the minimum number of eggs required for sharing; and
- (b) the number of recipients among whom eggs will be shared (this should not exceed two, excluding the egg provider); and
- (c) how these eggs will be allocated between the provider and recipient(s).

G.5.5 Proper information: egg sharing

S.7.4.1 Information for users

G.15.4 Egg sharing for research

G.15.4.1 As outlined in sections 15.2 and 15.3, the centre should draw up agreements between the centre and the egg provider and the centre and the egg recipient (in this case the research groups) including all the applicable information.

G.15.4.2 When eggs are being donated to research through an egg sharing agreement the centre must ensure that the eggs are divided between the egg donor and the recipient (the research project) by someone not directly involved in the research project.

G.15. Egg sharing agreements



Guidance

Related Sections

G.15.4.3 Where a centre offers egg sharing for treatment **and** research, equal benefits-in-kind should be available for both so there is parity and it is not advantageous to donate to either one or the other.



A.1 Introduction

- A.1.1** Standard licence conditions are conditions applied to all licences of a certain type. They may be either statutory (prescribed in legislation) or discretionary (applied by the HFEA pursuant to powers conferred on it by legislation). Additional conditions may be applied to licences individually under powers contained in the legislation.
- A.1.2** Licences are granted, and discretionary conditions applied to them, at the discretion of HFEA licence committees which comprises of five members of the Authority.
- A.1.3** Licence conditions generally provide for the manner in which licensable activities may be carried out by a licensee or set limitations on the conduct of licensable activities. Failure to comply with a licence condition is a breach of licence and may result in the revocation of a licence. As licence conditions can affect the way in which professionals provide treatment or carry out research, Centres must formally accept the conditions. There is a process by which Centres may appeal against the imposition of discretionary conditions and, more generally, against the revocation of, or refusal to grant, a licence.
- A.1.4** The Authority may also from time to time issue Directions in relation to certain matters. Directions generally relate to matters that are not to do with the conduct of treatment, and often concern information that must be recorded by the Centre or reported to the HFEA. Directions may be 'general' (applying equally to all Centres) or 'special' applying only to particular Centres, perhaps only for a certain period of time. Since they do not affect the conduct of treatment directly, Directions apply to all Centres equally and there is no mechanism for appeal. Nevertheless Directions have the same force as licence conditions (i.e. failure to comply with a Direction is a breach of licence and may result in the licence being revoked).

A.2 General conditions (Section 12)

- A.2.1** Except to the extent that the activities authorised by the licence fall within A.2.2, those activities shall be carried on only on the premises to which the licence relates and under the supervision of the Person Responsible.

Related Information

HFE Act 1990, s.12(1)(a) (as amended)

- A.2.2** Any activities to which section 3(1A) or 4(1)A to the Act applies (namely procurement, testing, processing or distribution of gametes or embryos intended for human application) shall be carried on only on the premises to which the licence relates or on relevant third party premises.

Related Information

HFE Act 1990, s.12(1)(aa) (as amended)

- A.2.3** Any member or employee of the Authority, on production, if so required, of a document identifying the person as such, shall at all reasonable times be permitted to enter those premises and inspect them (which includes inspecting any equipment or records and observing any activity).

Related Information

HFE Act 1990, s.12(1)(b) (as amended)

- A.2.4** Except in relation to the use of gametes in the course of providing basic partner treatment services or non-medical fertility services, the provisions of Schedule 3 to the Act shall be complied with (relating to consent to the use of sperm, eggs or embryos).

Related Information

HFE Act 1990, s.12(1)(c) (as amended)

- A.2.5** Proper records shall be maintained in such form as the Authority may specify in Directions.

Related Information

HFE Act 1990, s.12(1)(d) (as amended)

- A.2.6** No money or other benefit shall be given or received in respect of any supply of gametes or embryos unless authorised by Directions.

Related Information

HFE Act 1990, s.12(1)(e) (as amended)

- A.2.7** Where gametes or embryos are supplied to a person to whom another licence applies, that person shall also be provided with such information as the Authority may specify in Directions.

Related Information

HFE Act 1990, s.12(1)(f) (as amended)

- A.2.8** The Authority shall be provided, in such form and at such intervals as it may specify in Directions, with such copies of or extracts from the records, or such other information, as the Directions may specify.

Related Information

HFE Act 1990, s.12(1)(g) (as amended)

- A.2.9** It shall be a condition of every licence granted under paragraph 1, 1A or 2 of Schedule 2 to the Act that:

- (a) such information as is necessary to facilitate the traceability of gametes and embryos;
and

- (b) any information relating to the quality or safety of gametes or embryos shall be recorded and provided to the Authority upon request.

Related Information

HFE Act 1990, s.12(2) (as amended)

- A.2.10** No treatment services will be provided unless the woman and man being provided with the treatment services have been given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps and have been provided with such relevant information as is proper.

A.3 Traceability and coding system (Schedule 3A)

- A.3.1** The Centre shall establish, implement and comply with documented procedures to ensure that:

- (a) all gametes and embryos; and
- (b) all relevant data relating to anything coming into contact with those gametes or embryos are traceable from procurement of gametes to patient treatment or disposal and vice versa.

Related Information

Directive 2004/23/EC, Art.25(1)

Directive 2004/23/EC, Arts 8(1)

HFE Act 1990, Sched.3A, para.1 (as amended)

HFE Act 1990, Sched.3A, para.2 (as amended)

- A.3.2** The documented procedures referred to in condition A.3.1 above shall require the Centre to collect and retain, for a period of at least 30 years (and for such longer period as may be specified in Directions) in an appropriate readable storage medium, the information set out below and such other information as the Authority may specify in Directions.

- (a) Donor identification that will include at least:
- (i) identification of the Centre
 - (ii) unique donation ID number
 - (iii) date of procurement
 - (iv) place of procurement
 - (v) type of donation.
- (b) Product identification that will include at least:
- (i) identification of the Centre

- (ii) type of product
 - (iii) pool number (if applicable)
 - (iv) split number (if applicable)
 - (v) expiry date (if applicable)
 - (vi) gamete/embryo status (i.e. quarantined, suitable for use etc.)
 - (vii) description and origin of the product, processing steps applied, materials and additives coming into contact with gametes and embryos and having an effect on their quality and/or safety
 - (viii) identification of the facility issuing the final label.
- (c) Human application identification that will include at least:
- (i) date of distribution/disposal
 - (ii) identification of the clinician or end user/ facility.

Related Information

Directions D.1992/1
Directive 2004/23/EC, Art.8(4)
Directive 2006/86/EC, Annex VI
Directive 2006/86/EC, Art.9(2)

- A.3.3** The documented procedures referred to in condition A.3.1 above shall include a system which assigns a unique code to each donation and to each of the products associated with it, to enable them to be uniquely identified and labelled.

Related Information

Directive 2004/23/EC, Art. 8(2)
Directive 2004/23/EC, Art.9(1)
Directive 2006/86/EC, Art.10(1)

- A.3.4** Except in relation to partner donated gametes (or embryos created from such gametes) intended to be used for the purpose of assisted reproduction, the unique code referred to in condition A.3.3 above shall include, as a minimum, the information set out below and such other information as the Authority may specify in Directions:

- (a) Donor identification details:
- (i) identification of the Centre
 - (ii) unique donation ID number.

- (b) Product identification details:
 - (i) product code
 - (ii) split number (if applicable)
 - (iii) expiry date.

Related Information

Directive 2006/86/EC, Annex VII

- A.3.5** Centres shall have witnessing protocols in place to double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process.

These checks shall be completed and recorded at the time the relevant clinical or laboratory process/procedure takes place.

The record must be kept in the each patient's medical records. Witnessing protocols shall ensure that every sample of gametes or embryos can be identified at all times.

A.4 Serious adverse events and serious adverse reactions (Schedule 3A)

- A.4.1** The Centre shall establish, implement and comply with documented procedures to report, investigate, register and transmit information about Serious Adverse Events and Serious Adverse Reactions which occur on any premises to which a licence relates and any relevant third party premises.

Related Information

Directive 2004/23/EC, Art.11(1)
HFE Act 1990, Sched.3A, para.3 (as amended)

- A.4.2** The documented procedures referred to in paragraph A.3.2.1 above shall enable the Centre to communicate to the HFEA, without delay:
- (a) all relevant available information about suspected Serious Adverse Events and Reactions; and
 - (b) the conclusion of the investigation to analyse the cause and ensuing outcome in relation to Serious Adverse Events and Reactions.

Related Information

Directive 2006/86/EC, Art.5(2)(a)
Directive 2006/86/EC, Art.6(3)(a)

A.4.3 Serious Adverse Events — The Person Responsible shall notify the HFEA of any suspected serious adverse event by providing the information set out below and such other information as the Authority may specify in Directions:

- (a) identification of the Centre,
- (b) identification of the premises concerned,
- (c) report identification,
- (d) date of notification,
- (e) date of Serious Adverse Event,
- (f) an evaluation of the event by activity, (procurement, testing, transport, processing, storage, distribution or other) and specification of the source of error, (defect in gametes or embryos, equipment or material failure or defect), human error or other (to identify preventable causes), to be followed by a conclusion report including items (a) to (e) above.

Related Information

Directive 2004/23/EC, Art.11(3)

Directive 2006/86/EC, Art.6(4)(a) and Annex IV, Part A

A.4.4 The Centre shall thereafter notify the HFEA of the conclusion of the investigation into the Serious Adverse Event by providing at least the information set out below and any such other information as the Authority may specify in Directions:

- (a) identification of the Centre,
- (b) identification of the premises concerned,
- (c) report identification,
- (d) date when the Serious Adverse Event was confirmed,
- (e) date of the Serious Adverse Event,
- (f) root cause analysis,
- (g) corrective measures taken.

Related Information

Directive 2006/86/EC, Art.6(4)(c) and Annex IV, Part B

A.4.5 Serious Adverse Reactions — The Person Responsible shall notify the HFEA of any suspected Serious Adverse Reaction by providing the information set out below and such other information as the Authority may specify in Directions:

- (a) identification of the Centre,

- (b) identification of the premises concerned,
- (c) report identification,
- (d) date of notification,
- (e) individual affected (patient or donor),
- (f) date and place of procurement of gametes or application of gametes or embryos,
- (g) unique donation identification number,
- (h) date of suspected Serious Adverse Reaction,
- (i) details of gametes or embryos involved in the suspected Serious Adverse Reaction,
- (j) type of suspected Serious Adverse Reaction(s).

