SAQ Questionnaire
Example

Cloned on: 29/05/2012 By: Ian Peacock

1. Person Responsible (PR)

1 What proportion of the Person Responsible's job plan is allocated to the PR role?

<20% ○ 20-50% ○
51-80% ○ >80% ○

2. Staff

1	Does your centre provide treatment services including storage of gametes and/or recruitment of donors? If YES answer questions in section 1, if NO go to question 2 (continued)	Yes ○ No ○	
1.1	Does the centre have access to a nominated registered medical practitioner, within the UK, to advise on and oversee medical activities at all times? [T16] (continued)	Yes ○ No ○	
1.2	Are staff working under the auspices of the licence of such character to be suitable persons to participate in the activities authorised by the licence? [Act S.17 (1)(a)] (continued)	Yes ○ No ○	
1.3	Has your centre assessed the workforce requirements in the last year? [see 25.10] (continued)	Yes ○ No ○	
1.4	Is your centre operating with a full staff complement? [see T12] (continued)	1 ○ 2 ○ 3 ○ 4 ○	
1.5	Does your centre have a documented induction training procedure for all staff? [see T15] (continued)	1 ○ 2 ○ 3 ○ 4 ○	
1.6	Do all staff participate in relevant professional development? [T15] (continued)	1 ○ 2 ○ 3 ○ 4 ○	
1.7	Can all staff provide documented evidence of having demonstrated competence in their designated tasks? [see T12 and T15(a)] (continued)	1 ○ 2 ○ 3 ○ 4 ○	
2	Does your centre have an embryology laboratory? If YES answer questions in section 2, if NO go to question 3 (continued)	Yes ○ No ○	
2.1	Is the individual responsible for the clinical embryology laboratory registered with the HPC? [see T14, 2.19(c)] (continued)	Yes ○ No ○	
2.2	Are all eligible staff working in the clinical embryology laboratory registered with the HPC? (continued)	Yes ○ No ○	
3	Does your centre provide basic partner services only (IUI)? If YES answer questions in section 3, if NO you do not need to complete this section. (continued)	Yes ○ No ○	
3.1	Does your centre have access to a nominated registered scientist to advise on and oversee scientific activities? [see T16] (continued)	Yes ○ No ○	

3. Counselling

1 Is your centre responsible for taking consent under the terms of Schedule 3 of the Act (consent requiring that counselling is offfered)? Those taking consent for basic partner treatment services (IUI) are exempted from the requirement to offer counselling. (continued) Yes ○ No ○

1.1 Does your centre offer counselling to those providing consent: (continued)

1.1.1 as required by schedule 3 of the HF&E Act? [see Act schedule 3, S.3 (1)(a)] (continued) Yes ○ No ○ N/A ○

1.1.2 to agreed fatherhood? [see Act schedule 3Z part 2] (continued) Yes ○ No ○ N/A ○

1.1.3 to agreed female parenthood? [see Act schedule 3ZA part 2] (continued) Yes ○ No ○ N/A ○

1.2 Is there a counselling Standard Operating Procedure? [see T33b] (continued) Yes ○ No ○

1.3 Has your centre established quality indicators or objectives for counselling? [see T35] (continued) Yes ○ No ○

1.4 Have you audited how far counselling procedures comply with the approved protocols, the regulatory requirements and quality indicators in the last two years? [see T36] (continued) Yes ○ No ○

1.4.1 Have the findings of the audit been documented? [see T36] (continued) Yes ○ No ○

1.4.2 Have the corrective actions been documented? [see T36] (continued) Yes ○ No ○ N/A ○

1.4.3 Have all required corrective actions been implemented? [see T36] (continued) Yes ○ No ○ N/A ○

1.5 Can relevant staff provide documented evidence of the assessment of their competence to provide counselling? [see T15a] (continued) 1 ○ 2 ○ 3 ○ 4 ○

1.6 Does your centre ensure that a woman is not provided with treatment services using embryos or donated gametes unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services of that kind? [T60] (continued) Yes ○ No ○ N/A ○

1.7 Is the centres counsellor(s): (continued)

1.7.1 the holder of a recognised counselling, clinical psychology, counselling psychology or psychotherapy qualification to diploma of higher education level or above? [see 2.12(a)] (continued) Yes ○ No ○

1.7.2 accredited under the British Infertility Counselling Association accreditation scheme (i.e. not a member only)? [see 2.12(b)] (continued) Yes ○ No ○

1.7.2.1 Can the counsellor provide evidence of working towards accreditation through the British Infertility Counselling Association accreditation scheme? [see 2.12(b)] (continued) Yes ○ No ○

1.8 Can your centre refer people for specialist counselling if appropriate (for example genetic counselling, or counselling for oncology patients or others requiring the long-term storage of gametes or embryos)? [see 3.10, 2.26, 10.7] (continued) Yes ○ No ○

4. Provision of Information

1	Is your centre responsible for providing information to patients before they give consent? (continued)	Yes ○ No ○	
1.1	Is proper information provided to patients giving consent to treatment, as required by schedule 3 of (continued) the HF&E Act 1990 (as amended) ? [see Act, schedule 3 S.3 (1)(b)]	Yes ○ No ○	
1.2	Is there an SOP for the procedure to be followed when providing information to patients before they: (continued)		
1.2.1	consent to treatment? [see T33b] (continued)	Yes ○ No ○ N/A ○	
1.2.2	consent to donation for treatment? [see T33b] (continued)	Yes ○ No ○ N/A ○	
1.2.3	consent to donation for research? [see T33b] (continued)	Yes ○ No ○ N/A ○	
1.2.4	consent to use in training? [see T33b] (continued)	Yes ○ No ○ N/A ○	
1.3	Has your centre established quality indicators or objectives relevant to the provision of information? (continued) [seeT35]	1 ○ 2 ○ 3 ○ 4 ○	
1.4	Has your centre audited how far your procedures for the provision of information comply with the (continued) approved protocols, the regulatory requirements and quality indicators in the last two years? [see T36]	Yes ○ No ○	
1.4.1	Have the findings of the audit been documented? [see T36] (continued)	Yes ○ No ○ N/A ○	
1.4.2	Have the corrective actions been documented? [see T36] (continued)	Yes ○ No ○ N/A ○	
1.4.3	Have all required corrective actions been implemented? [see T36] (continued)	Yes ○ No ○ N/A ○	
1.5	Can relevant staff provide documented evidence of the assessment of their competence to provide (continued) information to those consenting to:		
1.5.1	treatment? [see T15b] (continued)	Yes ○ No ○ N/A ○	
1.5.2	donation of gametes for treatment? [see T15b] (continued)	Yes ○ No ○ N/A ○	
1.5.3	donation to research [see T15b] (continued)	Yes ○ No ○ N/A ○	
1.5.4	donation for use in training? [see T15b] (continued)	Yes ○ No ○ N/A ○	

5. Consent

1 Do staff at your centre have responsibility for obtaining consent? (continued) Yes ○ No ○

1.1 Is written consent obtained before gametes or embryos are used in treatment? [see T57] (continued) Yes ○ No ○

1.2 Is there an SOP for taking effective consent? [see T33b] (continued) Yes ○ No ○

1.3 Has your centre established quality indicators relevant to consent procedures? [see T35] (continued) Yes ○ No ○

1.4 Have you audited how far procedures for taking consent comply with the approved protocols, the (continued) regulatory requirements and quality indicators in the last two years? [see T36] Yes ○ No ○

