

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** 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] 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)] Yes No
- 1.3 Has your centre assessed the workforce requirements in the last year? [see 25.10] Yes No
- 1.4 Is your centre operating with a full staff complement? [see T12] 1 2 3 4
- 1.5 Does your centre have a documented induction training procedure for all staff? [see T15] 1 2 3 4
- 1.6 Do all staff participate in relevant professional development? [T15] 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)] 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** Yes No
- 2.1 Is the individual responsible for the clinical embryology laboratory registered with the HPC? [see T14, 2.19(c)] Yes No
- 2.2 Are all eligible staff working in the clinical embryology laboratory registered with the HPC? 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.** Yes No
- 3.1 Does your centre have access to a nominated registered scientist to advise on and oversee scientific activities? [see T16] 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 offered)? Those taking consent for basic partner treatment services (IUI) are exempted from the requirement to offer counselling.** Yes No
- 1.1 Does your centre offer counselling to those providing consent:
- 1.1.1 as required by schedule 3 of the HF&E Act? [see Act schedule 3, S.3 (1)(a)] Yes No
 N/A
- 1.1.2 to agreed fatherhood? [see Act schedule 3Z part 2] Yes No
 N/A
- 1.1.3 to agreed female parenthood? [see Act schedule 3ZA part 2] Yes No
 N/A
- 1.2 Is there a counselling Standard Operating Procedure? [see T33b] Yes No
- 1.3 Has your centre established quality indicators or objectives for counselling? [see T35] Yes No
- 1.4 Has your centre assessed how far counselling procedures comply with the approved protocols, the regulatory requirements and quality indicators in the last two years? [see T36] Yes No
- 1.4.1 Have all steps been taken to correct procedures where appropriate? [see T36] Yes No
- 1.5 Can relevant staff provide documented evidence of the assessment of their competence to provide counselling? [see T15a] 1 2 3 4
- 1.6 Before consent to treatment is taken is a woman and any man or woman who is to be the intended second parent given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services? [see T60] Yes No
 N/A
- 1.7 Is the centres counsellor(s):
- 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)] Yes No
- 1.7.2 accredited under the British Infertility Counselling Association accreditation scheme (i.e. not a member only)? [see 2.12(b)] 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)] 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] Yes No

4 Provision of Information

- 1 Is your centre responsible for providing information to patients before they give consent?** Yes No
- 1.1 Is proper information provided to patients giving consent to treatment, as required by schedule 3 of 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:
- 1.2.1 consent to treatment? [see T33b] Yes No
 N/A
- 1.2.2 consent to donation for treatment? [see T33b] Yes No
 N/A
- 1.2.3 consent to donation for research? [see T33b] Yes No
 N/A
- 1.2.4 consent to use in training? [see T33b] Yes No
 N/A
- 1.3 Has your centre established quality indicators or objectives relevant to the provision of information? [seeT35] 1 2 3 4
- 1.4 Has your centre audited how far your procedures for the provision of information comply with the 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] Yes No
 N/A
- 1.4.2 Have the corrective actions been documented? [see T36] Yes No
 N/A
- 1.4.3 Have all required corrective actions been implemented? [see Act, Schedule 3A (10)] Yes No
 N/A
- 1.5 Can relevant staff provide documented evidence of the assessment of their competence to provide information to those consenting to:
- 1.5.1 treatment? [see T15b] Yes No
 N/A
- 1.5.2 donation of gametes for treatment? [see T15b] Yes No
 N/A
- 1.5.3 donation to research [see T15b] Yes No
 N/A
- 1.5.4 donation for use in training? [see T15b] Yes No
 N/A

5 Consent

- 1 Do staff at your centre have responsibility for obtaining consent?** Yes No
- 1.1 Is written consent obtained before gametes or embryos are used in treatment? [see T57] Yes No
- 1.2 Is there an SOP for taking effective consent? [see T33b] Yes No
- 1.3 Has your centre established quality indicators relevant to consent procedures? [see T35] Yes No
- 1.4 Have you audited how far procedures for taking consent comply with the 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] Yes No
- 1.4.2 Have the corrective actions been documented? [see T36] Yes No
 N/A
- 1.4.3 Have all required corrective actions been implemented? [see Act, Schedule 3A (10)] Yes No
 N/A
- 1.5 Can relevant staff provide documented evidence of the assessment of their competence to take 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 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] 1 2 3 4
- 1.8 Is the identity of the person who gave consent cross-referenced to records when procedures are 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 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 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 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 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 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 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?** 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)] Yes No
- 1.2 Do you inform patients and their partners having treatment with donor gametes or embryos about parenthood laws? [see T60] 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)] 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)] 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 ? Yes No