Related Information

Directive 2004/23/EC, Art.11(3)

Directive 2006/86/EC, Art.5(3)(c) and Annex III, Part A

A.4.6 The Centre shall thereafter notify the HFEA of the conclusion of the investigation into the Serious Adverse Reaction by providing at least the information set out below and any such other information as the Authority may specify in Directions:

- (a) identification of the Centre,
- (b) identification of the premises concerned,
- (c) report identification,
- (d) date when the Serious Adverse Reaction was confirmed,
- (e) date of the Serious Adverse Reaction,
- (f) unique donation identification number,
- (g) confirmation of the type of reaction(s) or a change in the type of reaction(s),
- (h) clinical outcome, if known:
 - complete recovery
 - minor sequelae
 - serious sequelae
 - death
- (i) outcome of investigation and final conclusions,

- (j) recommendations for preventive and corrective actions.

Related Information

Directive 2006/86/EC, Art.5(3)(c) and Annex III, Part B

- A.4.7** The Centre shall ensure that an accurate, rapid and verifiable procedure is in place which will enable it to recall from distribution any product which may be related to a Serious Adverse Event or Reaction.

Related Information

Directive 2004/23/EC, Art.11(5)

A.5 Third party agreements and termination of licence activities (Schedule 3A)

- A.5.1** The Centre shall establish a written agreement with a Third Party for external activities which influence the quality and safety of gametes and embryos procured or processed and in particular where:

- (a) the Centre entrusts one of the stages of gamete or embryo processing to a Third Party,
- (b) a Third Party provides goods or services that affect gamete or embryo quality and safety assurance, including the process of distribution,
- (c) the Centre provides services to another Centre that is not licensed,
- (d) the Centre distributes gametes or embryos processed by Third Parties.

Related Information

Directive 2004/23/EC, Art.24(1)
HFE Act 1990, Sched.3A, para.4 (as amended)

- A.5.2** The Centre must evaluate and select Third Parties on the basis of their ability to meet the requirements of these licence conditions and the Standards set out in the HFEA Code of Practice.

Related Information

Directive 2004/23/EC, Art.24(2)

- A.5.3** Agreements with Third Parties must specify the terms of the relationship and responsibilities as well as the protocols to be followed to meet the required performance specification.

Related Information

Directive 2004/23/EC, Art.24(4)

- A.5.4** The Centre shall ensure that the following core requirements are included in any Third Party agreement, namely:
- (a) full address and named contact details of the Third Party, and nature of the service to be provided,
 - (b) identification of person(s) responsible for managing arrangement between the Centre and the Third Party,
 - (c) provision setting out how often the agreement will be reviewed and by whom,
 - (d) summary of the responsibilities of the Third Party and detailed procedures with regard to each party's respective responsibilities,
 - (e) any specific criteria that the service provided by the Third Party must meet, particularly in relation to quality and safety,
 - (f) description of how any test/diagnostic results are relayed to the commissioning Centre, including sign off and confirmation that the result applies to the correct sample.

- A.5.5** The Centre shall keep a complete list of agreements referred to in paragraph A.3.1 that they have established with Third Parties and such agreements shall specify the responsibilities of the Third Parties under any agreed procedures. Copies of these agreements shall be made available to the HFEA upon request.

Related Information

Directive 2004/23/EC, Art.24(3)-(5)

- A.5.6** The Centre must ensure that it is made a condition of any third party agreement referred to in paragraph A.3.3.1 above that the Third Party will meet the requirements of the relevant licence conditions and the Standards set out in the HFEA Code of Practice.

Related Information

Directive 2004/23/EC, Art.21(5)
HFE Act 1990, s.19(1)(f) (as amended)

- A.5.7** The Centre shall establish, implement and comply with documented procedures to ensure that, in the event of termination of activities for whatever reason, stored gametes and embryos shall (subject to the consent of the Donor) be transferred to another licensed Centre.

Related Information

Directive 2004/23/EC, Art.21(5)

A.6 Requirements for procurement of gametes and embryos (Schedule 3A)

A.6.1 The Centre must ensure that all persons to whom the licence applies who are authorised to procure gametes or embryos, or both, have successfully completed a suitable training programme.

Related Information

Directive 2006/17/EC, Art.2(2)
HFE Act 1990, Sched.3A, para.5 (as amended)

A.6.2 The Centre must ensure that it has written agreements with all staff or clinical teams responsible for Donor selection unless they are employed by the Centre. The written agreements must specify the protocols and procedures to be followed to assure compliance with the selection criteria for Donors as referred to in the licence condition at A.7 below headed "Selection Criteria and Laboratory Tests Required from Donors of Reproductive Cells"

Related Information

Directive 2006/17/EC, Art.2(3) and (4)

A.6.3 The Centre shall establish, implement and comply with Standard Operating Procedures (SOPs) for the verification of:

- (a) Donor identity,
- (b) the details of Donor or donor family consent or authorisation,
- (c) the assessment of the selection criteria for Donors,
- (d) the assessment of the laboratory test required for donors.

Related Information

Directive 2006/17/EC, Art.2(5)

A.6.4 The Centre shall also establish, implement and comply with Standard Operating Procedures describing the procedures for procurement, packaging, labelling and transportation of gametes, embryos or tissue/cell samples to the point of arrival at the Centre or, in the case of direct distribution, to the Centre responsible for their application or, in the case of tissue/cell samples to the laboratory for testing.

Related Information

Directive 2006/17/EC, Art.2(5)

A.6.5 The Centre must ensure that procurement takes place:

- (a) in appropriate facilities and following procedures that minimise bacterial or other contamination, and
- (b) in an environment that ensures the health, safety and privacy of donors.

Related Information

Directive 2006/17/EC, Art.2(6) and (8)

A.7 Selection criteria and laboratory tests required from donors of reproduction cells (Schedule 3A)

A.7.1 Partner-donated sperm (stored) — In relation to partner donated sperm, which is to be processed or stored, the Centre shall comply with the following selection criteria and requirements for laboratory tests, namely:

- (a) the clinician responsible for the Donor must determine and document, based on the patient's medical history and therapeutic indications, give justification for the donation and its safety for the recipient and any child(ren) that might result,
- (b) the following biological tests must be carried out to assess the risk of cross contamination unless the Centre can demonstrate that the risk of cross contamination and staff exposure has been addressed through the use of validated processes:
 - HIV 1 and 2: Anti-HIV – 1, 2
 - Hepatitis B: HBsAg / Anti-HBc
 - Hepatitis C: Anti-HCV-Ab
- (c) where HIV1 and 2, Hepatitis B or Hepatitis C Test results are positive or unavailable, or where the Donor is known to be a source of infection risk, a system of separate storage must be devised,
- (d) HTLV- 1 Antibody Testing must be performed for Donors living in or originating from high incidence areas or with sexual partners originating from those areas or where the Donor's parents originate from those areas,
- (e) in certain circumstances, additional testing may be required depending on the Donor's travel and exposure history and the characteristics of the tissue or cells donated (e.g. Rh D, Malaria, CMV, T.cruzi),
- (f) positive results will not necessarily prevent partner donation.

Related Information

Directive 2006/17/EC, Annex III, para.2
HFE Act 1990, Sched.3A, paras 6-8 (as amended)

A.7.2 Donations other than by partners — In relation to donations of gametes or embryos other than Patient Partner donated sperm or partner created embryos, the Centre shall comply with the selection criteria for Donors and the requirements for laboratory tests set out below, namely:

- (a) Donors must be selected on the basis of their age, health and medical history, provided on a questionnaire and through a personal interview performed by a qualified and trained healthcare professional. This assessment must include relevant factors that may assist in identifying and screening out persons whose donations could present a health risk to others, such as the possibility of transmitting diseases, (such as sexually transmitted infections) or health risks to themselves (e.g. superovulation, sedation or the risks associated with the egg collection procedure or the psychological consequences of being a donor),
- (b) The Donors must be negative for HIV1 and 2, HCV, HBV and syphilis on a serum or plasma sample tested as follows, namely:
 - HIV 1 and 2: Anti-HIV – 1, 2
 - Hepatitis B: HBsAg / Anti-HBc
 - Hepatitis C: Anti-HCV-Ab
 - Syphilis: see (c) below
- (c) a validated testing algorithm must be applied to exclude the presence of active infection with *Treponema Pallidum*. The non-reactive test, specific or non-specific, can allow gametes to be released. When a non-specific test is performed, a reactive result will not prevent procurement or release if a specific *Treponema* confirmatory test is non-reactive. The donor whose specimen test reacted on a *Treponema*-specific test will require a thorough risk assessment to determine eligibility for clinical use,
- (d) in addition to the requirements in (b) and (c) above, sperm Donors must be negative for Chlamydia on a urine sample tested by the Nucleic Acid Amplification Technique (NAT)
- (e) all Donors must be screened for CMV,
- (f) HTLV-1 antibody testing must be performed for Donors living in or originating from high incidence areas or with sexual partners originating from those areas or where the Donor's parents originate from those areas,
- (g) in certain circumstances, additional testing may be required depending on the Donor's history and the characteristics of the gametes donated (eg RhD, Malaria, *T.cruzi*).

Related Information

Directive 2006/17/EC, Annex II, paras 1.4 and 3
Directive 2006/17/EC, Annex III, para.3

A.7.3 General requirements to be met for determining biological markers — The Centre must ensure that the laboratory tests required by A.3.5.1 and A.3.5.2 above meet the following requirements, namely:

- (a) the test must be carried out by a qualified laboratory which has suitable accreditation (for example by CPA (UK) Ltd or another body accrediting to an equivalent standard), using CE marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge,
- (b) blood samples must be obtained at the time of donation,
- (c) sperm donations other than by Patient Partners will be quarantined for a minimum of 180 days, after which repeat testing is required.

Related Information

Directive 2006/17/EC, Annex II, para.2.1 and Annex III, para.4

A.8 Donation and procurement procedures (Schedule 3A)

A.8.1 Before the procurement of gametes, an authorised person must confirm and record:

- (a) that consent for the procurement has been obtained, and
- (b) how and by whom the Donor has been reliably identified.

