Human Fertilisation and Embryology Authority

Licensed centre - GB

Licence reference:	L0383-1-b
Licence for:	Storage only
Centre reference:	0383
Centre name:	Roylance Stability Storage Limited ta Sampled
Licensed premises:	Biocity Bo'Ness Road Newhouse Motherwell Lanarkshire ML1 5UH
Person Responsible:	Dr Shareef Nahas
Licence Holder:	Michael Whatmough

This Licence is granted under Section 11 of the Human Fertilisation and Embryology Act 1990 ('the Act') and is subject to conditions set out in the accompanying annexes. This Licence authorises the following activities to be carried out, at the above premises, under the supervision of the Person Responsible:

- Procuring embryos
- Processing embryos
- Distributing embryos
- Procuring gametes
- Processing gametes
- Distributing gametes
- Storage of embryos
- Storage of gametes
- Using embryos for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques

Signed

Peter Thompson

Chief Executive

Signed

Julia Chain

Chair

Valid from: 10/02/2026

Expires on: 12/01/2027

Human Fertilisation and Embryology Authority

Standard Licence Conditions – GB

Treatment and Storage Licences

Licensing

T1. The activities authorised by the licence must be carried out only on the premises specified in this licence and under the supervision of the person responsible (PR). However, where authorised by a licence, procurement, testing, processing or distribution of gametes or embryos intended for human application can also be carried out on relevant third party premises, provided that such premises, and the activities undertaken there, are covered by the terms of a written third party agreement.

T2. Suitable practices must be used in the course of activities authorised by this licence and in other activities carried out in the course of providing treatment services that do not require a licence.

T3. Any member or employee of the Authority, on production of a document identifying the person as such, if so required, must at all reasonable times be permitted to enter those premises and inspect them (including inspecting any equipment or records and observing any activity).

T4. In support of an inspection, the Authority must be provided, within 28 days of a request in writing being made, with such information as specified in the written requests or in Directions.

T5. **This licence condition has been removed.**

T6. When carrying out licensable activities, the centre shall only use those processes which have been expressly authorised by the Authority and published on the HFEA website (as amended from time to time).

T7. Where the PR is unable to carry out their duties for any reason the holder of the licence must inform the Authority immediately and apply to the Authority for a licence variation to nominate a substitute PR. This nominated substitute PR must not commence their post unless and until the Authority decides that they are suitable.

Person responsible (PR)

T8. **This licence condition has been removed.**

T9. The PR must have responsibility for:

a. ensuring the requirements imposed by section 31ZD of the Human Fertilisation and Embryology Act 1990 (as amended), in relation to the provision of information to donors about resulting children, are complied with

b. ensuring that the activities are carried out on suitable premises
c. ensuring the centre's staff co-operate fully with inspections and investigations by the Authority or other agencies responsible for law enforcement or regulation of healthcare
d. ensuring fees are paid to the Authority within the timescale specified in Directions or in writing
e. ensuring data provided to the Authority about activities and data, which the Authority is required to hold on its Register of Information, is accurate and provided by dates specified in Directions or in writing
f. ensuring requests for information and/or documents from the Authority are responded to promptly, and
g. notifying the Authority immediately if they become aware of any decision or proposal to close their centre.

T10. In the event of termination of activities, for whatever reason, the PR must ensure that all stored gametes, embryos or admixed embryos are transferred to another licensed centre or centres. The PR must ensure that all relevant information including traceability data and information concerning the quality and safety of gametes and embryos, is transferred with any stored gametes, embryos or admixed embryos, or that records containing this information are made accessible as required.

Personnel

T11. The centre must have an organisational chart which clearly defines accountability and reporting relationships.

T12. Personnel in the centre must be available in sufficient number and be qualified and competent for the tasks they perform. The competency of the personnel must be evaluated at appropriate intervals.

T13. All personnel must have job descriptions that accurately reflect their tasks, and responsibilities.