7 Multiple Births

- 1 Does your centre provide IVF or GIFT treatments?** Yes No
- 1.1 Does your licensed centre have a multiple births minimisation strategy? [see Directions ref 0003] Yes No
- 1.2 Can your centre provide documented evidence of the outcome of regular audits and evaluations of 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 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
- 2 Since you last completed a SAQ, have multiple embryos been transferred to a patient who meets the criteria for single embryo transfer, as set out in the multiple births minimisation strategy?** Yes No
- 2.1 Has your licensed centre:
- 2.1.1 recorded this fact in the patient's medical records and in the summary log? [see Directions ref 0003] Yes No
- 2.1.2 recorded in the patient's records a clear explanation of the reasons for transferring more than 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 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 embryos or four eggs have been placed in a woman?** Yes No
- 3.1 Does your centre maintain:
- 3.1.1 a detailed explanation in each patient's medical records explaining the reasons for transferring 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, 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)?** 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] Yes No
- 1.2 Is there an SOP for a WOC assessment? [see T33b] Yes No
- 1.3 Has your centre established quality indicators or objectives relevant to assessing the welfare of the child? [see T35] 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] Yes No
- 1.4.1 Have the findings of the audit been documented? [see T36] Yes No
- 1.4.2 Have the corrective actions been documented? [see T36] Yes No
 N/A
- 1.4.3 Have all required corrective actions been implemented? [see Act, Schedule 3A (10)] 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] Yes No
- 2 Does your centre provide treatment involving surrogacy?** 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] 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** Yes No
- 1.1 Is there an SOP for embryo biopsy? [see T33] Yes No
- 1.2 Has the biopsy procedure been validated based on studies performed by your centre, or on data 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] Yes No
- 1.4 Has your centre audited how far biopsy procedures comply with the 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] Yes No
 N/A
- 1.4.2 Have the corrective actions been documented? [see T36] Yes No
 N/A
- 1.4.3 Have all required corrective actions been implemented? [see Act, Schedule 3A (10)] Yes No
 N/A
- 1.5 Can relevant staff provide documented evidence of their competence to carry out embryo biopsy? [see T88] 1 2 3 4
- 1.6 Can you confirm that your centre has not carried out sex selection for social reasons? [see T88] Yes No
- 1.7 Can you confirm in every case that your centre has not transferred biopsied embryos in the same 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** Yes No
- 2.1 Is there an SOP for carrying out PGS? [see T33b] Yes No
- 2.2 Has the PGS procedure been validated based on studies performed by your centre, or on data from 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] Yes No
- 2.4 Has your centre audited how far PGS procedures comply with the approved protocols, the 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] Yes No
 N/A
- 2.4.2 Have the corrective actions been documented? [T36] Yes No
 N/A
- 2.4.3 Have all required corrective actions been implemented? [see Act, Schedule 3A (10)] Yes No
 N/A
- 2.5 Can all relevant staff provide documented evidence of the assessment of their competence in 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 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 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 (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]

Yes No

3.3 Has your centre evaluated the ability of the third party to meet the required standards? [see T112]

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 genetic illness? If no, you do not need to complete this module.** Yes No
- 1.1 Is there an SOP for PGD? [see T33b] Yes No
- 1.2 Has the PGD process been validated based on studies performed by your centre, or on data from 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] Yes No
- 1.4 Has your centre audited how far PGD procedures comply with the 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? [T36] Yes No
- 1.4.2 Have the corrective actions been documented? [T36] Yes No
 N/A
- 1.4.3 Have all required corrective actions been implemented? [see Act, Schedule 3A (10)]yES Yes No
 N/A
- 1.5 Can all relevant staff provide documented evidence of the assessment of their competence in 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 Ltd or an alternative body accrediting to an equivalent standard? [see T21] Yes No
- 1.7 Has your centre carried out PGD only for those genetic conditions, chromosomes or traits (or combinations of these) that are expressly authorised by the Authority? [see T89] No Yes
- 1.8 Can you confirm that your centre has not carried out sex selection for social reasons? [see T88] Yes No
- 1.9 Can you confirm that your centre has not transferred biopsied embryos in the same cycle as non-biopsied embryos? [see T88] Yes No