1.4.1 Have the findings of the audit been documented? [see T36] (continued) Yes ○ No ○

1.4.2 Have the corrective actions been documented? [see T36] (continued) Yes ○ No ○ N/A ○

1.4.3 Have all required corrective actions been implemented? [see T36] (continued) Yes ○ No ○ N/A ○

1.5 Can relevant staff provide documented evidence of the assessment of their competence to take (continued) consent? [see T15a] 1 ○ 2 ○ 3 ○ 4 ○

1.6 Is consent ever obtained on the day that a procedure occurs (for example, are patients ever asked (continued) to consent to storage on the day of embryo transfer or to consent to ICSI on the day of egg collection)? [see Schedule 3, Section 3 (1)(a)] Yes ○ No ○

1.7 Is the identity of the person giving consent verified when they give it? [see 5.10] (continued) 1 ○ 2 ○ 3 ○ 4 ○

1.8 Is the identity of the person who gave consent cross-referenced to records when procedures are (continued) carried out? [see 5.11] 1 ○ 2 ○ 3 ○ 4 ○

1.9 If you have satellite or transport providers that obtain consent, is there an agreement in place that (continued) complies with Directions 0010? [see Directions ref 0010, version 1] 1 ○ 2 ○ 3 ○ 4 ○

1.10 Does your centre have written, effective consent for the storage of all cryopreserved gametes (continued) currently in store? [see Act, Schedule 3, 8(1)] Yes ○ No ○

1.11 Does your centre have written , effective consent for the storage of all cryopreserved embryos (continued) currently in store? [see Act, Schedule 3, 8(2)] Yes ○ No ○

1.11.1 Where you do not have the written consent of both gamete providers because one of them (continued) has withdrawn consent, are all the relevant embryos being stored for the "statutory cooling-off period"? [see Schedule 3 4A(4)] Yes ○ No ○ N/A ○

2 Does your centre use embryos for training in embryo biopsy, embryo storage or other embryological (continued) techniques and/or for other training expressly authorised by HFEA? Yes ○ No ○

2.1 Does your centre ensure that in every case where embryos are being used for the purpose of (continued) training in embryo biopsy, embryo storage or other embryological techniques, both gamete providers have consented to the use of embryos, created using their gametes, for such training ? [see T94] Yes ○ No ○

6. Legal parenthood

1	Does your centre provide treatment with donor gametes or embryos to patients who are not married or in a civil partnership? (continued)	Yes ○	No ○
1.1	Has your centre established written procedures to obtain the relevant written records of consent to parenthood before treating a woman with donor sperm or embryos? [see T33(b)] (continued)	Yes ○	No ○
1.2	Does your centre ensure that a woman is not provided with treatment services using embryos or donated gametes unless she and any man or woman who is to be treated together with her have been provided with information about parenthood laws? [see T60] (continued)	Yes ○	No ○
1.3	Does your centre ensure that you do not provide treatment where a person who has previously consented to be the second parent of a child born has withdrawn their consent to parenthood before telling the woman being treated that they have withdrawn it? [see T64(b)] (continued)	Yes ○	No ○
1.4	Should a nominated second parent withdraw their consent to parenthood, does the centre ensure that the named woman is not treated until she is informed of this ? [seeT64 (b)] (continued)	Yes ○	No ○
1.5	Should a woman being treated withdraw her consent to a nominated second parent being the legal parent, or consent to a different person being the legal parent of any child born, does the centre have a procedure in place to ensure that the nominated second parent is informed of the change in writing ? (continued)	Yes ○	No ○

7. Multiple Births

1 Does your centre provide IVF or GIFT treatments? (continued) Yes ○ No ○

1.1 Does your licensed centre have a multiple births minimisation strategy? [see Directions ref 0003] (continued) Yes ○ No ○

1.2 Can your centre provide documented evidence of the outcome of regular audits and evaluations of (continued) the progress and effectiveness of the multiple births minimisation strategy? [see Directions ref 0003] Yes ○ No ○

1.3 Does your centre keep a summary log of cases in which multiple embryos have been transferred to (continued) a patient who meets the criteria for single embryo transfer, as set out in the multiple births minimisation strategy? [see Directions ref 0003] Yes ○ No ○

1.4 Is your centre likely to meet the current multiple birth rate target? [T123] (continued) Yes ○ No ○

2 Since you last completed a SAQ, have multiple embryos been transferred to a patient who meets the (continued) criteria for single embryo transfer, as set out in the multiple births minimisation strategy? Yes ○ No ○

2.1 Has your licensed centre: (continued)

2.1.1 recorded this fact in the patient's medical records and in the summary log? [see Directions ref (continued) 0003] Yes ○ No ○

2.1.2 recorded in the patient's records a clear explanation of the reasons for transferring more than (continued) one embryo? [see Directions ref 0003] Yes ○ No ○

2.1.3 made a note in the patient's records confirming that the risks associated with multiple (continued) pregnancy have been fully discussed with the patient? [see Directions ref 0003] 1 ○ 2 ○ 3 ○ 4 ○

3 Since you last completed a SAQ, has your centre provided licensed treatment cycles in which three (continued) embryos or four eggs have been placed in a woman? Yes ○ No ○

3.1 Does your centre maintain: (continued)

3.1.1 a detailed explanation in each patient's medical records explaining the reasons for transferring (continued) three embryos or four eggs? [see Directions ref 0003] Yes ○ No ○

3.1.2 a summary log in the format (form numbers 0003A and 0003B) set out in Directions 0003, (continued) including every treatment cycle involving placing three embryos or four eggs in a woman? [see Directions ref 0003] Yes ○ No ○

8. Welfare of the Child

1	Does your centre provide treatment services (excluding storage only)? (continued)	Yes ○ No ○	
1.1	Before any woman is provided with treatment services, do you take account of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth? [see T56] (continued)	Yes ○ No ○	
1.2	Is there an SOP for a WOC assessment? [see T33b] (continued)	Yes ○ No ○	
1.3	Has your centre established quality indicators or objectives relevant to assessing the welfare of the child? [see T35] (continued)	Yes ○ No ○	
1.4	Has your centre audited how far WOC procedures comply with the approved protocols, the regulatory requirements and quality indicators in the last two years?[see T36] (continued)	Yes ○ No ○	
1.4.1	Have the findings of the audit been documented? [see T36] (continued)	Yes ○ No ○	
1.4.2	Have the corrective actions been documented? [see T36] (continued)	Yes ○ No ○ N/A ○	
1.4.3	Have all required corrective actions been implemented? [see T36] (continued)	Yes ○ No ○ N/A ○	
1.5	Can staff provide documented evidence of the assessment of their competence to carry out a WOC assessment? [see T15a] (continued)	Yes ○ No ○	
2	Does your centre provide treatment involving surrogacy? (continued)	Yes ○ No ○	
2.1	When carrying out a welfare of the child assessment does your centre assess those commissioning the surrogacy arrangement and the surrogate along with any partner she has? [see T56] (continued)	Yes ○ No ○	