T14. Personnel carrying out licensed activities or other activities carried out for the purposes of providing treatment services that do not require a licence must, where appropriate, be registered in accordance with the appropriate professional and/or statutory bodies, (eg, General Medical Council, Health & Care Professions Council, Nursing and Midwifery Council).

T15. Personnel must be provided with initial/basic training. Training must be updated as required when procedures change or scientific knowledge develops, and adequate opportunity for relevant professional development must be provided. The training programme must ensure and document that each individual:

a. has demonstrated competence in the performance of their designated tasks
b. has an adequate knowledge and understanding of the scientific/technical processes and principles relevant to their designated tasks
c. understands the organisational framework, quality system and Health & Safety rules of the centre in which they work, and
d. is adequately informed of the broader ethical, legal and regulatory context of their work.

T16. The centre must have access to a nominated registered medical practitioner, within the UK, to advise on and oversee medical activities.

Premises and facilities

T17. A centre must have suitable facilities to carry out licensed activities, or other activities carried out for the purposes of providing treatment services that do not require a licence.

T18. **This licence condition has been removed.**

T19. **This licence condition has been removed.**

T20. In premises where the processing of gametes and embryos exposes them to the environment, the processing must take place in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality as defined in the current European Guide to Good Manufacturing Practice (GMP) Annex 1. It must be demonstrated and documented that the chosen environment achieves the quality and safety required.

NOTE: Centres storing ovarian or testicular tissue for use in transplantation must refer to the Human Tissue Authority's guidelines as the requirements for processing tissue for use in transplantation are different than those listed above.

T21. If the centre has laboratories or contracts third party laboratories or practitioners to undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, these laboratories must be accredited to conduct the relevant test(s) by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. The pathology disciplines involved in diagnosis and investigation include andrology, clinical genetics (cytogenetics and molecular genetics), haematology, bacteriology, virology and clinical biochemistry.

Equipment and materials

T22. For every critical activity, identifying information about all of the materials and equipment must be documented.

T23. Activities must be carried out using equipment and materials designated for the purpose and maintained to suit their intended purpose and must minimise any hazard to patients and/or staff.

T24. All critical equipment and technical devices must be identified and validated, regularly inspected and maintained in accordance with the manufacturer's instructions. Where equipment or materials affect critical processing or storage parameters (eg, temperature, pressure, particle counts, microbial contamination levels) they must be identified and be the subject of appropriate

monitoring, alerts, alarms and corrective action, as required, to detect malfunctions and defects, and to ensure that the critical parameters are maintained within acceptable limits at all times. All equipment with critical measuring function must be calibrated against a traceable standard if available.

T25. New, repaired and recommissioned equipment must be tested and validated before use. Test results must be documented.

T26. Maintenance, servicing, cleaning, disinfection and sanitation of all critical equipment and premises must be performed regularly and recorded accordingly.

T27. Procedures for the operation of each piece of critical equipment must be established and these procedures must document the action to be taken in the event of malfunctions or failure.

T28. Sterile instruments and devices must be used for the procurement of gametes and embryos. Instruments or devices must be of good quality, validated or specifically certified and regularly maintained for the procurement of tissues and cells.

T29. When reusable instruments are used, a validated cleaning and sterilisation procedure for removal of infectious agents has to be in place.

T30. Wherever possible only CE marked, CE and UK(NI) marked, or UKCA marked medical devices must be used.

NOTE: CE marked medical devices will continue to be accepted on the UK market until 30 June 2023. Medical devices placed on the GB market after 30 June 2023 must be UKCA marked rather than CE marked, as set out in the Medical Devices Regulations 2002 (as amended). This requirement does not prevent centres from continuing (after 30 June 2023) to use CE marked medical devices which were on the market prior to 1 July 2023. The UK Government has guaranteed unfettered access for NI businesses to the rest of the UK internal market. This means that any conformity mark held by a NI business which validates a medical device for sale on the NI market is valid for the whole of the UK. Accordingly, NI businesses can continue to place CE marked and CE and UK(NI) marked devices on the GB market after 30 June 2023.