11 Donor selection

- 1 Does the centre recruit gamete donors or sharers or provide treatment with donated embryos or provide treatment involving surrogacy?** Yes No
- 1.1 Is there an SOP for the process to be followed when selecting and recruiting donors? [T33(b)] Yes No
- 1.2 Has the centre established quality indicators relevant to the selection and recruitment of donors? [T35] Yes No
- 1.3 Have procedures for selecting and recruiting donors been audited against compliance with the approved protocols, the regulatory requirements and quality indicators in the last two years? [Schedule 3A (10) 2006/86/EC, Appendix 1 F and T36]?
- 1.3.1 Have the findings of the audit been documented? [T36] Yes No
- 1.3.2 Have the corrective actions been documented? [T36] Yes No
 N/A
- 1.3.3 Have all required corrective actions been implemented? [see Act, Schedule 3A (10)] Yes No
 N/A
- 1.4 Can all relevant staff provide documented evidence of the assessment of their competence in selecting and recruiting donors? [T15(a)] 1 2 3 4
- 1.5 Are donors selected on the basis of their
- 1.5.1 age? [T52(a)] 1 2 3
 4
- 1.5.2 health and medical history information provided on a questionnaire and through a personal interview performed by a qualified and trained healthcare professional? [T52(a)] 1 2 3
 4
- 1.6 Are donors screened for
- 1.6.1 HIV 1 and 2: Anti-HIV - 1, 2 [T52(b)] 1 2 3
 4
- 1.6.2 Hepatitis B: HBsAg / Anti-HBc [T52(b)] 1 2 3
 4
- 1.6.3 Hepatitis C: Anti-HCV-Ab [T52(b)] 1 2 3
 4
- 1.6.4 Syphilis [T52(b)] 1 2 3
 4
- 1.6.5 Chlamydia [T52(b)] 1 2 3
 4
- 1.6.6 CMV [T52(b)] 1 2 3
 4
- 1.7 Are donors of gametes and embryos screened in accordance with current professional guidance produced by the relevant professional bodies? [11.15]1d 1 2 3 4
- 1.8 Is screening carried out by a laboratory accredited by CPA (UK) Ltd or an alternative body accrediting to an equivalent standard? [T53(a)] 1 2 3 4

- 1.9 Is sperm to be used for donation quarantined for a minimum of 180 days, prior to repeat screening of the donor? [T53(c)] Yes No
- 1.9.1 Is the blood sample tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV? Yes No
- 1.9.2 Does processing include an inactivation step that has been validated for the viruses concerned? Yes No
- 1.10 Are frozen embryos to be used for donation quarantined for a minimum of 180 days, prior to repeat screening of both gamete providers? [T53(c)] Yes No
 N/A
- 1.10.1 Is the blood sample tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV? Yes No
 N/A
- 1.10.2 Does processing include an inactivation step that has been validated for the viruses concerned? Yes No
 N/A
- 1.11 Does the centre have procedures in place to identify when additional screening may be required? [T52(g)] 1 2 3 4
- 1.12 Can the centre provide donors with the following information if requested
- 1.12.1 the number of persons born as a result of the donation [Act 31ZD(3)] 1 2 3
 4
- 1.12.2 the sex of each of those persons [Act 31ZD(3)] 1 2 3
 4
- 1.12.3 the year of birth of each of those persons [Act 31ZD(3)] 1 2 3
 4