Related Information

Directive 2006/17/EC, Annex IV, para.1.1

A.8.2 The person in charge of the donation process shall ensure that the Donor has been properly informed of at least the following information prior to the procurement:

- (a) the purpose and nature of the procurement,
- (b) its consequences and risks,
- (c) analytical tests, if they are performed,
- (d) recording and protection of Donor data,
- (e) medical confidentiality,
- (f) therapeutic purpose and potential benefits,
- (g) information on the applicable safeguards intended to protect the Donor.

Related Information

Directive 2004/23/EC, Annex, Section A, paras 1 and 3
Directive 2004/23/EC, Art.15(3)

- A.8.3** The information referred to in A.8.2 above must be given by a trained person able to transmit it in an appropriate and clear manner, using terms that are easily understood by the Donor.

Related Information

Directive 2004/23/EC, Annex, Section A, para.2

- A.8.4** The Donor must be informed that s/he has the right to receive the confirmed results of the analytical tests, clearly explained.

Related Information

Directive 2004/23/EC, Annex, Section A, para.4

- A.8.5** Information must be given on the necessity for requiring the applicable mandatory consent, certification and authorisation in order that the gamete and/or embryo procurement can be carried out.

Related Information

Directive 2004/23/EC, Annex, Section A, para.5

- A.8.6** The health professional responsible for obtaining the health history must ensure that the Donor has:

- (a) understood the information provided,
- (b) had an opportunity to ask questions and been provided with satisfactory responses,
- (c) confirmed that all the information provided is true to the best of his/her knowledge.

Related Information

Directive 2006/17/EC, Annex IV, para.1.1

- A.8.7 Donor evaluation (not partner donation or autologous donation)** — In relation to Donor evaluation, other than Patient Partner donated sperm and partner created embryos and autologous Donors, an authorised person must collect and record the Donor's relevant medical and behavioural information. In order to acquire the appropriate information, different relevant sources must be used, including at least an interview with the Donor and the following when appropriate:

- (a) the medical records of the Donor,
- (b) an interview and / or correspondence with the treating physician,
- (c) an interview and / or correspondence with the General Practitioner,
- (d) a physical examination to detect any signs that may be sufficient in themselves to exclude the donor or which must be assessed in light of the Donor's medical and personal history,

- (e) The complete Donor records must be reviewed and assessed for suitability and signed by a qualified health professional.

Related Information

Directive 2006/17/EC, Annex IV, para.1.2

- A.8.8 Procurement procedures** — The procurement procedures for gametes and embryos must be appropriate for the type of Donor and type of material donated (i.e. gamete or embryo). There must be procedures in place to protect the safety of the Donor. The procurement procedures must protect those properties of the gamete or embryo that are required for their ultimate clinical use, and at the same time minimise the risk of microbiological contamination during the process.

Related Information

Directive 2006/17/EC, Annex IV, paras 1.3.1 and 1.3.2

- A.8.9** Any adverse event occurring during procurement that has or may have resulted in harm to the Donor and the outcome of any investigation to determine the cause must be recorded and reviewed.

Related Information

Directive 2006/17/EC, Annex IV, para.1.3.6

- A.8.10** Policies and procedures must be in place to minimise the risk of gamete or embryo contamination by staff who may be infected with transmissible diseases.

Related Information

Directive 2006/17/EC, Annex IV, para.1.3.7

- A.8.11** Sterile instruments and devices must be used for the tissue and cell procurement. Instruments or devices must be of a good quality, validated or specifically certified and regularly maintained for the purposes of procurement. When reusable instruments may be used, a validated cleaning and sterilisation procedure for the removal of infectious agents has to be in place. Wherever possible, only CE marked medical devices must be used and all concerned staff must have received appropriate training in the use of such devices.

Related Information

Directive 2006/17/EC, Annex IV, paras 1.3.8 to 1.3.10

- A.8.12 Donor documentation** — For each Donor, there must be a record containing:
- (a) the Donor identification (first name, family name and date of birth),
 - (b) age, sex, medical and behavioural history (the information collected must be sufficient to allow application of the exclusion criteria, where required),

- (c) the consent/authorisation form, where applicable,
- (d) clinical data, laboratory test results and the results of other tests carried out.

Related Information

Directive 2006/17/EC, Annex IV, para.1.4.1

- A.8.13** The organisation performing the procurement must produce a procurement report, which is passed on to the Centre. The report must contain at least:
- (a) the identification, name and address of the tissue establishment to receive the gametes or embryos,
 - (b) Donor identification data (including how and by whom the donor was identified),
 - (c) description and identification of procured gametes and embryos (including samples for testing where appropriate),
 - (d) identification of the person who is responsible for the procurement session, including signing,
 - (e) date, time (where relevant start and end) and location of procurement and procedure (SOP) used including any incidents that occurred; where relevant, environmental conditions at the procurement facility (description of the physical area where the procurement took place),
 - (f) ID/batch numbers of reagents and transport solutions used,
 - (g) where sperm is procured at home, the procurement report must state this and must contain only:
 - the name and address of the tissue establishment to receive the gametes or embryos, and
 - the Donor identification,
 - (h) all the records must be clear and readable, protected from unauthorised amendment and retained and readily retrieved in this condition throughout their specified retention period in compliance with data protection legislation,
 - (i) Donor records required for full traceability must be kept for a minimum of 30 years (or for such longer period as may be specified in directions) after clinical use, or the expiry date, in an appropriate archive acceptable to the HFEA.

Related Information

Directive 2006/17/EC, Annex IV para.1.4



- A.8.14 Packaging** — Following procurement, all recovered gametes and embryos must be packaged in a manner which minimises the risk of contamination and must be stored at temperatures that preserve the required characteristics and biological functions of the gametes or embryos. The packaging must also prevent contamination of those responsible for packaging and transportation.

Related Information

Directive 2006/17/EC, Annex IV, para.1.5.1

- A.8.15** The packaged gametes/embryos must be shipped in a container which is suitable for the transport of biological materials and which maintains the safety and quality of the gametes or embryos.

Related Information

Directive 2006/17/EC, Annex IV, para.1.5.2

- A.8.16** Any blood samples for testing must be accurately labelled to ensure identification with the Donor and must include a record of the time and place at which the specimen was taken.

Related Information

Directive 2006/17/EC, Annex IV, para.1.5.3

- A.8.17 Labelling of procured gametes/ embryos** — At the time of procurement, every package containing gametes or embryos must be labelled. The primary container must indicate the donation identification or code and whether it contains gametes or embryos. Where the size of the package permits, the following information must also be provided, namely:

- (a) date (and, where possible, time) of donation,
- (b) hazard warnings,
- (c) in the case of donations which are not stored, the label must identify the intended recipient.

If any of the information at points (a) to (c) above cannot be included on the primary package label, it must be provided on a separate sheet accompanying the primary package.

Related Information

Directive 2006/17/EC, Annex IV, para.1.6

- A.8.18 Labelling of the shipping container** — In the case of gametes or embryos shipped by an intermediary, every shipping container must be labelled with at least the following information:

- (a) TISSUES AND CELLS and HANDLE WITH CARE,

- (b) the identification of the establishment from which the package is being transported (address and phone number) and a contact person in the event of problems,
- (c) the identification of the tissue establishment of destination (address and phone number) and the person to be contacted to take delivery of the package,
- (d) the date and time of the start of transportation,
- (e) specifications concerning conditions of transport relevant to the quality and safety of the gametes or embryos,
- (f) in the case of all gametes and embryos, the following indication:
 - DO NOT IRRADIATE
- (g) When a product is known to be positive for a relevant infectious disease marker, the following indication:
 - BIOLOGICAL HAZARD
- (h) specifications concerning storage conditions (such as DO NOT FREEZE).

Related Information

Directive 2006/17/EC, Annex IV, para.1.7

A.9 Reception at the centre (Schedule 3A)

- A.9.1 Consent and Donor Identification** — In relation to the reception of gametes and embryos at the premises to which a licence relates or at relevant Third Party premises, the Centre must ensure compliance with the following requirements set out in A.9.2 – A.9.6.

Related Information

HFE Act 1990, Sched.3A, para.9(b) (as amended)

- A.9.2** When the gametes or embryos arrive at the Centre, there must be documented Verification that the consignment including the transport conditions, packaging, labelling and associated documentation and samples, meet the requirements of any Licence Conditions, the Standards contained in the Authority's Code of Practice and any specifications of the receiving Centre.

Related Information

Directive 2006/17/EC, Annex IV, para.2.1

- A.9.3** The Centre must ensure that the gametes and embryos received are quarantined until they, along with associated documentation, have been inspected or otherwise verified as conforming to requirements. The review of relevant donor/procurement information and thus acceptance of the donation needs to be carried out by specified/authorised persons.

Related Information

Directive 2006/17/EC, Annex IV, para.2.2

- A.9.4** The Centre must have documented policy and specifications against which each consignment of gametes or embryos are verified. These must include the technical requirements and other criteria considered by the Centre to be essential for the maintenance of acceptable quality. The Centre must have documented procedures for the management and segregation of non-conforming consignments, or those with incomplete test results, to ensure that there is no risk of contamination of other gametes and embryos being processed, preserved or stored.

Related Information

Directive 2006/17/EC, Annex IV, para.2.3

- A.9.5** The data that must be registered at the Centre (other than in respect of partner donated sperm and partner created embryos) include:
- (a) consent/authorisation, including the purpose(s) for which the gametes and embryos may be used and any specific instructions for disposal if the gametes or embryos are not used for the purpose for which consent was obtained,
 - (b) all required records relating to the procurement and the taking of the donor history,
 - (c) results of physical examination, of laboratory tests and other tests,
 - (d) a properly documented review of the complete Donor evaluation against a selection criteria by an authorised and trained person.

Related Information

Directive 2006/17/EC, Annex IV, para.2.4

- A.9.6** In the case of Patient Partner donated sperm and partner created embryos, the data to be registered at the Centre include:
- (a) consent, including the purpose(s) for which the gametes and embryos may be used and any specific instructions for disposal if the gametes or embryos are not used for the purpose for which consent was obtained,
 - (b) donor identification and characteristics; type of donor, age, sex and presence of risk factors,
 - (c) partner identification,

- (d) the place of procurement,
- (e) gametes and embryos obtained and relevant characteristics.