9. Embryo Biopsy and Testing

1	Does your centre carry out embryo biopsy for PGS or PGD? If no, go to question 2 (continued)	Yes ○ No ○	
1.1	Is there an SOP for embryo biopsy? [see T33)] (continued)	Yes ○ No ○	
1.2	Has the biopsy procedure been validated based on studies performed by your centre, or on data (continued) from published studies, or from well-established procedures? [see T72]	Yes ○ No ○	
1.3	Has your centre established quality indicators or objectives relevant to biopsy procedures? [see T35] (continued)	Yes ○ No ○	
1.4	Has your centre audited how far biopsy procedures comply with the approved protocols, the (continued) regulatory requirements and quality indicators in the last two years? [see T36]	Yes ○ No ○	
1.4.1	Have the findings of the audit been documented? [see T36] (continued)	Yes ○ No ○ N/A ○	
1.4.2	Have the corrective actions been documented? [see T36] (continued)	Yes ○ No ○ N/A ○	
1.4.3	Have all required corrective actions been implemented? [see T36] (continued)	Yes ○ No ○ N/A ○	
1.5	Can relevant staff provide documented evidence of their competence to carry out embryo biopsy? (continued) [see T15(b)]	1 ○ 2 ○ 3 ○ 4 ○	
1.6	With respect to any embryo testing programme involving biopsy, does your centre ensure that: (continued)		
1.6.1	no embryo is transferred to a woman where that embryo or any material removed from it or (continued) from the gametes that produced it, has been subject to a test that supplies genetic information about the embryo, unless the test has been expressly authorised by the Authority? [T88]	Yes ○ No ○	
1.6.2	any information derived from tests on an embryo, or any material removed from it or from the (continued) gametes that produced it, is not used to select embryos of a particular sex for social reasons? [T88]	Yes ○ No ○	
1.7	Can you confirm in every case that your centre has not transferred biopsied embryos in the same (continued) cycle as non-biopsied embryos? [see T77]	Yes ○ No ○	
2	Does your centre undertake analysis of blastomeres for PGS? If no, go to question 3 (continued)	Yes ○ No ○	
2.1	Is there an SOP for carrying out PGS? [see T33b] (continued)	Yes ○ No ○	
2.2	Has the PGS procedure been validated based on studies performed by your centre, or on data from (continued) published studies, or from well-established procedures? [see T72]	Yes ○ No ○	
2.3	Has your centre established quality indicators or objectives relevant to PGS procedures? [see T35] (continued)	Yes ○ No ○	
2.4	Has your centre audited how far PGS procedures comply with the approved protocols, the (continued) regulatory requirements and quality indicators in the last two years? [see T36]	Yes ○ No ○	
2.4.1	Have the findings of the audit been documented? [T36] (continued)	Yes ○ No ○ N/A ○	
2.4.2	Have the corrective actions been documented? [T36] (continued)	Yes ○ No ○ N/A ○	
2.4.3	Have all required corrective actions been implemented? [see T36] (continued)	Yes ○ No ○ N/A ○	
2.5	Can all relevant staff provide documented evidence of the assessment of their competence in (continued) carrying out PGS? [see T15a]	1 ○ 2 ○ 3 ○ 4 ○	
2.6	Is the laboratory that carries out the PGS accredited by Clinical Pathology Accreditation (CPA) UK Ltd (continued) or an alternative body accrediting to an equivalent standard? [see T21]	Yes ○ No ○	
3	Does a third party laboratory undertake genetic analysis of blastomeres for PGS, PGD or sex selection for (continued) the avoidance of serious genetic illness, on behalf of your centre?	Yes ○ No ○	
3.1	Is the laboratory that carries out the PGS and/or PGD accredited by Clinical Pathology Accreditation (continued) (CPA) UK Ltd or an alternative body accrediting to an equivalent standard? [see T21]	Yes ○ No ○	
3.2	Has your centre developed a third party agreement with the genetic testing laboratory ? [see T111] (continued)	Yes ○ No ○	
3.3	Has your centre evaluated the ability of the third party to meet the required standards? [see T112] (continued)	Yes ○ No ○	

10. Embryo testing and sex selection

1	Does your centre undertake analysis of blastomeres for PGD or sex selection for the avoidance of serious (continued) genetic illness? If no, you do not need to complete this module.	Yes ○ No ○
1.1	Is there an SOP for PGD? [see T33b] (continued)	Yes ○ No ○
1.2	Has the PGD process been validated based on studies performed by your centre, or on data from (continued) published studies, or from well-established procedures? [see T72]	Yes ○ No ○
1.3	Has your centre established quality indicators or objectives relevant to PGD procedures? [see T35] (continued)	Yes ○ No ○
1.4	Has your centre audited how far PGD procedures comply with the approved protocols, the (continued) regulatory requirements and quality indicators in the last two years? [see T36]	Yes ○ No ○
1.4.1	Have the findings of the audit been documented? [T36] (continued)	Yes ○ No ○
1.4.2	Have the corrective actions been documented? [T36] (continued)	Yes ○ No ○ N/A ○
1.4.3	Have all required corrective actions been implemented? [see T36] (continued)	Yes ○ No ○ N/A ○
1.5	Can all relevant staff provide documented evidence of the assessment of their competence in (continued) carrying out PGD? [see T15a]	1 ○ 2 ○ 3 ○ 4 ○
1.6	Is the laboratory that carries out the PGD accredited by Clinical Pathology Accreditation (CPA) UK (continued) Ltd or an alternative body accrediting to an equivalent standard? [see T21]	Yes ○ No ○
1.7	Does your centre ensure that embryo testing is only being carried out for those genetic conditions (continued) that are expressly authorised by the Authority? [see T89]	No ○ Yes ○
1.8	Does your centre ensure that information derived from tests on an embryo, or any material (continued) removed from it or from the gametes that produced it, is not used to select embryos of a particular sex for social reasons? [see T88]	Yes ○ No ○