12 Egg sharing

1 Does the centre recruit egg sharers donating for treatment purposes or for research purposes?

Yes No

1.1 Are treatment services provided to the egg share donor in the course of the donation cycle unless 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** Yes No
- 1.1 Are payments to donors restricted to expenses incurred in the UK and compensation for loss of earnings within the limits prescribed in directions? [Directions 0001 version 1] Yes No
- 1.2 Where your centre pays donors, do you keep a record of:
- 1.2.1 the actual expenses or lost earnings incurred by the donor? [Directions 0001 version 1] Yes No
- 1.2.2 how much you have reimbursed donors for expenses? [Directions 0001 version 1] Yes No
- 1.2.3 how much compensation for lost earnings you have paid the donor? [Directions 0001 version 1] Yes No
- 1.2.4 the receipts produced by the donor, and/or what the Person Responsible has done to satisfy themselves that the donor has actually incurred the expenses or lost earnings they have claimed for? [Directions 0001 version 1] Yes No
- 2 Has your centre imported any donated gametes? If no, go to question 3** Yes No
- 2.1 When gametes have been donated overseas have you checked that the donor has not received more than the prescribed amount of compensation for loss of earnings? [Directions 0001 version 1] Yes No
- 3 Has your centre provided treatment with gametes donated by an individual introduced by a third party or patient? If no, you have completed this module** Yes No
- 3.1 Where a third party or a patient has been involved in introducing a donor, have you checked that the donor has not received more than the prescribed amount of compensation? [Directions 0001 version 1] Yes No

14 Surrogacy

- 1 Does your centre provide treatment involving surrogacy? If no, you do not need to complete this module** Yes No
- 1.1 Does your centre screen the gamete providers in surrogacy arrangements as donors? [see T53c] Yes No
- 1.2 Does your centre register the gamete providers in surrogacy arrangements as donors? [see Directions 0003] Yes No
- 1.3 Does your centre quarantine sperm for 180 days before use? [see T53c] If YES you have completed this module Yes No
- 1.3.1 is the sample tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV? [see T53c] Yes No
 N/A
- 1.3.2 does the processing include an inactivation step that has been validated for the viruses concerned? [see T53c] Yes No
 N/A

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 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 procedures (SOPs)? [see T33b] Yes No
- 1.2 Have the critical procurement and processing procedures been validated? [see T72] Yes No
- 1.3 Has the centre established quality indicators or objectives relevant to procurement and processing procedures? [see T35] Yes No
- 1.4 In the last two years, has your centre audited how far procurement and processing procedures 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] Yes No
 N/A
- 1.4.2 Have the corrective actions been documented? [T36] Yes No
 N/A
- 1.4.3 Have all required corrective actions been implemented? [see Act, Schedule 3A (10)] Yes No
 N/A
- 1.5 Can all relevant staff provide documented evidence of having demonstrated competence in procurement and processing procedures? [T15a] Yes No
- 1.6 Does the clinician responsible for the patient document the justification for the use of their gametes 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 T68] Yes No
- 1.8 If the centre provided sperm for home insemination in the last year, was the sperm supplied thawed or in the process of thawing? [see CoP interpretation of mandatory requirements 15A, Act 4(1)(a)] Yes No
 N/A
- 2 Does the centre distribute gametes or embryos? If no, go to question 3** Yes No
- 2.1 Is there an SOP that details the circumstances, responsibilities and procedures for the release of stored material before distribution? [see T33b] Yes No
- 2.2 Are transport conditions including temperature and time limit, specified? [see T107] Yes No
- 2.3 Have all containers and packages been validated as fit for purpose? [see T108] Yes No
- 2.4 Does your centre have a recall procedure that defines the responsibilities and actions required 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 of mandatory requirements] Yes No
- 2.6 Does your centre have a procedure for the investigation of any recall as an adverse incident [CoP interpretation of mandatory requirements 15B] Yes No
- 2.7 When transporting gametes does your centre ensure that the shipping container or a separate sheet accompanying the container includes labelling as required by T107? [T107] Yes No