Related Information

Directive 2006/17/EC, Annex IV, para.2.5

A.10 Requirements for holding a licence (Schedule 2, paragraph 1, 1A or 2)

- A.10.1 Organisation and management** — The Centre must have an organisational structure and operational procedures appropriate to the activities authorised by the licence; there must be an organisational chart which clearly defines accountability and reporting relationships.

Related Information

Directive 2006/86/EC, Annex I, Part A, para.2

- A.10.2** The Centre must have access to a nominated Registered Practitioner to advise on and oversee the Centre's medical activities such as Donor selection, review of clinical outcomes or interaction as appropriate with clinical users.

Related Information

Directive 2006/86/EC, Annex I, Part A, para.3

- A.10.3** There must be a documented Quality Management System applied to the activities for which a Licence has been granted or is being sought, in accordance with the standards laid down in licence conditions, or the Standards set out in the Code of Practice.

Related Information

Directive 2006/86/EC, Annex I, Part A, para.4

- A.10.4** It must be ensured that risks inherent in the use and handling of biological material are identified and minimised, consistent with maintaining adequate quality and safety for the intended purpose of the gametes or embryos. The risks include those relating in particular to the procedures, environment, staff health status, specific to the Centre concerned.

Related Information

Directive 2006/86/EC, Annex I, Part A, para.5

- A.10.5** Agreements with Third Parties must specify the terms of the relationship and responsibilities as well as the protocols to be followed to meet the required performance specification.

Related Information

Directive 2006/86/EC, Annex I, Part A, para.6.



- A.10.6** There must a documented system in place supervised by the Person Responsible for ratifying that gametes and/or embryos meet appropriate specifications for safety and quality for release and for their distribution.

Related Information

Directive 2006/86/EC, Annex I, Part A, para.7

- A.10.7** In the event of termination of activities, the agreements concluded and the procedures adopted shall include Traceability data and material concerning the quality and safety of gametes and embryos.

Related Information

Directive 2006/86/EC, Annex I, Part A, para.8.

- A.10.8** There must be a documented system in place that ensures that identification of every gamete or embryo at all stages of the licensable activities.

Related Information

Directive 2006/86/EC, Annex I, Part A, para.9

- A.10.9 Personnel** — Personnel in the Centre must be available in sufficient number and be qualified for the tasks they perform. The competency of the personnel must be evaluated at appropriate intervals specified in the quality system.

Related Information

Directive 2006/86/EC, Annex I, Part B, para.1

- A.10.10** All personnel should have clear, documented and up-to-date job descriptions. Their tasks, responsibilities and accountability must be clearly documented and understood.

Related Information

Directive 2006/86/EC, Annex I, Part B, para.2

- A.10.11** Personnel must be provided with initial/basic training, updated training as required when procedures change or scientific knowledge develops, and adequate opportunity for relevant professional development. The training programme must ensure and document that each individual:

- (a) has demonstrated confidence in the performance of their designed tasks,
- (b) has an adequate knowledge and understanding of the scientific/ technical processes and principles relevant to their designated tasks,
- (c) understands the organisational framework, quality system and Health & Safety rules of the Centre in which they work, and

- (d) is adequately informed of the broader ethical, legal and regulatory context of their work.

Related Information

Directive 2006/86/EC, Annex I, Part B, para.3

- A.10.12 Equipment and Materials** — All equipment and materials must be designed and maintained to suit their intended purpose and must minimise any hazard to patients and/or staff.

Related Information

Directive 2006/86/EC, Annex I, Part C, para.1

- A.10.13** All critical equipment and technical devices must be identified and validated, regularly inspected and preventively maintained in accordance with the manufacturer's instructions. Where equipment or materials affect critical processing or storage parameters (e.g. temperature, pressure, particle counts, microbial contamination levels), they must be identified and be the subject of appropriate monitoring, alerts, alarms and corrective action, as required, to detect malfunctions and defects, and to ensure that the critical parameters are maintained within acceptable limits at all times. All equipment with critical measuring function must be calibrated against a traceable standard if available.

Related Information

Directive 2006/86/EC, Annex I, Part C, para.2

- A.10.14** New and repaired equipment must be tested when stored and must be validated before use. Test results must be documented.

Related Information

Directive 2006/86/EC, Annex I, Part C, para.3

- A.10.15** Maintenance, servicing, cleaning, disinfection and sanitation of all critical equipment must be performed regularly and recorded accordingly.

Related Information

Directive 2006/86/EC, Annex I, Part C, para.4

- A.10.16** Procedures for the operation of each piece of critical equipment, detailing the action to be taken in the event of malfunctions or failure, must be available.

Related Information

Directive 2006/86/EC, Annex I, Part C, para.5

- A.10.17** The procedures for licensable activities must detail the specifications for all critical materials and reagents. In particular, specifications for additives (e.g. solutions) and packaging materials must be defined. Critical reagents and materials must meet documented

requirements and specifications and when applicable the requirements of Council Directive 93/94/EEC of 14 June 1993 concerning medical devices and Directive 98/79/EC of the European Parliament under the Council of 27 October 1998 on In vitro Diagnostic Medical Devices.

Related Information

Directive 2006/86/EC, Annex I, Part C, para.6

- A.10.18 Facilities / premises** — A Centre must have suitable facilities to carry out the activities for which a licence has been granted, in accordance with licence conditions and the Standards set out in the Code of Practice.

Related Information

Directive 2006/86/EC, Annex I, Part D, para.1

- A.10.19** The processing of gametes and embryos while exposed to the environment must take place in an environment with specified air quality and cleanliness in order to minimise the risk of contamination, including cross contamination between donations. To achieve this, such gametes and embryos must be processed in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality as defined in the current European Guide to Good Manufacturing Practice (GMP) Annex 1 and Directive 2003/94/EC. The effectiveness of these measures must be annotated and monitored.

It must be demonstrated and documented that the chosen environment achieves the quality and safety required, taking into account, at least, the intended purpose, mode of application and immune status of the recipient. Appropriate garments and equipment for personal protection and hygiene must be provided in each relevant department of the Centre along with written hygiene and gowning instructions.

Related Information

Directive 2006/86/EC, Annex I, Part D, paras 2 and 5

- A.10.20** Where the licensed activities include storage of gametes or embryos, the storage conditions necessary to maintain the gametes or embryos, including relevant parameters such as temperature, humidity or air quality must be defined.

Related Information

Directive 2006/86/EC, Annex I, Part D, para.6

- A.10.21** The critical parameters (e.g. temperature, humidity, air quality) must be controlled, monitored and recorded to demonstrate compliance with the specified storage conditions.

Related Information

Directive 2006/86/EC, Annex I, Part D, para.7

- A.10.22** Storage facilities must be provided that clearly separate and distinguish gametes and embryos prior to release/ in quarantine from those that are released and those which are rejected, in order to prevent mix up and cross contamination between them. Physically separate areas or storage devices or secured segregation within the device must be allocated in both quarantine and released stored locations for holding gametes or embryos.

Related Information

Directive 2006/86/EC, Annex I, Part D, para.8

- A.10.23** The Centre must have written policies and procedures for controlled access, cleaning and maintenance, waste disposal and for the re-provision of services in an emergency situation.

Related Information

Directive 2006/86/EC, Annex I, Part D, para.9

- A.10.24 Documentation and Records** — There must be a system in place that results in clearly defined and effective documentation, correct records and registers and authorised Standard Operating Procedures (SOPs), for the activities for which a licence has been granted. The documents must be regularly reviewed and must conform to relevant licence conditions and the Standards set out in the Code of Practice. The system must ensure that work performed is standardised and that all steps are traceable (i.e. coding, Donor eligibility, procurement, processing, preservation, storage, transport, distribution or disposal including aspects relating to quality control and quality assurance).

Related Information

Directive 2006/86/EC, Annex I, Part E, para.1

- A.10.25** For every critical activity, the materials, equipment and personnel involved must be identified and documented.

Related Information

Directive 2006/86/EC, Annex I, Part E, para.2

- A.10.26** All changes to documents must be reviewed, dated, approved, documented and implemented promptly by authorised personnel.

Related Information

Directive 2006/86/EC, Annex I, Part E, para.3

- A.10.27** A document control procedure must be established to provide for the history of document reviews and changes and to ensure that any current versions of documents are in use.

Related Information

Directive 2006/86/EC, Annex I, Part E, para.4

A.10.28 Records must be shown to be reliable and a true representations of the results.

Related Information

Directive 2006/86/EC, Annex I, Part E, para.5

A.10.29 Records must be legible and indelible and may be hand written or transferred to another validated system, such as a computer or microfilm.

Related Information

Directive 2006/86/EC, Annex I, Part E, para.6

A.10.30 Without prejudice to the requirement to retain data for at least 30 years, all records, including raw data, which are critical to the safety and quality of the embryos and gametes shall be kept so as to ensure access to the data for at least 10 years after the expiry date, clinical use or disposal.

Related Information

Directive 2006/86/EC, Annex I, Part E, para.7

A.10.31 Records must meet the confidentiality requirements which are laid down in Licence Conditions and in the Standards contained in the Code of Practice. Access to registers and data must be restricted to persons authorised by the Person Responsible and to the HFEA for the purpose of inspection and control measures.

Related Information

Directive 2006/86/EC, Annex I, Part E, para.8

A.10.32 Quality Review —Trained and competent persons must audit the activities for which a licence is being sought against compliance with the approved protocols and the regulatory requirements. These audits should be performed in an independent way, at least every two years. Findings and corrective actions must be documented.

Related Information

Directive 2006/86/EC, Annex I, Part F, para.1

A.10.33 Deviations from the required standards of quality and safety must lead to documented investigations, which include a decision on possible corrective and preventive actions. The fact of nonconforming gametes and embryos must be decided in accordance with written procedures supervised by the Person Responsible and recorded. All affected gametes and embryos must be identified and accounted for.

Related Information

Directive 2006/86/EC, Annex I, Part F, para.1

- A.10.34** Corrective actions must be documented, initiated and completed in a timely and effective manner. Preventive/corrective actions should be assessed for effectiveness after implementation.

