

## The HFEA *Code of Practice* – Division I (Standards)

### Additional standards (to be incorporated into version 2 of the HFEA Standards)

Point of inclusion	Description/suggested text
3.1/-1	<p><b>[Insert new section:]</b>  <b>adverse incident</b>  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 reactions.</p>
3.2/1	<p><b>[Insert new section:]</b>  <b>clinical and scientific activities</b>  activities carried out in a clinical or scientific setting which relate to the provision of licensed treatment or the carrying out of licensed research</p>
4.1.2	<p><b>[Replace with]</b>  <b>Qualifications for the role of Person Responsible</b></p> <p>The Person Responsible shall at least meet the following qualification criteria</p> <ul style="list-style-type: none"> <li>a) possession of a diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences, or clinical healthcare, awarded on completion of a university course of study, or other course of study recognised in the United Kingdom as equivalent; and</li> <li>b) successful completion of the HFEA's PR assessment process; and</li> <li>c) at least two years' practical experience in relevant fields.</li> </ul> <p>The Centre shall provide information to the HFEA concerning the proposed Person Responsible. Where 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.</p>
4.1.2/1	<p><b>[Insert new section:]</b>  <b>Responsibilities of the Person Responsible</b>  The Person Responsible shall have responsibility for:</p> <ul style="list-style-type: none"> <li>a) ensuring that the gametes and embryos intended for human application in the Centre are procured, tested, processed, stored and distributed in accordance with the EC Directives and the H F &amp; E Act,</li> <li>b) providing information to the HFEA regarding substantial changes to its activities and seek prior written approval of such changes,</li> <li>c) notifying the HFEA of any adverse incidents and providing a report analysing the cause and the ensuing outcome,</li> <li>d) reporting annually to the HFEA, the activity of the Centre, including types and numbers of treatments, number of embryos used in each treatment episode and the fate of disposed gametes and embryos,</li> <li>e) ensuring that the character, qualifications and experience of those carrying out HFEA licensed activities are suited to the work they are doing at the centre <ul style="list-style-type: none"> <li>ensuring that proper equipment is used</li> </ul> </li> <li>f) ensuring that proper arrangements are made for the keeping and disposal of gametes and embryos</li> <li>g) ensuring that suitable practices are used in the course of activities carried on under the</li> </ul>

Point of inclusion	Description/suggested text
	<p>centre's licence</p> <p>h) ensuring that the conditions of the licence are complied with</p> <p>i) 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.</p>
6.2.1	<p><b>[Change wording of second paragraph of 6.2.1 to:]</b></p> <p>Personnel directly involved in clinical or scientific activities shall, where appropriate, be registered in accordance with the requirements of legislation and possess the appropriate qualifications or experience set out in relevant HFEA and professional guidance</p>
6.2.5(e)	<p><b>[Insert new sub-section after 6.2.5(d):]</b></p> <p>where the individual is in contact with patients, is prepared to offer appropriate emotional support to people suffering distress at any stage of their investigation, counselling or treatment, understands and can explain the role of counselling, and knows when and how to refer people to the qualified counsellor.</p>
6.5(a/1)	<p><b>[Insert new list item:]</b></p> <p>accurate recording of information</p>
7.2(c)	<p><b>[Replace with:]</b></p> <p>notification of the Information Commissioner in accordance with the Data Protection Act 1998,</p>
7.5	<p><b>[Delete and replace with following title and new sections 7.5, 7.5.1 and 7.5.2:]</b></p> <p><b>Consent</b></p>
7.5.1	<p><b>[Insert new section:]</b></p> <p><b>General</b></p> <p>The Centre shall comply with current professional guidelines on consent and relevant HFEA guidance.</p> <p>The Centre shall establish documented procedures for individuals considering or giving consent to examination and treatment or donation, and storage to ensure that</p> <p>a) only personnel authorised by the Centre take consent,</p> <p>b) reasonable steps are taken to verify the identity of individuals from whom consent is obtained,</p> <p>c) appropriate verbal and written information is provided in conjunction with obtaining consent and its provision is recorded,</p> <p>d) individuals are given an opportunity to ask questions and receive further advice and guidance by clinical staff,</p> <p>e) people seeking treatment or storage, or considering donation, confirm that information they have provided is true to the best of their knowledge</p>