- 2.8 Is all required information provided when distributing material? [T110] Yes No
- 2.9 Does the centre ensure that gametes and embryos are packaged and transported in a manner that 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 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 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 is secure ? [T108] Yes No
- 3 Does the centre contract a third party to distribute gametes or embryos? If No, go to section 4.** Yes No
- 3.1 Is a documented agreement in place that ensures the required conditions are maintained during 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 you have completed this section** Yes No
- 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 compliant with the requirements of T109? [T109] 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, 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? [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** Yes No
- 1.1 Is there an SOP for the procedure for storing gametes and/or embryos? [see T33b] Yes No
- 1.2 Have storage procedures been validated based on studies performed by your centre, or on data 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] Yes No
- 1.4 Has your centre audited how far storage procedures comply with the 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? [T36] Yes No
- 1.4.2 Have the corrective actions been documented? [T36] Yes No
 N/A
- 1.4.3 Have all required corrective actions been implemented? [see Act, Schedule 3A (10)] Yes No
 N/A
- 1.5 Can all relevant staff provide documented evidence of the assessment of their competence in 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)] Yes No
- 1.7 Before their material is stored, are the providers of gametes screened for:
- 1.7.1 HIV 1 and 2 (Anti-HIV-1,2)? [S50] Yes No
- 1.7.2 Hepatitis B (HBsAg Anti-HBc)? [S50] Yes No
- 1.7.3 Hepatitis C (Anti-HCV-Ab)? [S50] Yes No
- 1.8 If HIV 1 and 2, hepatitis B or hepatitis C test results are positive or unavailable, or if the gamete provider is known to be a source of infection risk, is the sample stored separately? [see Act Schedule 3A(11)- 2006/17/EC, S50(b)] Yes No
- 1.9 Is HTLV-I antibody testing performed if the gamete provider lives in or originates from high-incidence areas or has sexual partners originating from those areas, or if their parents originate from those areas? [Act Schedule 3A(11)- 2006/17/EC, S50(c)] Yes No
- 1.10 Are screening tests carried out in a laboratory accredited by Clinical Pathology Accreditation (CPA) 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 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.** Yes No
- 2.1 Does your centre hold an HTA licence? [17A] 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.** Yes No
- 1.1 Is the identification of samples and the patients or donors to whom they relate witnessed by two members of staff at all critical points of the clinical and laboratory process? [see T71] 1 2 3 4
- 1.2 Do two members of staff witness the procedure at the time it is done (i.e. they check it when it happens, not at a later time or the next day)? [see T71] Yes No
- 1.3 Is a record kept in each patient's/donor's medical records of:
- 1.3.1 the name, status and signature of the person performing the procedure or is hard copy of electronic witnessing retained? [see T71] Yes No
- 1.3.2 the name, status and signature of the person who witnesses the procedure or is hard copy of electronic witnessing retained? [see T71] Yes No
- 1.4 Is there an SOP for witnessing or do the SOPs for relevant procedures include witnessing requirements? [see T33b] Yes No
- 1.5 Has your centre established quality indicators or objectives relevant to witnessing? [see T35] 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] Yes No
- 1.6.1 Have the findings of the audit been documented? [T36] Yes No
- 1.6.2 Have the corrective actions been documented? [T36] Yes No
 N/A
- 1.6.3 Have the required corrective actions been implemented? [see Act, Schedule 3A (10)] Yes No
 N/A
- 1.7 Can all relevant staff provide documented evidence of the assessment of their competence in witnessing? [see T15a] 1 2 3 4

19 Traceability

- 1 Does your centre provide treatment services (including storage for treatment purposes) or recruit gamete 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 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 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)] Yes No
- 1.4 Has your centre established quality indicators or objectives relevant to traceability? [see T35] Yes No
- 1.5 Have traceability procedures been audited against compliance with the approved protocols, the 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] Yes No N/A
- 1.5.2 Have the corrective actions been documented? [T36] Yes No
- 1.5.3 Have all required corrective actions been implemented? [see Act, Schedule 3A (10)] Yes No N/A
- 1.6 Can relevant staff provide documented evidence of training in traceability procedures? [see T15(a)] Yes No
- 1.7 Are the containers (dishes, vials, ampoules, tubes etc) at all stages of procurement, processing, 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 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** 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] 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] 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:
- 1.3.1 treatments to achieve a sibling pregnancy? [see T54] 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] 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] Yes No
 N/A

21 Intra-Cytoplasmic Sperm Injection (ICSI)

- 1 Does your centre provide treatment using ICSI?** Yes No
- 1.1 Is there an SOP for the procedure for performing ICSI? [see T33b] 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] Yes No
- 1.3 Has your centre established quality indicators relevant to the performance of ICSI? [see T35] 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] Yes No
- 1.4.1 Have the findings of the audit been documented? [T36] Yes No
- 1.4.2 Have the corrective actions been documented? [T36] Yes No
 N/A
- 1.4.3 Have all required corrective actions been implemented? [see Act, Schedule 3A (10)] 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] 1 2 3 4