Related Information

Directive 2006/86/EC, Annex I, Part F, para.3

- A.10.35** The Centre must have processes in place to review the performance of the Quality Management System to ensure continuous and systematic improvement.

Related Information

Directive 2006/86/EC, Annex I, Part F, para.4

A.11 Requirements for holding a licence (Schedule 2, paragraph 1, 1A or 2)

- A.11.1** Centres must include in their Standard Operating Procedures all Processes, and modifications thereto, that affect quality and safety of gametes and embryos, and must ensure that they are carried out under controlled conditions. The Standard Operating Procedures must include special provisions for the handling of gametes and embryos to be disposed, in order to prevent the contamination of other gametes or embryos, the processing environment or personnel.

Related Information

Directive 2004/23/EC, Art.21(1) to (3)

- A.11.2** Centres must ensure that all storage Processes are carried out under controlled conditions.

Related Information

Directive 2004/23/EC, Art.21(2)

- A.11.3** Centres must establish and apply procedures for the control of packaging and storage areas, in order to prevent any situation arising that might adversely affect the properties or Quality of gametes and embryos.

Related Information

Directive 2004/23/EC, Art.21(3)

- A.11.4** Processed gametes or embryos shall not be distributed until all the requirements laid down in licence conditions and the Standards set out in the Code of Practice have been met.

Related Information

Directive 2004/23/EC, Art.21(4)



- A.11.5 Reception at the Centre** — In relation to the reception of gametes and embryos at the premises to which a licence relates or at relevant third party premises, the Centre must ensure compliance with the following requirements set out in A.11.6 – A.11.10.

Related Information

Directive 2006/17/EC, Annex IV, para.2.1

- A.11.6** When the gametes or embryos arrive at the Centre, there must be documented Verification that the consignment including the transport conditions, packaging, labelling and associated documentation and samples, meet the requirements of any licence conditions, the Standards set out in the Code of Practice and any specifications of the receiving Centre.

Related Information

Directive 2006/17/EC, Annex IV, para.2.2

- A.11.7** The Centre must ensure that the gametes and embryos received are quarantined until they, along with associated documentation, have been inspected or otherwise verified as confirming to requirements. The review of relevant donor/procurement information and thus acceptance of the donation needs to be carried out by specified/authorised persons.

Related Information

Directive 2006/17/EC, Annex IV, para.2.3

- A.11.8** The Centre must have documented policy and specifications against which each consignment of gametes or embryos are verified. These must include the technical requirements and other criteria considered by the Centre to be essential for the maintenance of acceptable quality. The Centre must have documented procedures for the management and segregation of nonconforming consignments, or those with incomplete test results, to ensure that there is no risk of contamination of other gametes and embryos being processed, preserved or stored.

Related Information

Directive 2006/17/EC, Annex IV, para.2.3

- A.11.9** The following data must be registered at the Centre (other than in respect of Patient Partner donated sperm and partner created embryos):

- (a) consent/authorisation, including the purpose(s) for which the gametes and embryos may be used and any specific instructions for disposal if the gametes or embryos are not used for the purpose for which consent was obtained,
- (b) all required records relating to the procurement and the taking of the Donor history,
- (c) results of physical examination, of laboratory tests and of other tests,
- (d) a properly documented review of the complete Donor evaluation against a selection criteria by an authorised and trained person.

Related Information

Directive 2006/17/EC, Annex IV, para.2.4

A.11.10 In the case of partner donated sperm and partner created embryos, the following data must be registered at the Centre:

- (a) consent, including the purpose(s) for which the gametes and embryos may be used and any specific instructions for disposal if the gametes or embryos are not used for the purpose of which consent was obtained,
- (b) Donor identification and characteristics: age, sex and presence of risk factors,
- (c) Patient Partner identification,
- (d) the place of procurement,
- (e) gametes and embryos obtained and relevant characteristics.

Related Information

Directive 2006/17/EC, Annex IV, para.2.5

A.11.11 Processing — The critical processing procedures must be validated and must not render the gametes or embryos clinically ineffective or harmful to the recipient. This Validation may be based on studies performed by the establishment itself, or on data from published studies or from well-established processing procedures, by retrospective evaluation of the clinical results of tissues provided by the establishment.

Related Information

Directive 2006/86/EC, Annex II, Part B, para.1

A.11.12 The centre's procedures must be able to demonstrate that the validated Process can be carried out consistently and effectively in the Centre environment by the staff.

Related Information

Directive 2006/86/EC, Annex II, Part B, para.2

A.11.13 The procedures must be documented in SOPs, which must conform to the validated method and to the Requirements of licence conditions and Standards set out in the Code of Practice.

Related Information

Directive 2006/86/EC, Annex II, Part B, para.3

A.11.14 It must be ensured that all Processes are conducted in accordance with the approved SOPs.

Related Information

Directive 2006/86/EC, Annex II, Part B, para.4

- A.11.15** Before implementing any significant change in Processing, the modified Process must be validated and documented.

Related Information

Directive 2006/86/EC, Annex II, Part B, para.6

- A.11.16** The Processing procedures must undergo regular critical examination to ensure that they continue to achieve the intended results.

Related Information

Directive 2006/86/EC, Annex II, Part B, para.7

- A.11.17** Procedures for disposing of gametes and embryos must prevent the contamination of other donations and products, the processing environment or personnel.

Related Information

Directive 2006/86/EC, Annex II, Part B, para.8

- A.11.18 Storage and release of products** — The maximum storage time must be specified for each type of storage condition. The selected period must take into account, among other things, the possible deterioration of the quality of the released gametes and embryos.

Related Information

Directive 2006/86/EC, Annex II, Part C, para.1

- A.11.19** There must be a system for ensuring gametes or embryos cannot be released until all requirements of licence conditions and Standards set out in the Code of Practice have been satisfied. There must be a standard operating procedure that details the circumstances, responsibilities and procedures for the release of gametes or embryos for distribution.

Related Information

Directive 2006/86/EC, Annex II, Part C, para.2

- A.11.20** A system for the identification of donor gametes or embryos throughout any phase of processing in the Centre must clearly distinguish released from non-released (quarantined) and discarded products.

Related Information

Directive 2006/86/EC, Annex II, Part C, para.3

- A.11.21** Records must demonstrate that before gametes and embryos are released all appropriate specifications are met, in particular all current declaration forms, relevant medical records, processing records and test results have been verified according to a written Procedure

by a person authorised for this task by the Person Responsible. If a computer is used to release results from the laboratory, an audit trail should indicate who is responsible for their release.

Related Information

Directive 2006/86/EC, Annex II, Part C, para.4

- A.11.22** A documented risk assessment approved by the Person Responsible must be undertaken to determine the fate of all stored gametes and embryos following the introduction of any new Donor selection or testing criterion or any significantly modified processing step that enhances safety or Quality.

Related Information

Directive 2006/86/EC, Annex II, Part C, para.5

- A.11.23 Distribution and Recall** — Critical transport conditions, such as the temperature and time limit, must be defined to maintain the required properties of the gametes or embryos.

Related Information

Directive 2006/86/EC, Annex II, Part D, para.1

- A.11.24** The container/package must be secure and ensure that the gametes or embryos are maintained in the specified conditions. All containers and packages need to be validated as fit for purpose.

Related Information

Directive 2006/86/EC, Annex II, Part D, para.2

- A.11.25** There must be personnel authorised within the Centre to assess the need for recall and to initiate and co-ordinate the necessary actions.

Related Information

Directive 2006/86/EC, Annex II, Part D, para.4

- A.11.26** An effective recall procedure for donated gametes must be in place, including a description of the responsibilities and actions to be taken. This must include notification to the Authority.

Related Information

Directive 2006/86/EC, Annex II, Part D, para.5

- A.11.27** Actions must be taken within predefined periods of time and must include tracing all relevant gametes and embryos and, where applicable, must include trace-back. The purpose of the investigation is to notify consignees and recipients of gametes and embryos procured from the same Donor in the event that they might have been put at risk.

Related Information

Directive 2006/86/EC, Annex II, Part D, para.6

- A.11.28** Procedures must be in place for the handling of requests for gametes or embryos. The rules for allocation of gametes and embryos to certain patients or healthcare institutions must be documented and made available to these parties upon request.

Related Information

Directive 2006/86/EC, Annex II, Part D, para.7

- A.11.29** A documented system must be in place for the handling of returned products including criteria for their acceptance if applicable.

Related Information

Directive 2006/86/EC, Annex II, Part D, para.8

- A.11.30 Final Labelling for Distribution** — The primary gamete/embryo container must be labelled with at least the following information:

- (a) type of gametes or embryos
- (b) identification number or code of the gametes/embryos and lot or batch number where applicable
- (c) identification of the Centre
- (d) expiry date
- (e) in the case of directed donations the label must identify the intended recipient
- (f) when gametes and embryos are known to be positive for a relevant infectious disease marker, it must be marked as “BIOLOGICAL HAZARD”.

If any of the information under the points above cannot be included on the primary container label, it must be provided on a separate sheet accompanying the primary container. The sheet must be packaged with the primary container in a manner that ensures that they remain together.

Related Information

Directive 2006/86/EC, Annex II, Part E, para.1

- A.11.31** The following information must be provided either on the label or on accompanying documentation:

- (a) description the gametes/embryos,
- (b) morphology and functional data where relevant,

- (c) date of distribution of the gametes/embryos,
- (d) biological determinations carried out on the Donor and results,
- (e) storage recommendations,
- (f) instructions for opening the container, package and any required manipulation/reconstitution,
- (g) instructions for reporting Serious Adverse Reactions and/or Events.

Related Information

Directive 2006/86/EC, Annex II, Part E, para.2

A.11.32 External labelling of the shipping container — For transport, the primary container must be placed in a shipping container that must be labelled with at least the following information:

- (a) identification of the originating Centre, including an address and phone number,
- (b) identification of the organisation responsible for human application or destination, including address and phone number,
- (c) a statement that the package contains human gametes/embryos and the words “HANDLE WITH CARE”,
- (d) recommended transport conditions (e.g. keep cool, in upright position, etc),
- (e) safety instructions.