11. Donor selection

1	Does the centre recruit gamete donors or sharers or provide treatment with donated embryos or provide (continued) treatment involving surrogacy?	Yes ○ No ○	
1.1	Is there an SOP for the process to be followed when selecting and recruiting donors? [T33(b)] (continued)	Yes ○ No ○	
1.2	Has the centre established quality indicators relevant to the selection and recruitment of donors? (continued) [T35]	Yes ○ No ○	
1.3	Have procedures for selecting and recruiting donors been audited against compliance with the (continued) approved protocols, the regulatory requirements and quality indicators in the last two years? [Schedule 3A (10) 2006/86/EC, Appendix 1 F and T36]?	Yes ○ No ○	
1.3.1	Have the findings of the audit been documented? [T36] (continued)	Yes ○ No ○	
1.3.2	Have the corrective actions been documented? [T36] (continued)	Yes ○ No ○ N/A ○	
1.3.3	Have all required corrective actions been implemented? [see T36] (continued)	Yes ○ No ○ N/A ○	
1.4	Can all relevant staff provide documented evidence of the assessment of their competence in (continued) selecting and recruiting donors? [T15(a)]	1 ○ 2 ○ 3 ○ 4 ○	
1.5	Are donors selected on the basis of their (continued)		
1.5.1	age? [T52(a)] (continued)	1 ○ 2 ○ 3 ○ 4 ○	
1.5.2	health and medical history information provided on a questionnaire and through a personal (continued) interview performed by a qualified and trained healthcare professional? [T52(a)]	1 ○ 2 ○ 3 ○ 4 ○	
1.6	Are donors screened for (continued)		
1.6.1	HIV 1 and 2: Anti-HIV - 1, 2 [T52(b)] (continued)	1 ○ 2 ○ 3 ○ 4 ○	
1.6.2	Hepatitis B (HBsAg and Anti-HBc) [T52(b)] (continued)	1 ○ 2 ○ 3 ○ 4 ○	
1.6.3	Hepatitis C: Anti-HCV-Ab [T52(b)] (continued)	1 ○ 2 ○ 3 ○ 4 ○	
1.6.4	Syphilis [T52(b)] (continued)	1 ○ 2 ○ 3 ○ 4 ○	
1.6.5	Chlamydia [T52(b)] (continued)	1 ○ 2 ○ 3 ○ 4 ○	
1.7	Are donors of gametes and embryos screened in accordance with current professional guidance (continued) produced by the relevant professional bodies? [11.15]1d	1 ○ 2 ○ 3 ○ 4 ○	
1.8	Are the laboratory tests required by licence condition T52: (continued)		
1.8.1	carried out by a qualified laboratory, which has suitable accreditation (for example by CPA (continued) (UK) Ltd or another body accrediting to an equivalent standard) using CE marked testing kits where appropriate and tests validated for the purpose in accordance with current scientific knowledge?	Yes ○ No ○	
1.8.2	are blood samples obtained within a timeframe specified by the Authority? (continued)	Yes ○ No ○	
1.9	Is sperm to be used for donation quarantined for a minimum of 180 days, prior to repeat screening of (continued) the donor or is the donor's blood sample additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV or does processing include a validated inactivation step for the virus concerned? [T53(c)]	Yes ○ No ○	
1.10	Are frozen embryos to be used for donation quarantined for a minimum of 180 days, prior to repeat (continued) screening of the donor or is the donor's blood sample additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV or does processing include a validated inactivation step for the virus concerned? [T53(c)]	Yes ○ No ○ N/A ○	
1.11	Does the centre have procedures in place to identify when additional screening may be required? (continued) [T52(g)]	1 ○ 2 ○ 3 ○ 4 ○	
1.12	Can the centre provide donors with the following information if requested (continued)		
1.12.1	the number of persons born as a result of the donation [Act 31ZD(3)] (continued)	1 ○ 2 ○ 3 ○ 4 ○	
1.12.2	the sex of each of those persons [Act 31ZD(3)] (continued)	1 ○ 2 ○ 3 ○ 4 ○	
1.12.3	the year of birth of each of those persons [Act 31ZD(3)] (continued)	1 ○ 2 ○ 3 ○ 4 ○	

12. Egg sharing

1	Does the centre recruit egg sharers donating for treatment purposes or for research purposes? (continued)	Yes	No
1.1	Are treatment services provided to the egg share donor in the course of the donation cycle unless (continued) there is a medical reason why they cannot be provided at that time? [Directions 0001 version 1]	Yes	No

13. Payment for donors

1	Does your centre recruit gamete donors? If no, go to question 2 (continued)	Yes ○ No ○	
1.1	Are payments to donors restricted to the limits prescribed in directions? [Directions 0001 version 3] (continued)	Yes ○ No ○ N/A ○	
1.2	Where your centre compensates donors an excess amount as specified in paragraph 8 of (continued) Directions 0001 (version 3) do you keep:		
1.2.1	a record of the actual excess expenses incurred by the donor? (continued)	Yes ○ No ○ N/A ○	
1.2.2	a record of the amount reimbursed to the donor? (continued)	Yes ○ No ○ N/A ○	
1.2.3	the receipts produced by the donor, and/or the steps taken by the person responsible to (continued) satisfy themselves that the excess expenses claimed by the donor have in fact been incurred?	Yes ○ No ○ N/A ○	
2	Has your centre imported any donated gametes? If no, go to question 3 (continued)	Yes ○ No ○	
2.1	When gametes have been donated overseas have you checked that the donor has not received (continued) compensation which exceeds:		
2.1.1	reasonable expenses incurred by the donor in connection with the donation of gametes (continued) provided to that centre [Directions 0001 version 3]?	Yes ○ No ○	
2.1.2	loss of earnings (but not for other costs or inconveniences) incurred by the donor up to a (continued) daily maximum of £61.28 but with an overall limit of £250 for each course or cycle of donation (local currency equivalent) [Directions 0001 version 3]	Yes ○ No ○	
2.2	When gametes have been donated overseas have you kept a record (provided by the overseas (continued) centre) of:		
2.2.1	the receipts produced by the donor, and/or the steps taken by the person responsible to (continued) satisfy themselves that the excess expenses claimed by the donor have in fact been incurred [Directions 0001 version 3]	Yes ○ No ○ N/A ○	
3	Has your centre provided treatment with gametes obtained from a donor sourced by another agency or (continued) intermediary, including introductory agencies and internet websites? If no, you have completed this module	Yes ○ No ○	
3.1	Where you have obtained gametes from a donor sourced by another agency or intermediary, (continued) including introductory agencies and internet websites have you		
3.1.1	taken reasonable steps to ensure that the requirements Directions 0001 have not been (continued) breached	Yes ○ No ○	
3.1.2	kept a record of the steps taken for this purpose (continued)	Yes ○ No ○	

14. Surrogacy

1	Does your centre provide treatment involving surrogacy? If no, you do not need to complete this module (continued)	Yes	No
1.1	Does your centre screen the gamete providers in surrogacy arrangements as donors? [see T53c] (continued)	Yes	No
1.2	Does your centre register the gamete providers in surrogacy arrangements as donors? [see (continued) Directions 0003]	Yes	No
1.3	Is sperm to be used for surrogacy quarantined for a minimum of 180 days, prior to repeat screening (continued) of the donor or is the donor's blood sample additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV or does processing include a validated inactivation step for the virus concerned? [T53(c)]	Yes	No