T31. The procedures for licensable activities must detail the specifications for all critical materials and reagents. In particular, specifications for additives (eg, solutions) and packaging materials must be defined. Critical reagents and materials must meet documented requirements and specifications and, when applicable, the requirements of the Medical Devices Regulations 2002 (as amended).

Quality management

T32. The centre must put in place a quality management system and implement this system to continually improve the quality and effectiveness of the service provided in accordance with the conditions of this licence and the guidance on good practice as set out in the HFEA's Code of Practice.

T33. The following documentation must form part of the quality management system:

a. a quality manual
b. standard operating procedures (SOPs) for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence
c. guidelines
d. training and reference manuals, and
e. reporting forms.

T34. A document control procedure must be established that records the history of document reviews and ensures that only current versions of documents are in use.

T35. Required standards of quality and safety, in the form of quality indicators for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence, must be established.

T36. Centres must audit the activities and processes authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence against compliance with the regulatory requirements and their own approved protocols and quality indicators. These audits must be performed at least every two years, by trained and competent staff and in an independent way. Findings and corrective actions must be documented and implemented.

Records and information

T37. Proper records must be maintained in such form as the Authority may specify in Directions.

T38. Records must be legible and indelible and may be hand written or transferred to another validated system, such as a computer or microfilm.

T39. Such information must be recorded as the Authority may specify in Directions about the following:

a. the persons for whom services are provided in pursuance of the licence
b. the services provided for them
c. the persons whose gametes are kept or used for the purpose of services provided in pursuance of the licence or whose gametes have been used in bringing about the creation of embryos so kept or used
d. any child appearing to the person responsible to have been born as a result of treatment in pursuance of the licence

e. any mixing of egg and sperm and any taking of an embryo from a woman or other acquisition of an embryo
f. such information as the Authority may specify in directions as to the persons whose consent is required under schedule to the Human Fertilisation and Embryology Act 1990 (as amended), the terms of their consent and the circumstances of the storage and as to such other matters as the Authority may specify in directions must be included in the records maintained in pursuance of the licence, and
g. such other matters as the Authority may specify in Directions.

T40. Information must not be removed from any records maintained in pursuance of the licence before the expiry of such period as may be specified in Directions for records of the class in question.

T41. The Authority must be provided, in such form and at such intervals as it may specify in Directions, with such copies of or extracts from the records, or such other information, as the Directions may specify.

T42. Where gametes or embryos are supplied to a person to whom another licence applies, that person must be provided with such information as the Authority may specify in Directions.

Data protection and confidentiality

T43. The centre must ensure that all information is kept confidential and only disclosed in circumstances permitted by law.

T44. The centre must have processes in place to ensure that access to a centre's health data and 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. Such processes shall include:

a. 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
b. establishing and maintaining procedures to resolve all data discrepancies
c. preventing unauthorised disclosure of information whilst guaranteeing the traceability of gamete, embryo or tissue (cell) donations
d. considering and responding to applications for access to confidential records and correctly identifying applicants, and
e. receiving, checking and arranging authorised access to confidential data and records.

T45. Access to registers and data must be restricted to persons authorised by the PR and to the Authority for the purpose of inspection and control measures.

Patient/donor records

T46. For each patient/donor the centre must maintain a record containing:

a. patient/donor identification: first name, surname, date of birth, age and sex

b. how, and by whom, the patient/donor has been reliably identified
c. the services provided to them
d. medical history
e. welfare of the child assessment
f. consent, including 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, and
g. clinical and laboratory data and the results of any test carried out.

T47. All records must be clear and readable, protected from unauthorised amendment and retained and readily retrieved in this condition throughout their specified retention period in compliance with data protection legislation.

T48. Patient/donor records required for full traceability must be kept for a minimum of 30 years (or for such longer period as may be specified in Directions) after clinical use, or the expiry date, in an appropriate archive acceptable to the Authority.

Patient selection criteria and laboratory tests

T49. The clinician responsible for the patient must 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.