Related Information

Directive 2006/86/EC, Annex II, Part F

A.12 Conditions of licences for treatment (section 13)

A.12.1 Such information shall be recorded as the Authority may specify in directions about the following:

- (a) the persons for whom services are provided in pursuance of the licence,
- (b) the services provided for them,
- (c) the persons whose gametes are kept or used for the purpose of services provided in pursuance of the licence or whose gametes have been used in bringing about the creation of embryos so kept or used,
- (d) any child appearing to the person responsible to have been born as a result of treatment in pursuance of the licence,
- (e) any mixing of egg and sperm and any taking of an embryo from a woman or other acquisition of an embryo, and

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

Related Information

HFE Act 1990, s.13(2)

- A.12.2** The records maintained in pursuance of the licence shall include any information recorded in pursuance of A.12.1 above and any consent of a person whose consent is required under Schedule 3 of the HFE Act 1990.

Related Information

HFE Act 1990, s.13(3)

- A.12.3** No information shall be removed from any records maintained in pursuance of the licence before the expiry of such period as may be specified in directions for records of the class in question.

Related Information

HFE Act 1990, s.13(4)

- A.12.4** A woman shall not be provided with treatment services other than basic partner 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.

Related Information

HFE Act 1990, s.13(5) (as amended)

- A.12.5** A woman shall not be provided with any treatment services involving:

- (a) the use of any gametes of any person, if that person's consent is required under paragraph 5 of Schedule 3 of the HFE Act 1990 for the use in question,
- (b) the use of any embryo the creation of which was brought about in vitro, or
- (c) the use of any embryo taken from a woman, if the consent of the women from whom it was taken is required under paragraph 7 of that Schedule for the use in question,

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

Related Information

HFE Act 1990, s.13(6)

- A.12.6** Suitable procedures shall be maintained:

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

Related Information

HFE Act 1990, s.13(7)

A.13 Additional conditions of licences for treatment (Schedule 2, paragraph 1(2))

- A.13.1** Where the Centre proposes to introduce new activities or treatment services not specified in the licence, these may not be commenced until notification has been given to the Authority and, where the Authority considers it necessary, an application has been made to the Authority for a licence relating to the new activities, and such a licence has been granted.

Related Information

HFE Act 1990, Sched.2, para.1(2)

- A.13.2** In support of an inspection the Authority shall be provided, within 28 days of a request in writing being made, with such information as specified in the written request or in Directions.

Related Information

HFE Act 1990, Sched.2, para.1(2)

- A.13.3** In consideration of the grant of the licence (or its variation to designate the individual named in this licence as Person Responsible), the Person Responsible agrees that s/he will pay to the Authority any additional fee, as defined in section 16(6) of the Act, within 28 days of the date of the notice of such additional fee.

Related Information

HFE Act 1990, Sched.2, para.1(2)

- A.13.4** That a copy of the Certificate of Licence (first page of the licence) describing the activities authorised by the licence must be displayed at the licensed premises in a position or positions in which it can easily be read by persons who are receiving treatment services or providing gametes or embryos for use for the purpose of activities governed by the Act, or who may wish to do so.

Related Information

HFE Act 1990, Sched.2, para.1(2)

- A.13.5** That the Person Responsible advises the HFEA immediately if they become aware of any decision or proposal to close their Centre.

Related Information

HFE Act 1990, Sched.2, para.1(2)

- A.13.6** With respect to any Intra-cytoplasmic Sperm Injection (ICSI) programme the following conditions apply:
- (a) that ICSI and other embryos should only be transferred during the same treatment cycle in exceptional circumstances, with an upper limit of 2% of all ICSI embryo transfers, and should only be carried out by ICSI practitioners who have demonstrated technical competence. The circumstances justifying such a transfer should be specified in the patient's notes and such cycles should be notified to the Authority on a monthly basis,
 - (b) that oocytes which have failed after 24 hours to fertilise by normal IVF procedure are not to be used in ICSI treatment,
 - (c) that clinical ICSI is carried out only by trained, competent staff,
 - (d) that the Person Responsible notifies the Authority before clinical ICSI procedures are first carried out by a particular practitioner at that centre.

Related Information

HFE Act 1990, Sched.2, para.1(2)

- A.13.7** With respect to any PGD or PGS programme involving blastomere/polar body biopsy the following conditions apply:
- (a) that embryos from which biopsies have been taken, or resulting from gametes from which biopsies have been taken, may not be transferred with any other (non- biopsy) embryos in the same treatment cycle,
 - (b) that no embryo or material removed from it may be subjected to a test which supplies genetic information about the embryo that is not expressly authorised by the licence issued to the Centre,
 - (c) that no embryo may be transferred to a woman where that embryo or any material removed from it or from the gametes that produced it, has been subject to a test, which supplies genetic information about the embryo, that is not expressly authorised by the licence issued to the Centre,
 - (d) that Centres should not use any information derived from tests on an embryo, or any material removed from it or from the gametes that produced it, to select embryos of a particular sex for social reasons,
 - (e) that blastomere/polar body biopsy is carried out only by trained competent staff recognised as such by the Authority.

Related Information

HFE Act 1990, Sched.2, para.1(2)

A.13.8 With respect to any PGD programme the following conditions apply:

- (a) that preimplantation testing may only be carried out for those genetic conditions, chromosomes or traits (or combinations of these), and using the specific tests (or combinations of tests), that are expressly authorised by the licence issued to the Centre,
- (b) that, where the Centre wishes to carry out preimplantation testing which is not expressly authorised by the Centre's licence, the Centre must submit an application in the form specified in Directions for that purpose to the Authority. The preimplantation testing concerned must not be commenced until the Centre has received written confirmation from the Authority that the testing may be carried out under the Centre's licence.

Related Information

HFE Act 1990, Sched.2, para.1(2)

A.13.9 With respect to any PGS programme for aneuploidy the following conditions apply:

- (a) that preimplantation genetic screening (PGS) for aneuploidy may only be carried out for the chromosomes, or combination of chromosomes, and using the specific tests, or combinations of tests, that are expressly authorised by the licence issued to the Centre. Where the Centre wishes to carry out preimplantation screening for aneuploidy which is not expressly authorised by the Centre's licence, the centre must submit an application to the Authority in the form specified in Directions for that purpose. The preimplantation screening concerned must not be commenced until the Centre has received written confirmation from the Authority that the screening may be carried out under the Centre's licence,
- (b) that Centres should not use any information derived from tests on an embryo, or any material removed from it or from the gametes that produced it, to select embryos of a particular sex for social reasons,
- (c) that PGS for aneuploidy may only be used in the treatment of the following categories of patient:
 - (i) women over 35 years of age,
 - (ii) women with a history of recurrent miscarriage not caused by translocations or other chromosomal rearrangements,
 - (iii) women with several previous failed IVF attempts where embryos have been transferred,
 - (iv) women with a family history of aneuploidy not caused by translocations or other chromosomal rearrangements,
 - (v) male partners whose sperm has higher than normal levels of aneuploidy.

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

Related Information

HFE Act 1990, Sched.2, para.1(2)

- A.13.10** The Centre may not attempt to produce embryos in vitro unless there is an intention to store or use the resulting embryo(s) or unless there is a specific reason why it is necessary to do in connection with the provision of treatment services for a particular woman.

Related Information

HFE Act 1990, Sched.2, para.1(2)

- A.13.11** The Centre may not:

- (a) select the sex of embryos for social reasons, or
- (b) attempt to produce embryos in vitro by embryo splitting for treatment purposes.

Related Information

HFE Act 1990, Sched.2, para.1(2)

A.13.12 With respect to any donor gamete or embryo treatment programme the following conditions apply:

- (a) that gametes taken from a person who has given such consent as is required by paragraph 5 of Schedule 3 to the Human Fertilisation and Embryology Act 1990 (a 'gamete donor') and who last provided information as to their identity before 1 April 2005 to a person to whom a licence applies, and
- (b) that embryos, the creation of which was brought about using gametes taken from any person who has given a consent under paragraph 2(1)(b) of Schedule 3 to the Human Fertilisation and Embryology Act 1990 (an 'embryo donor') and who last provided information as to their identity before 1 April 2005 to a person to whom a licence applies,

may not be used for a purpose for which such consent would be required, except—

- (i) in the case of gametes supplied by the Donor before 1 April 2005, where the woman to be treated or, where she is receiving treatment together with another person, that person, is the parent of a child conceived as a result of treatment services provided before 1 April 2006 using gametes provided by the Donor of those gametes, or
- (ii) in the case of embryos created before 1 April 2005, where the woman to be treated or, where she is receiving treatment together with another person, that person, is the parent of a child conceived as a result of treatment services provided before 1 April 2006 using embryos donated by those who provided the gametes from which those embryos were created, or
- (iii) in the case of embryos, where the embryos were created before 1 April 2006 using gametes supplied by a Donor before 1 April 2005 together with the gametes of the woman to be treated or, where she is receiving treatment together with another person, with the gametes of a Donor together with the gametes of that person, and not transferred to the woman to be treated before that date.

In the case of treatments falling within the exemptions at (i) to (iii) above, the gametes or, as the case may be, embryos, may be kept in storage and used in accordance with the consent of the gamete providers until the expiry of the maximum permitted storage period.

Related Information

HFE Act 1990, Sched.2, para.1(2)

A.14 Conditions of licences for non-medical fertility services (Section 13A)

A.14.1 The requirements of A.12.1 to A.12.3 and A.12.6 shall be complied with.

Related Information

HFE Act 1990, s.13A(2) (as amended)

- A.14.2** A woman shall not be provided with any non-medical fertility services involving the use of sperm other than partner-donated sperm unless the woman being provided with the services has been given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and has been provided with such relevant information as is proper.

Related Information

HFE Act 1990, s.13A(3) (as amended)

- A.14.3** Donors of sperm, other than partner-donated sperm, shall be provided with such information as the Authority specifies in Directions for the purpose of securing compliance with the requirements of A.8.2 to A.8.6.

Related Information

HFE Act 1990, s.13A(4) (as amended)

A.15 Conditions of storage licences (Section 14)

- A.15.1** Gametes of a person or an embryo taken from a woman shall be placed in storage only if received from that person or woman or acquired from a person to whom a licence applies and that an embryo, the creation of which has been brought about in vitro otherwise than in pursuance of this licence, shall be placed in storage only if acquired from a person to whom a licence applies.