15. Procuring, processing and transporting gametes and embryos

1	Does your centre procure and/or process gametes and/or embryos for use in treatment (including storage (continued) for treatment purposes) or donation? If No to both of the above, go to question 2	Yes ○ No ○	
1.1	Are all critical procurement and processing procedures documented in standard operating (continued) procedures (SOPs)? [see T33b]	Yes ○ No ○	
1.2	Have the critical procurement and processing procedures been validated? [see T72] (continued)	Yes ○ No ○	
1.3	Has the centre established quality indicators or objectives relevant to procurement and processing (continued) procedures? [seeT35]	Yes ○ No ○	
1.4	In the last two years, has your centre audited how far procurement and processing procedures (continued) comply with the approved protocols, the regulatory requirements and quality indicators? [see T36]	Yes ○ No ○	
1.4.1	Have the findings of the audit been documented? [T36] (continued)	Yes ○ No ○ N/A ○	
1.4.2	Have the corrective actions been documented? [T36] (continued)	Yes ○ No ○ N/A ○	
1.4.3	Have all required corrective actions been implemented? [see T36] (continued)	Yes ○ No ○ N/A ○	
1.5	Can all relevant staff provide documented evidence of having demonstrated competence in (continued) procurement and processing procedures? [T15B]	Yes ○ No ○	
1.6	Does the clinician responsible for the patient document the justification for the use of their gametes (continued) or embryos created with their gametes in treatment, based on the patient's medical history and therapeutic indications? [T49]	Yes ○ No ○	
1.7	If sperm is produced at home, does the centre record this in the gamete provider's records? [see (continued) T68]	Yes ○ No ○	
1.8	If the centre provided sperm for home insemination in the last year, was the sperm supplied thawed (continued) or in the process of thawing? [see CoP interpretation of mandatory requirements 15A, Act 4(1)(a)]	Yes ○ No ○ N/A ○	
1.9	Prior to the processing of patient gametes or embryos intended for use in treatment or storage, does (continued) your centre carry out the following biological tests to assess the risk of cross contamination:		
1.9.1	HIV 1 and 2: Anti-HIV – 1, 2? [T50] (continued)	Yes ○ No ○	
1.9.2	Hepatitis B: HBsAg and Anti-HBc? [T50] (continued)	Yes ○ No ○	
1.9.3	Hepatitis C: Anti-HCV-Ab? [T50] (continued)	Yes ○ No ○	
1.10	Prior to the processing of patient gametes or embryos intended for use in treatment or storage, does (continued) your centre perform HTLV- 1 antibody testing for patients 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? [T50f]	Yes ○ No ○	
1.11	In appropriate circumstances does your centre carry out additional testing depending on the (continued) patient's travel and exposure history and the characteristics of the tissue or cells donated (eg, Rh D, Malaria, CMV, T.cruzi) ? [T50(g)]	Yes ○ No ○	
1.12	Are the laboratory tests required by licence condition T50: (continued)		
1.12.1	carried out by a qualified laboratory, which has suitable accreditation (for example by CPA (continued) (UK) Ltd or another body accrediting to an equivalent standard) using CE marked testing kits where appropriate and tests validated for the purpose in accordance with current scientific knowledge? [T50]	Yes ○ No ○	
1.12.2	are blood samples obtained within a timeframe specified by the Authority? [T50] (continued)	Yes ○ No ○	
2	Does the centre distribute gametes or embryos? If no, go to question 3 (continued)	Yes ○ No ○	
2.1	Is there an SOP that details the circumstances, responsibilities and procedures for the release of (continued) stored material before distribution? [see T33b]	Yes ○ No ○	
2.2	Are transport conditions including temperature and time limit, specified? [see T107] (continued)	Yes ○ No ○	
2.3	Have all containers and packages been validated as fit for purpose? [see T108] (continued)	Yes ○ No ○	
2.4	Does your centre have a recall procedure that defines the responsibilities and actions required (continued) when a distribution is recalled? [CoP mandatory requirements 15B]	Yes ○ No ○	
2.5	Does your centre have a procedure for handling returned gametes and embryos? [CoP interpretation (continued) of mandatory requirements]	Yes ○ No ○	
2.6	Does your centre have a procedure for the investigation of any recall as an adverse incident [CoP (continued) interpretation of mandatory requirements 15C)	Yes ○ No ○	
2.7	When transporting gametes does your centre ensure that the shipping container or a separate sheet (continued) accompanying the container includes labelling as required by T107? [T107]	Yes ○ No ○	
2.8	Is all required information provided when distributing material? [T110] (continued)	Yes ○ No ○	
2.9	Does the centre ensure that gametes and embryos are packaged and transported in a manner that (continued) minimises the risk of contamination? [T105]	Yes ○ No ○	
2.10	Does the centre ensure that gametes and embryos are packaged and transported in a manner that (continued) preserves the required characteristics and biological functions of the gametes and embryos? [T105	Yes ○ No ○	
2.11	Does the centre ensure that gametes and embryos are packaged and transported in a manner that (continued) prevents contamination of those responsible for packaging and transportation? [T105]	Yes ○ No ○	
2.12	Does your centre ensure that the container/ package used for transportation of gametes/ embryos (continued) is secure ? [T108]	Yes ○ No ○	
3	Does the centre contract a third party to distribute gametes or embryos? If No, go to section 4. (continued)	Yes ○ No ○	
3.1	Is a documented agreement in place that ensures the required conditions are maintained during (continued) distribution? [CoP interpretation mandatory requirements 15B]	Yes ○ No ○	
4	Does your centre receive gametes or embryos from other licensed centres or third party premises? If NO (continued) you have completed this section	Yes ○ No ○	

15. Procuring, processing and transporting gametes and embryos (continued)

4.1 Does your centre have a documented procedure for the receipt of gametes and/or embryos from another centre or third party premises that is complaint with the requirements of T109? [T109] (continued) Yes ○ No ○

16. Import and Export

1	Has your centre imported or exported gametes or embryos under general directions in the last year ? If no, (continued) you do not need to complete this module.	Yes ○	No ○
1.1	Can your centre provide evidence that it complied with all the requirements of Directions 0006? (continued) [Directions 0006]	Yes ○	No ○

17. Storage of gametes and embryos

1	Does your centre store gametes or embryos for treatment purposes ? If no, go to question 2 (continued)	Yes ○	No ○
1.1	Is there an SOP for the procedure for storing gametes and/or embryos? [see T33b] (continued)	Yes ○	No ○
1.2	Have storage procedures been validated based on studies performed by your centre, or on data (continued) from published studies, or from well-established procedures? [see T72]	Yes ○	No ○
1.3	Has your centre established quality indicators or objectives relevant to storage? [see T35] (continued)	Yes ○	No ○
1.4	Has your centre audited how far storage procedures comply with the approved protocols, the (continued) regulatory requirements and quality indicators in the last two years? [see T36]	Yes ○	No ○
1.4.1	Have the findings of the audit been documented? [T36] (continued)	Yes ○	No ○
1.4.2	Have the corrective actions been documented? [T36] (continued)	Yes ○	No ○ N/A ○
1.4.3	Have all required corrective actions been implemented? [see T36] (continued)	Yes ○	No ○ N/A ○
1.5	Can all relevant staff provide documented evidence of the assessment of their competence in (continued) storing cryopreserved material? [see T15a]	1 ○	2 ○ 3 ○ 4 ○
1.6	Is all material currently in storage within the limit of the statutory storage period? [see Act 14(1)(c)] (continued)	Yes ○	No ○
1.7	Before their material is stored, are the providers of gametes screened for: (continued)		
1.7.1	HIV 1 and 2: Anti-HIV – 1, 2? [T50] (continued)	Yes ○	No ○
1.7.2	Hepatitis B: HBsAg and Anti-HBc? [T50] (continued)	Yes ○	No ○
1.7.3	Hepatitis C: Anti-HCV-Ab? [T50] (continued)	Yes ○	No ○
1.8	If HIV 1 and 2, hepatitis B or hepatitis C test results are positive or unavailable, or if the gamete (continued) provider is known to be a source of infection risk, is the sample stored separately? [see Act Schedule 3A(11)- 2006/17/EC, T50(b)]	Yes ○	No ○
1.9	Is HTLV-I antibody testing performed if the gamete provider lives in or originates from high-incidence (continued) areas or has sexual partners originating from those areas, or if their parents originate from those areas? [Act Schedule 3A(11)- 2006/17/EC, T50(c)]	Yes ○	No ○
1.10	Are screening tests carried out in a laboratory accredited by Clinical Pathology Accreditation (CPA) (continued) UK Ltd or an alternative body accrediting to an equivalent standard? [see T51]	Yes ○	No ○
1.11	Does your centre operate a bring-forward system to ensure you get sufficient advance notice of (continued) the end of the consented storage period? [see 17.7]	Yes ○	No ○
2	Does your centre store ovarian or testicular tissue? If no, you have completed this module. (continued)	Yes ○	No ○
2.1	Does your centre hold an HTA licence? [17A] (continued)	Yes ○	No ○