Point of inclusion	Description/suggested text
7.5.2	<p><b>[Insert new section:]</b>  <b>Consent to storage and use of gametes and embryos</b></p> <p>The Centre shall establish documented procedures for obtaining consent to the storage or use of gametes to ensure that:</p> <p>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 for another person to store or use their gametes</p> <p>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</p> <p>c) people seeking treatment or storage, or considering donation are given sufficient time to reflect upon their decisions before giving their consent</p> <p>d) the consent given is effective in accordance with the relevant legislation</p> <p>e) the consent given is recorded in writing and in accordance with relevant Directions issued by the HFEA</p> <p>f) a copy of the signed consent form shall be available for those who have given consent</p>
7.6.2(a)/1	<p><b>[Insert new list item:]</b>  implications counselling, support counselling and therapeutic counselling are each made available as appropriate.</p>
7.6.2(c)	<p><b>[replace with:]</b>  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.</p>
7.6.2(e)	<p><b>[replace with:]</b>  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.</p>
7.6.2(f)	<p><b>[replace with:]</b>  where a couple or individual is proposing to undergo fertility treatment and the possibility of donation arises, donor implications counselling shall be provided as in (a) above.</p>
7.6.2/1	<p><b>[Insert new section:]</b>  <b>Welfare of the Child</b></p> <p>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, and of any other child who may be affected by the birth.</p>
7.6.3(f)/1	<p><b>[Insert new list item:]</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</p>
7.6.3 NOTE 1	<p><b>[Delete: replaced with guidance at 4.2]</b></p>
7.6.3 NOTE 2	<p><b>[Delete: replaced with guidance at 4.1]</b></p>

Point of inclusion	Description/suggested text
7.6.3/2	<p><b>[Insert new paragraph text:]</b>  <b>Surrogacy</b>  Centres shall ensure that consideration is only given to the use of assisted conception techniques to produce a surrogate pregnancy where the commissioning mother is unable for physical or other medical reasons to carry a child or where her health may be seriously impaired by doing so.</p>
7.7.1(a-1)	<p><b>[Insert new list item:]</b>  that procurement conforms with appropriate age limits for gamete providers</p>
7.7.1(a)/1	<p><b>[Insert new list item:]</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</p>
7.7.1(b)	<p><b>[re-draft as:]</b>  patient, patient partner and donor identification (7.5),</p>
7.7.7	<p><b>[replace with:]</b>  <b>Labelling of packages containing procured gametes</b>  At the time of procurement each package containing gametes 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  a) date (and time where possible) of donation  b) identity of the 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 (see also 7.3.2 Coding).</p>
7.8.1	<p><b>[replace second paragraph with:]</b>  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 accreditation by CPA(UK)Ltd or another body accrediting to an equivalent standard.</p>
7.8.3(a)/1	<p><b>[Insert new paragraph text:]</b>  that 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</p>
7.8.3(c)/1	<p><b>[Insert new paragraph text:]</b>  that, 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,</p>
7.8.3(d)/1	<p><b>[Insert new list item:]</b>  that appropriate measures are in place for the handling of contaminated samples</p>
7.8.3/1	<p><b>[Insert new paragraph text:]</b>  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.</p>
7.8.4(b)/1	<p><b>[insert new list item:]</b>  no gametes or embryos are placed in storage unless those people who provided the gametes have been screened in accordance with current recommended guidance,</p>

Point of inclusion	Description/suggested text
7.8.4(b)/2	<p><b>[insert new list item:]</b>  <u>Storage centres shall carry out reviews of stored gametes and embryos at least once every two years, in order:</u>  <u>(i) to reconcile the centre's records with material in storage; and</u>  <u>(ii) to review the purpose and duration of storage; and</u>  <u>(iii) to identify any action that needs to be taken</u></p>
7.8.4(c)/1	<p><b>[insert new list item:]</b>  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,</p>
7/1.	<p><b>[Insert new part title:]</b>  <b>Research processes</b></p>
7/1.1	<p><b>[Insert new sub-part title:]</b>  <b>General</b></p>
7/1.1.1	<p><b>[Insert new paragraph text:]</b>  Where embryos are used for research, the research centre shall record at the outset  (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.</p>
7/1.2.1	<p><b>[Insert new paragraph text:]</b>  <b>Disclosure of interests</b>  Staff involved in research shall follow relevant guidelines produced by the respective professional bodies</p> <p>The Centre shall ensure that  (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) donors are given information on 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  (c) everyone in the research team, including nurses and non-medical staff, is informed about the way in which the research is being financed and managed</p>
8.4.1	<p><b>[Change first paragraph to:]</b>  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 that</p>
8.4.1(a)	<p><b>[replace with:]</b>  the responsibilities and authorities for personnel responsible for the management of adverse incidents are defined,</p>
8.4.1(b)	<p><b>[replace with:]</b>  the identification and investigation of adverse incidents, that includes proactive identification through risk assessment and internal audit,</p>
8.4.1(c)	<p><b>[replace with:]</b>  the recording of adverse incidents, including analysis of cause, corrective action taken and ensuing outcome,</p>
8.4.1(e)	<p><b>[replace with:]</b>  the identification of any donor who might have contributed to the adverse incident,</p>

Point of inclusion	Description/suggested text
8.4.1(f)	<p><b>[replace with:]</b>  the control and verifiable recall of any gametes or embryos procured or applied in association with the particular adverse incident, within a predefined time,</p>
8.4.1(h)	<p><b>[replace with:]</b>  the control and verifiable recall of any material, and the investigation of any equipment used in association with the adverse incident,</p>
8.4.2	<p><b>[replace title with:]</b>  <b>Notification of serious adverse reactions</b></p>
8.5.1/1	<p><b>[Insert new paragraph text:]</b>  Centres 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.</p>