Related Information

HFE Act 1990, s.14(1)(a)

- A.15.2** Gametes or embryos which are or have been stored shall not be supplied to a person otherwise than in the course of providing treatment services unless that person is a person to whom a licence applies.

Related Information

HFE Act 1990, s.14(1)(b)

- A.15.3** No gametes or embryos shall be kept in storage for longer than the statutory storage period and, if stored at the end of the period, shall be allowed to perish.

Related Information

HFE Act 1990, s.14(1)(c)

- A.15.4** Such information as the Authority may specify in Directions as to the persons whose consent is required under Schedule 3 to the HFE Act 1990, the terms of their consent and the circumstances of the storage and as to such other matters as the Authority may specify in Directions shall be included in the records maintained in pursuance of this licence.

Related Information

HFE Act 1990, s.14(1)(d)

- A.15.5** No information shall be removed from any records maintained in pursuance of the licence before the expiry of such period as may be specified in Directions for Records of the class in question.

Related Information

HFE Act 1990, s.14(2)

A.16 Additional conditions of storage licences (Schedule 2, paragraph 2(2))

- A.16.1** Where the Centre proposes to introduce new activities or treatment services not specified in the licence, these may not be commenced until notification has been given to the Authority and, where the Authority considers it necessary, an application has been made to the Authority for a licence relating to the new activities and such a licence has been granted.

Related Information

HFE Act 1990, Sched.2, para.2(2)

- A.16.2** That in support of an inspection the Authority shall be provided, within 28 days of a request in writing being made, with such information as specified in the written request or in Directions.

Related Information

HFE Act 1990, Sched.2, para.2(2)

- A.16.3** In consideration of the grant of the licence (or its variation to designate the individual named in this licence as Person Responsible), the Person Responsible agrees that he will pay to the Authority any additional fee, as defined in section 16(6) of the Act, within 28 days of the date of the notice of such additional fee.

Related Information

HFE Act 1990, Sched.2, para.2(2)

- A.16.4** A copy of the Certificate of Licence (first page of the licence) describing the activities authorised by the licence must be displayed at the licensed premises in a position or positions in which it can easily be read by persons who are receiving treatment services or providing gametes or embryos for use for the purpose of activities governed by the Act, or who may wish to do so.

Related Information

HFE Act 1990, Sched.2, para.2(2)

- A.16.5** The Person Responsible advises the HFEA immediately if they become aware of any decision or proposal to close their Centre.

Related Information

HFE Act 1990, Sched.2, para.2(2)

- A.16.6** With respect to treatment involving storage of eggs and any other subsequent activities the following conditions apply:
- (a) that the use of cryopreserved oocytes in treatment services shall be restricted to oocytes frozen at the preovulatory stage,
 - (b) that before a woman gives consent to the storage and/or use of cryopreserved oocytes in treatment services she must be given an oral explanation supported by relevant written material,
 - (i) of all risks associated with the cryopreservation and thawing of oocytes
 - (ii) that counselling is available,
 - (c) that Donors of cryopreserved oocytes shall be subject to the existing screening requirements as set out in the Code of Practice,
 - (d) that the Centre shall not mix, in the same treatment cycle:
 - (i) fresh oocytes with oocytes that have been cryopreserved,
 - (ii) embryos that have been created using cryopreserved oocytes with embryos created using fresh oocytes, or
 - (iii) cryopreserved embryos that have been created using cryopreserved oocytes with cryopreserved embryos that have been created using fresh oocytes.

Related Information

HFE Act 1990, Sched.2, para.2(2)

- A.16.7** With respect to treatment involving storage of eggs within ovarian tissue the following conditions apply:
- (a) that any oocytes obtained from cryopreserved ovarian tissue, shall not be used in any treatment services until such time as the Authority is satisfied that sufficient evidence on safety and efficacy is available to justify the introduction in to clinical practice of the replacement of embryos resulting from cryopreserved ovarian tissue,
 - (b) that before a woman gives consent to the storage of oocytes within cryopreserved ovarian tissue for their intended use in treatment services, she must be given an oral explanation supported by the relevant written material:

- (i) oocytes obtained from cryopreserved ovarian tissue cannot be used in treatment,
- (ii) of the risks associated with the removal cryopreservation and thawing of ovarian tissue,
- (iii) that counselling is available.

Related Information

HFE Act 1990, Sched.2, para.2(2)

A.17 Conditions of licences: human application (section 14A)

- A.17.1** A licence may not authorise the storage, procurement, testing, processing or distribution of gametes or embryos unless it contains the conditions required by Schedule 3 to the Act.

Related Information

HFE Act 1990, s.14A(2) (as amended)

- A.17.2** In relation to any gametes or embryos imported from Gibraltar or an EEA state other than the United Kingdom, compliance with the requirements of the laws or other measures adopted in the relevant territory or state for the purpose of implementing the first, second and third Directives shall be taken to be compliance with the conditions required by Schedule 3A to the Act.

Related Information

HFE Act 1990, s.14A(3) (as amended)

- A.17.3** A.17.2 shall not apply to any licence conditions imposed by the Authority which amount to more stringent protective measures.

Related Information

HFE Act 1990, s.14A(4) (as amended)

A.18 Conditions of research licences (section 15)

- A.18.1** The records maintained in pursuance of the licence shall include such information as the Authority may specify in directions about such matters as the Authority may so specify.

Related Information

HFE Act 1990, s.2 (as amended)

- A.18.2** No information shall be removed from any Records maintained in pursuance of the licence before the expiry of such period as may be specified in Directions for records of the class in question.



Related Information

HFE Act 1990, s.3 (as amended)

- A.18.3** No embryo appropriated for the purposes of any project of research shall be kept or used otherwise than for the purposes of such a project.

Related Information

HFE Act 1990, s.4

A.19 Additional conditions of licences for research (Schedule 2, paragraph 2(7))

- A.19.1** Where the Centre proposes to introduce new activities or treatment services not specified in the licence, these may not be commenced until notification has been given to the Authority and, where the Authority considers it necessary, an application has been made to the Authority for a licence relating to the new activities, and such a licence has been granted.

Related Information

HFE Act 1990, Sched.2, para.3(7)

- A.19.2** That, in support of an inspection, the Authority shall be provided, within 28 days of a request in writing being made, with such information as may be specified in the written request or in Directions.

Related Information

HFE Act 1990, Sched.2, para.3(7)

- A.19.3** A copy of the Certificate of Licence (first page of the licence) describing the activities authorised by the licence must be displayed at the licensed premises in a position or positions in which it can easily be read by persons who are receiving treatment services or providing gametes or embryos for use for the purpose of activities governed by the Act, or who may wish to do so.

Related Information

HFE Act 1990, Sched.2, para.3(7)

- A.19.4** The Person Responsible advises the HFEA immediately if they become aware of any decision or proposal to close their Centre.

Related Information

HFE Act 1990, Sched.2, para.3(7)

- A.19.5** With respect to any programme of research involving creation of embryos in vitro and/or use of donated embryo for research the following condition applies:

- (a) that the Centre shall, within a period specified in Directions, provide the Authority with a progress report as specified in Directions.

Related Information

HFE Act 1990, Sched.2, para.3(7)

A.19.6 With respect to any programme of research involving, or with the intention of involving, the extraction of human embryonic stem cells or the derivation of stem cell lines from embryos provided (or embryos created from gametes provided) by patients undergoing fertility treatment, the following conditions apply:

- (a) that the Centre must ensure that a designated individual who is not directly involved in the patient's treatment is available to discuss with patients the project of research and the possibility of donating material to the project,
- (b) that the Centre must ensure that clinical and research roles are separated, so that individuals involved in advising patients regarding clinical decisions about their licensed treatment are not involved in the research project to which patients are considering donating embryos,
- (c) that the Centre must uniquely label each embryo donated to the research project in accordance with any Directions and/ or guidance issued by the Authority,
- (d) that before donors give consent to donation of their embryos for use in the research project, they must be given oral information supported by relevant written material which confirms:
 - (i) the specific research project, including any tests may be performed as part of the licensed research project on embryos or cells derived from the embryos,
 - (ii) that any stem cells lines created may continue indefinitely and be used in many different research projects,
 - (iii) that the decision whether to donate will not affect their treatment in any way,
 - (iv) whether the embryos will be reversibly or irreversibly anonymised, and the implications of this,
 - (v) whether any information will be fed back to the Donors,
 - (vi) that the Donors can vary or withdraw the terms of their consent until the point at which the embryos are used in the project of research,
 - (vii) that once an embryo has been used in the project of research the donors have no control over any future use of the embryonic cells and any stem cell lines derived,
 - (viii) that stem cell lines derived in this project will be deposited in the MRC Stem Cell Bank and the implications of this including that they may be used for other projects,



- (ix) that stem cell lines must not be generated from donated embryos where the consent from the relevant Donors, or one of them, places a constraint on future use,
 - (x) that cell lines may be used for commercial purposes, but that the Donor will not benefit financially from this,
 - (xi) that any cell lines derived, or discoveries made using them, could be patented, but that the Donor will not benefit financially from this,
 - (xii) how the research is funded, including any benefit which will accrue to researchers and/ or their departments,
- (e) that the Centre must ensure:
- (i) that a sample of all stem cell lines derived from embryos that are developed or used in the course of the research project be deposited in a stem cell bank in accordance with any relevant bank guidelines,
 - (ii) that the remainder of all stem cell lines (insofar as not used or destroyed as part of or in the course of the research project) be deposited in the stem cell bank in accordance with any relevant bank guidelines.

Related Information

HFE Act 1990, Sched.2, para.3(7)

B.1 Introduction

There are a number of guidelines from professional organisations (see B.2) and information from other sources that constitute recommended good practice and that are particularly relevant to the provision of assisted conception services licensable by the HFEA. It is expected that Centres being assessed by the HFEA should, where appropriate, operate in conformity with this recommended good practice.