18. Witnessing

1	Does your centre carry out procedures involving the manipulation of gametes or embryos for use in treatment? If no, you do not need to complete this module. (continued)	Yes ○ No ○
1.1	Does you centre 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? [see T71] (continued)	1 ○ 2 ○ 3 ○ 4 ○
1.2	Are witnessing checks completed and recorded at the time the relevant clinical or laboratory process/procedure takes place (i.e. they check it when it happens, not at a later time or the next day? [see T71] (continued)	Yes ○ No ○
1.3	Is a record of witnessing checks kept in each patient's/donor's medical record? [see T71] (continued)	Yes ○ No ○
1.4	Is there an SOP for witnessing or do the SOPs for relevant procedures include witnessing requirements? [see T33b] (continued)	Yes ○ No ○
1.5	Has your centre established quality indicators or objectives relevant to witnessing? [see T35] (continued)	Yes ○ No ○
1.6	In the last two years, has your centre audited how far witnessing procedures comply with the approved protocols, the regulatory requirements and quality indicators? [see T36] (continued)	Yes ○ No ○
1.6.1	Have the findings of the audit been documented? [T36] (continued)	Yes ○ No ○
1.6.2	Have the corrective actions been documented? [T36] (continued)	Yes ○ No ○ N/A ○
1.6.3	Have the required corrective actions been implemented? [see T36] (continued)	Yes ○ No ○ N/A ○
1.7	Can all relevant staff provide documented evidence of the assessment of their competence in witnessing? [see T15a] (continued)	1 ○ 2 ○ 3 ○ 4 ○

19. Traceability

1	Does your centre provide treatment services (including storage for treatment purposes) or recruit gamete (continued) donors? If no , you do not need to complete this module	Yes ○ No ○
1.1	Does your centre ensure that all gametes and embryos are traceable from procurement of gametes (continued) to patient treatment or disposal and vice versa? [see T99]	1 ○ 2 ○ 3 ○ 4 ○
1.2	Does your centre ensure that all relevant data about anything coming into contact with those (continued) gametes or embryos (for example, equipment and results of equipment performance monitoring, materials and consumables) is traceable? [see T99]	1 ○ 2 ○ 3 ○ 4 ○
1.3	Is there a documented SOP for procedures to ensure traceability? [see T33(b)] (continued)	Yes ○ No ○
1.4	Has your centre established quality indicators or objectives relevant to traceability? [see T35] (continued)	Yes ○ No ○
1.5	Have traceability procedures been audited against compliance with the approved protocols, the (continued) regulatory requirements and quality indicators in the last two years? [see Schedule 3A (10) 2006/86/EC, Appendix 1 F and T36]?	Yes ○ No ○
1.5.1	Have the findings of the audit been documented? [T36] (continued)	Yes ○ No ○ N/A ○
1.5.2	Have the corrective actions been documented? [T36] (continued)	Yes ○ No ○
1.5.3	Have all required corrective actions been implemented? [see T36] (continued)	Yes ○ No ○ N/A ○
1.6	Can relevant staff provide documented evidence of training in traceability procedures? [see T15(a)] (continued)	Yes ○ No ○
1.7	Are the containers (dishes, vials, ampoules, tubes etc) at all stages of procurement, processing, (continued) use and storage of gametes and embryos labelled with the patient's/donor's full name and a further identifier or a uniquely identifying donor code (including labelling in the form of electronic tags) ? [see T101]	1 ○ 2 ○ 3 ○ 4 ○
1.8	Does your centre have procedures in place to ensure data necessary for traceability is stored for at (continued) least 30 years (and for such longer period as may be specified in Directions)? [see T103]	Yes ○ No ○

20. Donor Assisted Conception

1 Does your centre provide treatment with donor gametes or embryos? If no, you do not need to complete this module (continued) Yes ○ No ○

1.1 Are those receiving treatment with donated gametes or embryos provided with information on the importance of informing any resulting child at an early age that the child results from the gametes of a person who is not their parent? [see T63a] (continued) Yes ○ No ○

1.2 Are patients given information on how to tell any resulting child at an early age that he or she results from the gametes of a person who is not their parent? [see T63b] (continued) Yes ○ No ○

1.3 Where a donor has not consented to their identity being known (ie gametes were donated before April 2005), is treatment with their gametes or embryos created from their gametes limited to: (continued)

1.3.1 treatments to achieve a sibling pregnancy? [see T54] (continued) Yes ○ No ○ N/A ○

1.3.2 treatments using embryos that were created before 1 April 2006 using donor sperm and the eggs of the woman to be treated [see T54] (continued) Yes ○ No ○ N/A ○

1.3.3 treatments using embryos that were created before 1 April 2006 using donated eggs together with the sperm of the man having treatment with the woman to be treated? [see T54] (continued) Yes ○ No ○ N/A ○

21. Intra-Cytoplasmic Sperm Injection (ICSI)

1	Does your centre provide treatment using ICSI? (continued)		Yes ○ No ○
1.1	Is there an SOP for the procedure for performing ICSI? [see T33b] (continued)		Yes ○ No ○
1.2	Have procedures for ICSI been validated based on studies performed by your centre, or on data from published studies, or from well-established procedures? [see T72] (continued)		Yes ○ No ○
1.3	Has your centre established quality indicators relevant to the performance of ICSI? [see T35] (continued)		Yes ○ No ○
1.4	Has your centre audited how far procedures for the performance of ICSI comply with the approved protocols, the regulatory requirements and quality indicators in the last two years? [see T36]? (continued)		Yes ○ No ○
1.4.1	Have the findings of the audit been documented? [T36] (continued)		Yes ○ No ○
1.4.2	Have the corrective actions been documented? [T36] (continued)		Yes ○ No ○ N/A ○
1.4.3	Have all required corrective actions been implemented? [see T36] (continued)		Yes ○ No ○ N/A ○
1.5	Can all relevant staff provide documented evidence of the assessment of their competence in the performance of ICSI? [see T15a] (continued)		1 ○ 2 ○ 3 ○ 4 ○

22. Research and training

1	Does your centre use embryos for training in embryo biopsy, embryo storage or other embryological (continued) techniques and/or in training activities that are expressly authorised by the Authority?	Yes	No
1.1	Does your centre ensure that no embryos used for the purpose of training in embryo biopsy, embryo (continued) storage or other embryological techniques are kept or used for providing treatment? [T92]	Yes	No
1.2	Does your centre ensure that embryos are only used for training activities that have been expressly (continued) authorised by the Authority? [see T93]	Yes	No
1.3	Has you centre used embryos for the purpose of training persons in embryo biopsy, embryo storage (continued) or other embryological techniques, only where both gamete providers have consented to the use of their embryos, created using their gametes, for the purpose of training ?	Yes	No
1.4	Does your centre have procedures in place to ensure that there is no actual or perceived conflict of (continued) interest between the use of embryos in training and the use of embryos in the provision of treatment services? [see T95]	Yes	No
1.5	Prior to giving consent, is each gamete provider provided with the necessary information on the (continued) nature of the training for which embryos will be used ? [T97]	Yes	No
1.6	Prior to giving consent is each gamete provider informed that the decision whether to donate will not (continued) affect their treatment in any way ?	Yes	No
1.7	Prior to giving consent is every gamete provider informed that they can vary or withdraw the terms (continued) of their consent until the point the embryos are used in training? [see T97]	Yes	No
1.8	Prior to giving consent is each gamete provider provided with information on whether any (continued) information will be fed back to them? [see T97]	Yes	No