T50. Prior to the processing of patient gametes or embryos, intended for use in treatment or storage, the centre must:

a. Carry out the following biological tests to assess the risk of cross contamination:
   - HIV 1 and 2: Anti-HIV – 1, 2
   - Hepatitis B: HBsAg and Anti-HBc
   - Hepatitis C: Anti-HCV-Ab
b. Devise a system of storage which clearly separates:
   - quarantined/unscreened gametes and embryos
   - gametes and embryos which have tested negative, and
   - gametes and embryos which have tested positive
c. Perform HTLV-1 antibody testing for patients living in or originating from high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas
d. In certain circumstances, carry out additional testing depending on the patient's travel and exposure history and the characteristics of the tissue or cells donated (eg, Rh D, Malaria, CMV, T.cruzi).

Positive results will not necessarily prevent the use of the partners' gametes.

NOTE: Centres storing ovarian or testicular tissue for use in transplantation must refer to the Human Tissue Authority's guidelines as the requirements for screening patients prior to the storing of their tissue for use in transplantation are different than those listed above.

T51. The centre must ensure that the laboratory tests required by licence condition T50 meet the following requirements, namely:

a. the test must be carried out by a laboratory which is accredited to conduct that test by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard, using CE marked, CE and UK(NI) marked, or UKCA marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge, and
b. blood samples must be obtained within a timeframe specified by the Authority.

NOTE: CE marked medical devices (including testing kits) will continue to be accepted on the UK market until 30 June 2023. Medical devices placed on the GB market after 30 June 2023 must be UKCA marked rather than CE marked, as set out in the Medical Devices Regulations 2002 (as amended). This requirement does not prevent centres from continuing (after 30 June 2023) to use CE marked medical devices which were on the market prior to 1 July 2023. The UK Government has guaranteed unfettered access for NI businesses to the rest of the UK internal market. This means that any conformity mark held by a NI business which validates a medical device for sale on the NI market is valid for the whole of the UK. Accordingly, NI businesses can continue to place CE marked and CE and UK(NI) marked devices on the GB market after 30 June 2023.

Donor selection and laboratory tests

T52. Prior to the use and/or storage of donor gametes and/or embryos created with donor gametes the centre must comply with the selection criteria for donors and the requirements for laboratory tests and storage set out below, namely:

a. donors must be selected on the basis of their age, health and medical history, provided on a questionnaire and through a personal interview performed by a qualified and trained healthcare professional. This assessment must include relevant factors that may assist in identifying and screening out persons whose donations could present a health risk to others, such as the possibility of transmitting diseases, (such as sexually transmitted infections) or health risks to themselves (eg, superovulation, sedation or the risks associated with the egg collection procedure or the psychological consequences of being a donor)
b. subject to (j) below, the donors must be negative for HIV1 and 2, HCV, HBV and syphilis on a serum or plasma sample tested as follows, namely:
   - HIV 1 and 2: Anti-HIV – 1, 2
   - Hepatitis B: HBsAg and Anti-HBc
   - Hepatitis C: Anti-HCV-Ab
   - Syphilis: see (d) below
c. the centre must devise a system of storage which clearly separates:
   - quarantined/unscreened gametes and embryos
   - gametes and embryos which have tested negative, and
   - gametes and embryos which have tested positive
d. a validated testing algorithm must be applied to exclude the presence of active infection with Treponema pallidum. The non-reactive test, specific or non-specific, can allow gametes to be released. When a non-specific test is performed, a reactive result will not prevent procurement or release if a specific Treponema confirmatory test is non-reactive. The donor whose specimen test reacted on a Treponema-

specific test will require a thorough risk assessment to determine eligibility for clinical use

e. in addition to the requirements in (b) and (d) above, sperm donors must be negative for chlamydia on a urine sample tested by the nucleic acid amplification technique (NAT)

f. **This requirement has been removed**

g. HTLV-1 antibody testing must be performed for donors living in or originating from high prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas

h. in certain circumstances, additional testing may be required depending on the donor's history and the characteristics of the gametes donated (eg, RhD, Malaria, T.cruzi), and

i. genetic screening for autosomal recessive genes known to be prevalent, according to international scientific evidence, in the donor's ethnic background and an assessment of the risk of transmission of inherited conditions known to be present in the family must be carried out, after consent is obtained. Complete information on the associated risk and on the measures undertaken for its mitigation must be communicated and clearly explained to the recipient

j. the requirement for donors to be negative for HIV 1 and 2 under the requirements set out in (b) does not apply in the following circumstances:

(i) the donor has a plasma HIV RNA viral load of no more than 200 copies per millilitre on –

(a) a date no more than six months and no less than 21 days before the date of the donation; and

(b) a date no more than seven days before the date of donation;

(ii) the donor has been receiving antiretroviral treatment for a period of at least six months up to and including the date of donation;

(iii) the donor and the recipient declare that they have a qualifying relationship, meaning a relationship between:

(a) friends,

(b) family, or

(c) persons who have been introduced to each other by a third party for the purpose of conceiving; and

(iv) the recipient declares that they –

(a) reasonably believe, on the facts known to them at the time, that the donor has tested positive for HIV;

(b) understand the health risks involved in being treated with the donation; and

(c) consent to being treated with the donation in light of the matters referred to in sub-paragraphs j(iv)(a) and j(iv)(b).

T53. The centre must ensure that the laboratory tests required by licence condition T52 meet the following requirements, namely:

a. The test must be carried out by a laboratory which is accredited to conduct that test by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard, using CE marked, CE and UK(NI) marked, or UKCA marked testing kits where appropriate.
b. Blood samples must be obtained within a timeframe specified by the Authority, and
c. Donor sperm must be quarantined for a minimum of 180 days, after which repeat serological testing is required. If the blood sample taken at the time of donation is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, the donor sperm must be quarantined for a minimum of three months, after which a further donor blood sample should be taken and subjected to repeat serological and NAT testing.

NOTE: CE marked medical devices (including testing kits) will continue to be accepted on the UK market until 30 June 2023. Medical devices placed on the GB market after 30 June 2023 must be UKCA marked rather than CE marked, as set out in the Medical Devices Regulations 2002 (as amended). This requirement does not prevent centres from continuing (after 30 June 2023) to use CE marked medical devices which were on the market prior to 1 July 2023. The UK Government has guaranteed unfettered access for NI businesses to the rest of the UK internal market. This means that any conformity mark held by a NI business which validates a medical device for sale on the NI market is valid for the whole of the UK. Accordingly, NI businesses can continue to place CE marked and CE and UK(NI) marked devices on the GB market after 30 June 2023.

T54. Gametes from non-identifiable donors must not be used in licensed treatment except in the following circumstances:

a. the gametes were supplied to the centre before 1 April 2005; and
b. the woman having treatment (or the person that she is having treatment with) has a child that was conceived from the gametes before 1 April 2006; and
c. the gametes are to be used to create a genetically related sibling for that child.

Embryos from non-identifiable donors must not be used in licensed treatment except in the following circumstances:

a. the embryos were created before 1 April 2005; and
b. the woman having treatment (or the person that she is having treatment with) has a child that was conceived from the embryos before 1 April 2006; and
c. the embryo is to be used to create a genetically related sibling for that child.

Embryos which were created before 1 April 2006, and which were created using the gametes of the woman to be treated (or the person that she is being treated with) and the gametes of a non-identifiable donor, may continue to be used in treatment (regardless of whether or not there are any existing genetically related siblings).

T55. Potential donors that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop:

a. a serious physical or mental disability
b. a serious illness, or
c. any other serious medical condition,

must not be preferred to those that are not known to have such an abnormality.

Welfare of the child, provision of information, counselling and consent

T56. A woman must not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth.