B.2 Guidelines and information for good practice

- B.2.1** Laboratory Andrology - Guidelines for Good Practice, Association of Biomedical Andrologists, March 2004
<http://www.andrology.pwp.blueyonder.co.uk>
- B.2.2** Accreditation Standards and Guidelines for IVF Laboratories, (Association of Clinical Embryologists, March 1999)
<http://www.embryologists.org.uk>
- B.2.3** Guidelines for the Screening of Semen Donors for Donor Insemination, (British Andrology Society,) July 1999, *Human Reproduction* 14 (7) 1823-1826
<http://humrep.oxfordjournals.org>
- B.2.4** Recommendations for Good Practice on the Screening of Egg and Embryo Donors, (British Fertility Society,) 2000, *Human Fertility* (2000) 3, 162-165
- B.2.5** Fertility Assessment and Treatment for People with Fertility Problems, (National Collaborating Centre for Women's and Children's Health, February 2004)
<http://www.nice.org.uk>
- B.2.6** Embryo Transfer: Recommendations for Good Practice, (British Fertility Society,) *Human Reproduction* 12 Natl. Suppl. JBFS 2(2) 88-92 1997
- B.2.7** Performing Intra Uterine Insemination and Embryo Transfer: RCN Guidance for Fertility Nurses, (Royal College of Nursing, December 2004)
<http://www.rcn.org.uk>
- B.2.8** Guidelines for nurses carrying out egg retrieval, (Royal College of Nursing 2000)
- B.2.9** BICA Guidelines for Good Practice in Infertility Counselling, (British Infertility Counselling Association: Sheffield, UK 2006)

B.3 General issues

- B.3.1** National Minimum Standards and Regulations for Independent Health Care, (Department of Health, 2002)
<http://www.dh.gov.uk>
- B.3.2** Standards for Better Health, (Department of Health, April 2006)
<http://www.dh.gov.uk>
- B.3.3** The NMC Code of Professional Conduct: Standards for Conduct, Performance and Ethics, (Nursing and Midwifery Council, November 2004)
<http://www.nmc-uk.org>
- B.3.4** Good Medical Practice, (General Medical Council, 2001)
<http://www.gmc-uk.org>
- B.3.5** Fertility: Assessment and treatment for people with fertility problems (Guideline 11), (National Institute for Clinical Excellence, 2004)
<http://www.nice.org.uk>
- B.3.6** Ethical Framework for Good Practice in Counselling and Psychotherapy, (British Association for Counselling and Psychotherapy, 2002)
<http://www.bacp.co.uk>
- B.3.7** Codes of Practice for Social Care Workers and Employers, (General Social Care Council, September 2002)
<http://www.gsc.org.uk>

B.4 Consent

- B.4.1** Reference Guide to Consent for Examination or Treatment, (Department of Health, April 2001)
<http://www.dh.gov.uk>



B.4.2 Seeking Patients' Consent: The Ethical Considerations, (General Medical Council, November 1998)

<http://www.gmc-uk.org>

B.4.3 Human Tissue Authority Code of Practice 1: Consent, (Human Tissue Authority, July 2006)

<http://www.hta.gov.uk>

B.5 Records and confidentiality

B.5.1 Records Management: NHS Code of Practice, Parts 1 & 2, (Department of Health, April 2006)

<http://www.dh.gov.uk>

B.5.2 After the Hundred Year Rule: Guidance for archivists and records managers on access to medical records under the Freedom of Information Act, (Health Archives Group, Society of Archivists, 2004)

<http://www.archives.org.uk>

B.5.3 Code of Practice on Confidential Personal Information, (Healthcare Commission, January 2005)

<http://www.healthcarecommission.org.uk>

B.5.4 Confidentiality and Disclosure of Information: General Medical Services, Personal Medical Services, and Alternative Provider Medical Services, Code of Practice, (Department of Health, March 2005)

<http://www.dh.gov.uk>

B.5.5 Confidentiality: NHS Code of Practice, (Department of Health, November 2003)

<http://www.dh.gov.uk>

B.6 Safe sedation

B.6.1 Implementing and Ensuring Safe Sedation Practice for Healthcare Procedures in Adults, (Academy of Medical Royal Colleges, 2002)

<http://www.rcoa.ac.uk>

B.7 Good manufacturing practice

B.7.1 Guide to Good Manufacturing Practice for Medicinal Products, 93/94/EEC, 1993

B.7.2 Rules and guidance for pharmaceutical manufacturers and distributors Guide to Good Manufacturing Practice for Medicinal Products, 91/356/EEC, 1991

B.7.3 The Control of Substances Hazardous to Health Regulations, 1999 (S.I. 1999 No. 437)

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<http://www.opsi.gov.uk>

B.7.4 Safety in Health Service Laboratories: Safe Working and Prevention of Infection in Clinical Laboratories, (Health Service Advisory Committee, 1991)

<http://www.hse.gov.uk>

B.8 Tissue storage and donation

B.8.1 Use of Human Organs and Tissue: A Draft Interim Statement for Consultation by the Department of Health, (Department of Health, April 2003)

<http://www.dh.gov.uk>

B.8.2 A Code of Practice for Tissue Banks Providing Tissues of Human Origin For Therapeutic Purposes, (Department of Health, 2001)

<http://www.dh.gov.uk>

B.8.3 Guidance on the Microbiological Safety of Human Organs, Tissues and Cells Used in Transplantation, (Department of Health, August 2000)

<http://www.dh.gov.uk>

B.8.4 Code of Practice 2: Donation of organs, tissue and cells for transplantation, (Human Tissue Authority, July 2006)

<http://www.hta.gov.uk>

B.8.5 Code of Practice 5: Removal, storage and disposal of human organs and tissues, (Human Tissue Authority, July 2006)

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B.9 Communicable diseases

- B.9.1** Protection against Blood-borne Viruses in the Workplace: HIV and Hepatitis, (Advisory Committee on Dangerous Pathogens, 1995)
<http://www.hse.gov.uk>
- B.9.2** Guidance for Clinical Health Care Workers: Protection against Blood-borne Viruses, (Department of Health, April 1998)
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- B.9.3** Revised Advice on Laboratory Containment Measures for Work with Tissue Samples in Clinical Cytogenetics Laboratories, (Advisory Committee On Dangerous Pathogens, 2001)

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

<http://www.rcpath.org>
- B.9.4** HIV Infected Health Care Workers: A Consultation Paper on Management and Patient Notification, (Department of Health, July 2002)
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- B.9.5** Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products, (Medicines Central Agency, 2004)
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- B.9.6** Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection, (Advisory Committee On Dangerous Pathogens, April 1998)
<http://www.dh.gov.uk>
- B.9.7** Protecting Health Care and Patients from Hepatitis B, (Department of Health, August 1993 and Scottish Office, 2003)
<http://www.dh.gov.uk>
- B.9.8** Hepatitis C Infected Health Care Workers, (Scotland Health Department, November 2002)
<http://www.show.scot.nhs.uk>

B.9.9 Hepatitis B Infected Health Care Workers, (National Health Service Scotland, 2000)
<http://www.show.scot.nhs.uk>

B.9.10 Guidance on the Management of AIDS/HIV Infected Health Care Workers and Patient Notification, (National Health Service Scotland, 2005)
<http://www.scotland.gov.uk>

B.10 Clinical trials

B.10.1 Clinical Trials Directive 2001/20/EC
<http://eudract.emea.eu.int>

B.11 Primary legislation

B.11.1 Public Records Act 1958 (6&7 Eliz.2, c.51)

B.11.2 Medicines Act 1968 (c.67)

B.11.3 Health and Safety at Work Act 1974 (c.37)

B.11.4 Adoption Act 1976 (c.36)

B.11.5 Medical Act 1983 (c.54)
<http://www.gmc-uk.org>

B.11.6 Surrogacy Arrangements Act 1985 (c.49)

B.11.7 Children Act 1989 (c.41)
<http://www.opsi.gov.uk>

B.11.8 Access to Health Records Act 1990 (c.23)
<http://www.opsi.gov.uk>

B.11.9 Human Fertilisation and Embryology Act 1990 (c.37)
<http://www.opsi.gov.uk>

B.11.10 HFE (Disclosure of Information) Act 1992 (c.54)
<http://www.opsi.gov.uk>



- B.11.11** Criminal Justice and Public Order Act 1994 (c.33)
<http://www.opsi.gov.uk>

- B.11.12** Data Protection Act 1998 (c.29)
<http://www.opsi.gov.uk>

- B.11.13** Human Rights Act 1998 (c.42)
<http://www.opsi.gov.uk>

- B.11.14** Care Standards Act 2000 (c.14)
<http://www.opsi.gov.uk>

- B.11.15** Freedom of Information Act 2000 (c.36)
<http://www.opsi.gov.uk>

- B.11.16** Human Reproductive Cloning Act 2001 (c.23)
<http://www.opsi.gov.uk>

- B.11.17** Adoption and Children Act 2002 (c.38)
<http://www.opsi.gov.uk>

- B.11.18** HFE (Deceased Fathers) Act 2003 (c.24)
<http://www.opsi.gov.uk>

- B.11.19** Health and Social Care (Community Health and Standards) Act 2003 (c.43)
<http://www.opsi.gov.uk>

- B.11.20** The Human Tissue Act 2004 (c.30)
<http://www.opsi.gov.uk>

B.12 Secondary legislation

- B.12.1** Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 (S.I. 1991 No. 1540)
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- B.12.2** Human Fertilisation and Embryology (Special Exemptions) Regulations 1991 (S.I. 1991 No. 1588)
<http://www.opsi.gov.uk>
- B.12.3** Human Fertilisation and Embryology Authority (Licence Committees and Appeals) Regulations 1991 (S.I. 1991 No.1889)
<http://www.opsi.gov.uk>
- B.12.4** Parental Orders (Human Fertilisation and Embryology) Regulations 1994 (S.I. 1994 No.2767)
<http://www.opsi.gov.uk>
- B.12.5** Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996 (S.I. 1996 No. 375)
<http://www.opsi.gov.uk>
- B.12.6** Human Fertilisation and Embryology (Research Purposes) Regulations 2001 (S.I. 2001 No.3968)
<http://www.opsi.gov.uk>
- B.12.7** The Private and Voluntary Care (England) Regulations 2001 (S.I. 2001 No. 3968)
<http://www.opsi.gov.uk>
- B.12.8** The Control of Substances Hazardous to Health Regulations 2002 (S.I. 2002 No.2677)
<http://www.opsi.gov.uk>
- B.12.9** Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004 (S.I. 2004 No. 1511)
<http://www.opsi.gov.uk>



B.12.10 Environmental Information Regulations 2004 (S.I. 2004 No. 3391)

<http://www.opsi.gov.uk>



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