23. The Quality Management System

1	Does your centre provide treatment services (including storage for treatment purposes) or recruit gamete donors or derive stem cells for human application?		Yes ○ No ○
1.1	Does your centre have a quality management system? [see T32] (continued)		Yes ○ No ○
1.2	Does your centre have a quality manual? [see T33] (continued)		Yes ○ No ○
1.3	Does your centre have training and reference manuals? [see T33] (continued)		1 ○ 2 ○ 3 ○ 4 ○
1.4	Are procedures for all activities included on the centre's licence, and for those activities carried out in the course of providing treatment services that do not require a licence, documented in standard operating procedures (SOPs)? [see T33b] (continued)		Yes ○ No ○
1.5	Where relevant, do SOPs detail the specifications for any critical materials and reagents used in the procedure? [see T31] (continued)		1 ○ 2 ○ 3 ○ 4 ○
1.6	Has your centre established quality indicators for all licensed activities and for other activities carried out in the course of providing treatment services that do not require a licence? [see T35] (continued)		1 ○ 2 ○ 3 ○ 4 ○
1.7	In the last two years, has your centre audited how far all licensed activities, or activities carried out in the course of providing treatment services that do not require a licence, comply with the approved protocols, the regulatory requirements and quality indicators? [see T36] (continued)		Yes ○ No ○
1.7.1	Have the findings of the audit been documented? [T36] (continued)		Yes ○ No ○
1.7.2	Have the corrective actions been documented? [T36] (continued)		Yes ○ No ○ N/A ○
1.7.3	Have all required corrective actions been implemented? [see T36] (continued)		Yes ○ No ○ N/A ○
1.8	Does your centre have processes in place for reviewing the performance of the quality management system to ensure continuous and systematic improvement? [see Act Schedule 3A (10)] (continued)		Yes ○ No ○

24. Third-party agreements

1	Does a third party procure, test or process gametes or embryos (or all) on behalf of your centre? (continued)	Yes ○ No ○	
1.1	Where a third party procures gametes and/or embryos on behalf your centre, does the third party (continued) provide a report that complies with [T117]	Yes ○ No ○	
2	Is your centre supplied with any goods or services (including distribution services) which may affect the (continued) quality or safety of gametes or embryos intended for use in treatment or in the preparation of stem cells for human application?	Yes ○ No ○	
2.1	Has your centre established written agreements with third parties who provide goods or services (continued) that influence the quality and safety of gametes and embryos? [T111]	1 ○ 2 ○ 3 ○ 4 ○	
2.2	Has your centre evaluated the ability of all third parties to meet the required standards? [T112] (continued)	1 ○ 2 ○ 3 ○ 4 ○	
2.3	Does the content of all third-party agreements comply with standard licence condition [T114] (continued)	1 ○ 2 ○ 3 ○ 4 ○	
2.4	Is it a condition of all agreements that the third party will meet the requirements of the relevant (continued) licence conditions and the guidance set out in the HFEA Code of Practice? [T116]	1 ○ 2 ○ 3 ○ 4 ○	
2.5	Does your centre keep a complete list of all third-party agreements? [T115] (continued)	Yes ○ No ○	

25. Premises and Facilities

1	Are all activities carried out on the licensed premises? [see Act S.12(1)] (continued)	Yes ○ No ○
1.1	Are some activities carried out on the premises of a third party? [see Act S.12(1) and T1] (continued)	Yes ○ No ○
2	Are all licensed premises in the same building? [see Act Schedule 2 S.4(2)(d)]] (continued)	Yes ○ No ○
3	Does your centre keep records of regular cleaning and disinfection of the premises? [see T26] (continued)	1 ○ 2 ○ 3 ○ 4 ○
4	Does your centre process gametes or embryos (or both) intended for treatment purposes or store (continued) gametes or embryos (or both) for treatment purposes?	Yes ○ No ○
4.1	Can your centre provide documented evidence that the processing of gametes and embryos takes (continued) place in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality? [see T20]	Yes ○ No ○
5	Does a third party undertake the diagnosis and investigation of your centre's patients, patients' partners or (continued) donors, or their gametes, embryos or any material removed from them?	Yes ○ No ○
5.1	Are laboratories that undertake the diagnosis and investigation of your centre's patients, patients' (continued) partners or donors, or their gametes, embryos or any material removed from them, accredited by CPA(UK) Ltd or another body accrediting to an equivalent standard? [see T20]	Yes ○ No ○

26. Equipment and Materials

1 Does your centre process gametes and/or embryos intended for treatment purposes or provide storage (continued) for treatment purposes or donation? [see T22] Yes ○ No ○

1.1 Is it possible to track all the equipment and materials used in the procurement and processing of (continued) gametes and/or embryos intended for human application? [see T22] 1 ○ 2 ○ 3 ○ 4 ○

1.2 Is your centre able to provide documented evidence of the maintenance and regular inspection of (continued) equipment in accordance with the manufacturer's instructions? [see T23] 1 ○ 2 ○ 3 ○ 4 ○

1.3 Has critical equipment been validated? [see T24] (continued) 1 ○ 2 ○ 3 ○ 4 ○

1.4 Can your centre provide documented evidence of the revalidation of equipment after repair? [see (continued) T25] 1 ○ 2 ○ 3 ○ 4 ○

1.5 Does your centre have documented procedures for the operation of all critical equipment? [T27] (continued) Yes ○ No ○

1.5.1 Do the documented procedures outline what to do if the equipment malfunctions or fails? (continued) 1 ○ 2 ○ 3 ○ 4 ○

1.6 Is equipment or materials that affect critical processing or storage parameters (e.g. temperature, (continued) pressure, particle counts microbial contamination levels) subject to:

1.6.1 monitoring? [see T24] (continued) 1 ○ 2 ○ 3 ○ 4 ○

1.6.2 alerts? [see T24] (continued) 1 ○ 2 ○ 3 ○ 4 ○

1.6.3 alarms? [see T24] (continued) 1 ○ 2 ○ 3 ○ 4 ○

1.6.4 corrective action? [see T24] (continued) 1 ○ 2 ○ 3 ○ 4 ○

1.7 Is equipment with a critical measuring function calibrated against a traceable standard if available (continued) (e.g. CO_2 monitoring devices, particle counting devices, thermometers)? [see T24] 1 ○ 2 ○ 3 ○ 4 ○

1.8 Does your centre keep records of regular cleaning and disinfection of the equipment? [see T26] (continued) 1 ○ 2 ○ 3 ○ 4 ○

1.9 Are sterile instruments or devices used for the procurement of gametes and/or embryos? [see T28] (continued) 1 ○ 2 ○ 3 ○ 4 ○

1.10 Are the instruments or devices used for the procurement of gametes and/or embryos of good (continued) quality, validated or specifically certified and regularly maintained? [see T28] 1 ○ 2 ○ 3 ○ 4 ○