T57. Gametes or embryos must not be used in the provision of treatment services (except in the use of gametes in the course of providing basic partner treatment services or non-medical fertility services) or placed in storage unless effective consent is in place from each gamete provider in accordance with Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended).

T58. Prior to giving consent gamete providers must be provided with information about:

a. the nature of the treatment
b. its consequences and risks
c. any analytical tests, if they are to be performed
d. the statutory storage period applicable in their circumstances (storage periods will differ depending on whether gamete providers are storing for own use or donating for use in someone else's treatment or whether they are consenting to use for training or research purposes)
e. the requirement, for patients who are storing for use in their own treatment, to renew their consent in writing every 10 years (or at the end of any shorter period they consented to)
f. the legal requirement to remove gametes or embryos from storage and for these to be disposed of once they may no longer lawfully be kept
g. the recording and protection of personal data and confidentiality
h. the right to withdraw or vary their consent, and
i. the availability of counselling.

T59. The information referred to in licence condition T58 must be given by trained personnel in a manner and using terms that are easily understood by the gamete provider.

T60. A woman must not be 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, and have been provided with such relevant information as is proper.

T61. A woman must not be provided with treatment services where there is an intended second parent unless, either before or after both have consented to the man or woman being the intended second parent, she and the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of the woman being provided with treatment services and have been provided with such relevant information as is proper.

T62. The reference in licence conditions T60 and T61 above to the intended second parent is a reference to:

a. any man with respect to whom the agreed fatherhood conditions in Section 37 of the Human Fertilisation and Embryology Act 2008 ("the 2008 Act") are for the time being

satisfied in relation to treatment provided to the woman mentioned in licence conditions T60 and T61, and

b. any woman with respect to whom the agreed female parenthood conditions in Section 44 of the 2008 Act are for the time being satisfied in relation to treatment provided to the woman mentioned in licence conditions T60 and T61.

T63. In the case of treatment services using donated gametes, or embryos created using donated gametes, the person receiving treatment and any intended second parent, must be provided with information about:

a. the importance of informing any resulting child at an early age that they were born as a result of such treatment, and
b. suitable methods of informing such a child of that fact.

T64. In cases where the nominated second parent withdraws their consent to be treated as the parent of any child born to a named woman, the PR must:

a. notify the woman in writing of the receipt of the notice from the second parent, and
b. ensure that no treatment services are provided to the named woman until she has been notified of the second parent's withdrawal of consent.

T65. If a woman withdraws her consent to her nominated second parent being treated as the legal parent, or consents to a different person being the legal parent of any child resulting from treatment, the PR must notify the original nominated second parent in writing of this.

Procurement of gametes and embryos

T66. **This licence condition has been removed.**

T67. **This licence condition has been removed.**

T68. Where the sperm is procured at home, the centre must record this in the gamete provider's records.

T69. No money or other benefit must be given or received in respect to any supply of gametes, embryos or human admixed embryos unless authorised by Directions.

T70. There must be a documented system in place that ensures the identification of all gametes and embryos from procurement to use or disposal.

Processing and use of gametes and embryos

T71. Centres must have in place robust and effective processes to ensure that no mismatches of gametes or embryos or identification errors occur. Centres must double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process. These checks must be completed and recorded at the time the relevant clinical or laboratory process/procedure takes place. A record must be kept in each patient's/donor's medical record.

T72. The critical processing procedures must be validated and must not render the gametes or embryos clinically ineffective or harmful to the recipient. This validation may be based on studies performed by the establishment itself, or on data from published studies or from well-established processing procedures, by retrospective evaluation of the clinical results of tissues provided by the establishment.

T73. Before implementing any significant change in processing, the modified process must be validated and documented.

T74. There must be a documented system in place for ratifying that gametes and/or embryos meet appropriate specifications of safety and quality for use and for their transportation/distribution.

Storage of gametes and embryos

T75. Centres must ensure that all storage processes are carried out under controlled conditions.