22 Research and training

- 1 Does your centre use embryos for training in embryo biopsy, embryo storage or other embryological 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 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 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 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 Has the centre established documented procedures to ensure that clinical and training roles are separated? [see T95] Yes No
- 1.5 Has your centre established documented procedures to ensure that the number of embryos used in training is kept to a minimum? [see T96] Yes No
- 1.6 Prior to giving consent, is each gamete provider provided with the necessary information on the nature of the training for which embryos will be used ? [T97] Yes No
- 1.7 Prior to giving consent is each gamete provider informed that the decision whether to donate will not affect their treatment in any way ? Yes No
- 1.8 Prior to giving consent is every gamete provider informed that they can vary or withdraw the terms of their consent until the point the embryos are used in training? [see T97] Yes No
- 1.9 Prior to giving consent is each gamete provider provided with information on whether any 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] Yes No
- 1.2 Does your centre have a quality manual? [see T33] Yes No
- 1.3 Does your centre have training and reference manuals? [see T33] 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] Yes No
- 1.5 Where relevant, do SOPs detail the specifications for any critical materials and reagents used in the procedure? [see T31] 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] 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] Yes No
- 1.7.1 Have the findings of the audit been documented? [T36] Yes No
- 1.7.2 Have the corrective actions been documented? [T36] Yes No
 N/A
- 1.7.3 Have all required corrective actions been implemented? [see Act, Schedule 3A (10)] 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)] 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?** Yes No
- 1.1 Where a third party procures gametes and/or embryos on behalf your centre, does the third party provide a report that complies with T105? [T105] Yes No
- 2 Is your centre supplied with any goods or services (including distribution services) which may affect the 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 that influence the quality and safety of gametes and embryos? [T99] 1 2 3 4
- 2.2 Has your centre evaluated the ability of all third parties to meet the required standards? [T100] 1 2 3 4
- 2.3 Does the content of all third-party agreements comply with standard licence condition T102? [T102] 1 2 3 4
- 2.4 Is it a condition of all agreements that the third party will meet the requirements of the relevant licence conditions and the guidance set out in the HFEA Code of Practice? [T104] 1 2 3 4
- 2.5 Does your centre keep a complete list of all third-party agreements? [T103] Yes No

25 Premises and Facilities

- 1 Are all activities carried out on the licensed premises? [see Act S.12(1)]** Yes No
- 1.1 Are some activities carried out on the premises of a third party? [see Act S.12(1) and T1] Yes No
- 2 Are all licensed premises in the same building? [see Act Schedule 2 S.4(2)(d)]** Yes No
- 3 Is a copy of the Certificate of Licence (the first page of the centre's licence) displayed at the licensed premises in a position or positions in which it can easily be read? [see T5]** Yes No
- 4 Does your centre keep records of regular cleaning and disinfection of the premises? [see T26]** 1 2 3 4
- 5 Has your centre made changes to the premises where licensed activities are carried out in the time since the last inspection?** Yes No
- 5.1 Before altering or adding to existing premises, did the person responsible contact the HFEA to inform us of the change? [see T18] Yes No
- 6 Does your centre process gametes or embryos (or both) intended for treatment purposes or store gametes or embryos (or both) for treatment purposes?** Yes No
- 6.1 Can your centre provide documented evidence that the processing of gametes and embryos takes 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
- 7 Does a third party undertake the diagnosis and investigation of your centre's patients, patients' partners or donors, or their gametes, embryos or any material removed from them?** Yes No
- 7.1 Are laboratories that undertake the diagnosis and investigation of your centre's patients, patients' 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 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 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 equipment in accordance with the manufacturer's instructions? [see T23] 1 2 3 4
- 1.3 Has critical equipment been validated? [see T24] 1 2 3 4
- 1.4 Can your centre provide documented evidence of the revalidation of equipment after repair? [see T25] 1 2 3 4
- 1.5 Does your centre have documented procedures for the operation of all critical equipment? [T27] Yes No
- 1.5.1 Do the documented procedures outline what to do if the equipment malfunctions or fails? 1 2 3 4
- 1.6 Is equipment or materials that affect critical processing or storage parameters (e.g. temperature, pressure, particle counts microbial contamination levels) subject to:
- 1.6.1 monitoring? [see T24] 1 2 3 4
- 1.6.2 alerts? [see T24] 1 2 3 4
- 1.6.3 alarms? [see T24] 1 2 3 4
- 1.6.4 corrective action? [see T24] 1 2 3 4
- 1.7 Is equipment with a critical measuring function calibrated against a traceable standard if available (e.g. CO2 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] 1 2 3 4
- 1.9 Are sterile instruments or devices used for the procurement of gametes and/or embryos? [see T28] 1 2 3 4
- 1.10 Are the instruments or devices used for the procurement of gametes and/or embryos of good 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] 1 2 3 4
- 2 Does your centre use any reusable instruments?** Yes No
- 2.1 Does your centre have a validated cleaning and sterilisation procedure for removing infectious 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] Yes No
- 2 Does your centre have documented procedures for reporting serious adverse events and serious adverse reactions that occur? [see T106] Yes No
- 3 Does your centre contract third parties to procure, process or distribute gametes and/or embryos? Yes No
- 3.1 Are third parties aware of the requirement to report adverse incidents to the primary centre? [T106] Yes No