1.11 Where possible are the medical devices used at your centre CE marked ? [see T30] (continued) 1 ○ 2 ○ 3 ○ 4 ○

2 Does your centre use any reusable instruments? (continued) Yes ○ No ○

2.1 Does your centre have a validated cleaning and sterilisation procedure for removing infectious (continued) agents? [see T29] Yes ○ No ○

27. Adverse Incidents

1	In the time since you last completed a self assessment, has your centre reported to the HFEA any serious adverse events and/or serious adverse reactions that have occurred on any premises to which the centre's licence relates and any relevant third-party premises? [see T106] (continued)	Yes ○ No ○
2	Does your centre have documented procedures for reporting serious adverse events and serious adverse reactions that occur? [see T106] (continued)	Yes ○ No ○
3	Does your centre contract third parties to procure, process or distribute gametes and/or embryos? (continued)	Yes ○ No ○
3.1	Are third parties aware of the requirement to report adverse incidents to the primary centre? [T106] (continued)	Yes ○ No ○

28. Complaints

1 Does your centre have and keep to a complaints procedure? [The National Health Service (Complaints) (continued) Regulations 2004, The Private and Voluntary Health Care (England) Regulations 2001]

Yes ○ No ○

30. Confidentiality and Privacy

1	Does your centre have access to confidential patient or donor identifying information except for that (continued) concerning the provision of basic partner services (IUI)?	Yes ○ No ○
1.1	Does your centre ensure that all information is kept confidential and only disclosed in circumstances (continued) permitted by law? [see T43]	1 ○ 2 ○ 3 ○ 4 ○
1.2	Does your centre have an SOP to ensure that all information is kept confidential and only disclosed (continued) in circumstances permitted by law? [see T33b]	Yes ○ No ○
1.3	In the last two years, has your centre audited how far procedures to ensure that all information is (continued) kept confidential comply with the approved protocols, regulatory requirements and quality indicators? [see T36]?	Yes ○ No ○
1.3.1	Have the findings of the audit been documented? [T36] (continued)	Yes ○ No ○
1.3.2	Have the corrective actions been documented? [T36] (continued)	Yes ○ No ○ N/A ○
1.3.3	Have all required corrective actions been implemented? [see T36] (continued)	Yes ○ No ○ N/A ○
1.4	Can relevant staff provide documented evidence of having received training in maintaining (continued) confidentiality? [see T15a]	1 ○ 2 ○ 3 ○ 4 ○
1.5	Does your centre have processes in place to ensure that access to a centre's health data and (continued) records is secure at all times; conforms with legislative requirements; and is only available to persons named on a centre's licence or authorised by the Person Responsible? [T44]	Yes ○ No ○
1.6	Do the processes ensure the systems in place for establishing and maintaining data security (continued) measures and safeguards against any unauthorised data additions, deletions or modifications to patient/donor files or records; and the transfer of information? [T44a]	Yes ○ No ○
1.7	Are there processes in place to resolve all data discrepancies? [T44b] (continued)	Yes ○ No ○
1.8	Are there processes in place to prevent unauthorised disclosure of information whilst guaranteeing (continued) the traceability of gamete, embryo or tissue (cell) donations? [T44c]	Yes ○ No ○
1.9	Are there processes in place for considering and responding to applications for access to (continued) confidential records and correctly identifying applicants? [T44d]	Yes ○ No ○
1.10	Are there systems in place for receiving, checking and arranging authorised access to confidential (continued) data and records? [T44e]	Yes ○ No ○
1.11	Is access to registers and data restricted to people authorised by the Person Responsible [see T45] (continued)	Yes ○ No ○
1.12	Is access to areas where confidential identifying information can be seen or obtained (records (continued) stores, laboratories, cryostores etc) restricted to people authorised by the Person Responsible? [see Act section 33A(1)]	1 ○ 2 ○ 3 ○ 4 ○

31. Record Keeping and Document Control

1	Does your centre provide treatment services (including storage for treatment purposes) or recruit donors? (continued)	Yes ○ No ○	
1.1	Is there an SOP for the process for submitting data to the HFEA in compliance with Directions 0005? (continued) [see T33b]	Yes ○ No ○	
1.2	Has your centre established quality indicators relevant to submission of data to the HFEA? [see T35] (continued)	Yes ○ No ○	
1.3	In the last two years, has your centre audited how far procedures for submission of data to the (continued) HFEA comply with the approved protocols, the regulatory requirements and quality indicators? [see T36]?	Yes ○ No ○	
1.3.1	Have the findings of the audit been documented? [T36] (continued)	Yes ○ No ○	
1.3.2	Have the corrective actions been documented? [T36] (continued)	Yes ○ No ○ N/A ○	
1.3.3	Have all required corrective actions been implemented? [seeT36] (continued)	Yes ○ No ○ N/A ○	
1.4	Can relevant staff provide documented evidence of having received training in submitting data to the (continued) HFEA? [see T15a]	1 ○ 2 ○ 3 ○ 4 ○	
1.5	Does your centre have a document control procedure that records the history of document reviews (continued) and ensures that only current versions of documents are in use? [see T34]	1 ○ 2 ○ 3 ○ 4 ○	
1.6	Is consent and/or withdrawal of consent documented in accordance with the general Directions (continued) 0007? [see Directions 0007]	Yes ○ No ○	
1.7	For each patient/donor, does the centre maintain a record containing: (continued)		
1.7.1	patient/donor identification: first name, surname, date of birth, age and sex? [see T46] (continued)	1 ○ 2 ○ 3 ○ 4 ○	
1.7.2	how, and by whom, the patient/donor has been reliably identified? [see T46] (continued)	1 ○ 2 ○ 3 ○ 4 ○	
1.7.3	the services provided to them? [see T46] (continued)	1 ○ 2 ○ 3 ○ 4 ○	
1.7.4	medical history? [see T46] (continued)	1 ○ 2 ○ 3 ○ 4 ○	
1.7.5	welfare-of-the-child assessment? [see T46] (continued)	1 ○ 2 ○ 3 ○ 4 ○	
1.7.6	consent, including consent to the purpose or purposes for which their gametes or embryos (continued) created using their gametes may be used, and any specific instructions for use and/or disposal? [see T46]	1 ○ 2 ○ 3 ○ 4 ○	
1.7.7	clinical and laboratory data and the results of any test carried out? [see T46] (continued)	1 ○ 2 ○ 3 ○ 4 ○	
1.8	Does your centre have procedures in place to ensure that records are protected from unauthorised (continued) amendment; are retained; and can be readily retrieved in this condition throughout their specified retention period? [T47]	Yes ○ No ○	
1.9	Are patient/donor records required for full traceability kept for at least 30 years (or for such longer (continued) period as may be specified in Directions) after clinical use, or the expiry date, in an appropriate archive acceptable to HFEA? [T48]	Yes ○ No ○	

32. Disclaimer

1 Persons submitting this application should note that Section 18 of the Human Fertilisation & Embryology Act (continued) 1990 (as amended) states that "a Licence Committee may revoke a licence if it is satisfied that any information given for the purposes of application for the grant of the licence was in any material respect false or misleading". They should also note that under section 41(3) provision of false or misleading information, knowingly or in a reckless manner, is a criminal offence.

2 I the Person Responsible confirm the information provided on this application is to the best of my (continued) knowledge, true and accurate. Confirm ☐

3 Comments (continued)