T76. Gametes of a person must be placed in storage only if –

a. received from that person
b. acquired in circumstances in which by virtue of paragraph 9 and 10 of Schedule 3 to the Human Fertilisation and Embryology Act 1990 (as amended) that person's consent to the storage is not required, or
c. acquired from a person to whom a licence or third party agreement applies.

T77. Embryos taken from a woman must be placed in storage only if –

a. received from that woman, or
b. acquired from a person to whom a licence or third party agreement applies.

T78. Embryos which have been created in vitro otherwise than in pursuance of this licence must be placed in storage only if acquired from a person to whom a licence or third party agreement applies.

T79. Gametes and embryos that have been kept in storage pursuant to this licence must be removed from storage and disposed of once they may no longer lawfully be so kept.

T80. Gametes must not be kept in storage for longer than such period not exceeding 55 years beginning with the day on which they are first placed in storage.

T81. a. Embryos must not be kept in storage for treatment purposes[1] for longer than such period not exceeding 55 years beginning with the day on which they are first so kept.

b. Embryos kept in storage for training purposes[2] but not for treatment purposes, must not be so kept for longer than such period not exceeding 10 years beginning with the day on which consent to the storage of the embryo for that purpose was given under Schedule 3.

T82. **This licence condition has been removed.**

T83. Gametes or embryos which are or have been stored must not be supplied to a person otherwise than in the course of providing treatment services, unless that person is a person to whom a licence applies.

T84. **This licence condition has been removed.**

T85. A documented risk assessment must be undertaken to determine the fate of all stored gametes and embryos following the introduction of any new donor/patient selection or testing criterion or any significantly modified processing step that enhances safety or quality.

Embryo testing

T86. Embryos that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop:

a. a serious physical or mental disability
b. a serious illness, or
c. any other serious medical condition,

must not be preferred to those that are not known to have such an abnormality.

T87. Embryos that are known to be of a particular sex and are known to carry a particular risk, compared with embryos of that sex in general, that any resulting child will have or develop:

a. a gender-related serious physical or mental disability
b. a gender-related serious illness, or

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[1] "Treatment purposes" are the purposes referred to in paragraph 2(1)(a) or (b) of Schedule 3 of the Human Fertilisation and Embryology Act 1990. This includes:
"A consent to the use of any embryo must specify one or more of the following purposes—
(a) use in providing treatment services to the person giving consent, or that person and another specified person together,
(b) use in providing treatment services to persons not including the person giving consent".

[2] "Training purpose" is the purpose referred to in paragraph 2(1)(ba) of Schedule 3. This includes:
"A consent to the use of any embryo must specify one or more of the following purposes—
(ba) use for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques."

c. any other gender-related serious medical condition,

must not be preferred to those that are not known to carry such a risk.

T88. With respect to any embryo testing programme involving biopsy the centre must ensure that:

a. no embryo is transferred to a woman where that embryo or any material removed from it or from the gametes that produced it, has been subject to a test that supplies genetic information about the embryo, unless the test has been expressly authorised by the Authority, and
b. any information derived from tests on an embryo, or any material removed from it or from the gametes that produced it, is not used to select embryos of a particular sex for social reasons.

T89. With respect to any embryo testing programme the centre must ensure that embryo testing is only being carried out for those genetic conditions that are expressly authorised by the Authority.

T90. **This licence condition has been removed.**

T91. Centres may use non-invasive procedures, for example metabolomics, to test and select for the viability of embryos. However, centres must not use these procedures to test for specific gene, chromosome or mitochondrion abnormality without prior authorisation from the Authority.

Use of embryos for training staff

T92. Embryos kept in storage for training[3] or research but not for treatment purposes must not be so kept for longer than such period not exceeding 10 years beginning with the day on which consent to the storage of the embryo for that purpose was given under Schedule 3.

a. Where consent under Schedule 3 is given to the storage of an embryo for training or research purposes by different persons on different days, the day on which consent was given is to be taken as a reference to the last of those days.
b. No embryo appropriated for the purpose of training staff in embryological techniques must be kept or used for the provision of treatment services.