28 Complaints

1 Does your centre have and keep to a complaints procedure? [The National Health Service (Complaints) 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 concerning the provision of basic partner services (IU)?** Yes No
- 1.1 Does your centre ensure that all information is kept confidential and only disclosed in circumstances 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 in circumstances permitted by law? [see T43 and T33b] Yes No
- 1.3 In the last two years, has your centre audited how far procedures to ensure that all information is 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] Yes No
- 1.3.2 Have the corrective actions been documented? [T36] Yes No
 N/A
- 1.3.3 Have all required corrective actions been implemented? [see Act, Schedule 3A (10)] Yes No
 N/A
- 1.4 Can relevant staff provide documented evidence of having received training in maintaining confidentiality? [see T15a] 1 2 3 4
- 1.5 Does your centre have an SOP for the control of access to health data and records? [see T44] Yes No
- 1.6 Does the SOP document the systems in place for establishing and maintaining data security measures and safeguards against any unauthorised data additions, deletions or modifications to patient/donor files or records; and the transfer of information? [see T44a] Yes No
- 1.7 Does the SOP document the systems in place for establishing and maintaining procedures to resolve all data discrepancies? [see T44b] Yes No
- 1.8 Does the SOP document the systems in place for preventing unauthorised disclosure of information while guaranteeing the traceability of gamete, embryo or tissue (cell) donations? [see T44c] Yes No
- 1.9 Does the SOP document the systems in place for considering and responding to applications for access to confidential records and for correctly identifying applicants? [see T44d] Yes No
- 1.10 Does the SOP document the systems in place for receiving, checking and arranging authorised access to confidential data and records? [see T44e] Yes No
- 1.11 Is access to registers and data restricted to people authorised by the Person Responsible [see T45] Yes No
- 1.12 Is access to areas where confidential identifying information can be seen or obtained (records 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?** Yes No
- 1.1 Is there an SOP for the process for submitting data to the HFEA in compliance with Directions 0005? [see T33b] Yes No
- 1.2 Has your centre established quality indicators relevant to submission of data to the HFEA? [see T35] Yes No
- 1.3 In the last two years, has your centre audited how far procedures for submission of data to the 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] Yes No
- 1.3.2 Have the corrective actions been documented? [T36] Yes No
 N/A
- 1.3.3 Have all required corrective actions been implemented? [see Act, Schedule 3A (10)] Yes No
 N/A
- 1.4 Can relevant staff provide documented evidence of having received training in submitting data to the HFEA? [see T15a] 1 2 3 4
- 1.5 Does your centre have a document control procedure that records the history of document reviews 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 0007? [see Directions 0007] Yes No
- 1.7 For each patient/donor, does the centre maintain a record containing:
- 1.7.1 patient/donor identification: first name, surname, date of birth, age and sex? [see T46] 1 2 3
 4
- 1.7.2 how, and by whom, the patient/donor has been reliably identified? [see T46] 1 2 3
 4
- 1.7.3 the services provided to them? [see T46] 1 2 3
 4
- 1.7.4 medical history? [see T46] 1 2 3
 4
- 1.7.5 welfare-of-the-child assessment? [see T46] 1 2 3
 4
- 1.7.6 consent, including consent to the purpose or purposes for which their gametes or embryos 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] 1 2 3
 4
- 1.8 Does your centre have procedures in place to ensure that records are protected from unauthorised 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 period as may be specified in Directions) after clinical use, or the expiry date, in an appropriate archive acceptable to HFEA? [T48] Yes No