T93. Embryos may only be used, for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques and in those activities that are expressly authorised by the Authority.

[3] "Training purpose" is the purpose referred to in paragraph 2(1) (ba) of Schedule 3 of the Human Fertilisation and Embryology Act 1990 and includes use for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques.

T94. Embryos may only be used, for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques, where both gamete providers have consented to the use of embryos, created using their gametes, for the purpose of training.

T95. The centre must have procedures in place to ensure that there is no actual or perceived conflict of interest between the use of embryos in training and the use of embryos in the provision of treatment services. This would normally consist of:

a. having a designated individual, who is not directly involved in the patient's treatment, to discuss with the patient the training activity and the possibility of donating material for it; and
b. making sure that the person obtaining consent for the use of the embryos in training is not involved in the training project.

Where limited staffing makes this difficult to achieve, the centre must develop its own robust procedures for ensuring that conflict of interest requirement is met.

T96. **This licence condition has been removed.**

T97. Prior to giving consent, each gamete provider must be provided with the necessary information including:

a. the nature of the training for which embryos will be used
b. that the decision whether to donate will not affect their treatment in any way
c. that they can vary the terms of, or withdraw their consent until the point the embryos are used in training
d. that if they give consent to storage of embryos for training purposes, their embryos may be stored for up to 10 years, calculated from the date consent to storage for training purposes was given, and
e. whether any information will be fed back to them.

T98. The information referred to in licence condition T97 must be given by trained personnel in a manner and using terms that are easily understood by the persons providing gametes.

Traceability and coding

T99. The centre must establish, implement and comply with documented procedures to ensure that:

a. all gametes and embryos, and
b. all relevant data relating to anything coming into contact with those gametes or embryos

are traceable from procurement of gametes to patient treatment or disposal and vice versa.

T100. The documented procedures referred to in licence condition T99 include the following information:

a. the unique and accurate identification of each patient/donor
b. the unique and accurate identification of each set of gametes and embryos
c. date of procurement

d. place of procurement
e. type of treatment
f. description and origin of any and all products associated with the procurement, processing, use and storage of gametes and embryos, and
g. description of all processing steps applied to the procurement, use and storage of gametes and embryos.

T101. The centre must ensure that all containers (dishes, vials, ampoules, tubes etc) used in the course of procurement, processing, use and storage of gametes and embryos are labelled with the patient's/donor's full name and a further identifier. If at some stages (eg, labelling patient/donor sperm) it is not possible to label the dishes or tubes with the patient/donor name then it must be ensured that the patient/donor code used is uniquely identifying.

T102. The centre must record such information as is necessary to facilitate the traceability of gametes and embryos and any information relating to the quality or safety of gametes and embryos. This information must be provided to the Authority upon request.

T103. The centre must keep data necessary to ensure traceability for a minimum of 30 years (and for such longer period as may be specified in Directions) in an appropriate readable storage medium.

T104. Records not covered by licence condition T103 and test results that impact on the safety and quality of the embryos and gametes, must be kept so as to ensure access to the data for at least 10 years after the expiry date, clinical use or disposal.

Import, export and transportation/distribution of gametes and embryos

T105. All gametes and embryos must be packaged and transported in a manner that minimises the risk of contamination and preserves the required characteristics and biological functions of the gametes or embryos. The packaging must also prevent contamination of those responsible for packaging and transportation.

T106. The packaged gametes/embryos must be shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos.

T107. The transport conditions, including temperature and time limit, must be specified and the labelling of every shipping container must include as a minimum:

a. a label marked "TISSUES AND CELLS" and "HANDLE WITH CARE"
b. the identification of the establishment from which the package is being transported (address and telephone number) and a contact person in the event of problems
c. the identification of the tissue establishment of destination (address and telephone number) and the person to be contacted to take delivery of the package
d. the date and time of the start of transportation
e. the type of gametes/embryos plus their identification code

f. specifications concerning conditions of transport relevant to the quality and safety of the gametes or embryos
g. specifications concerning storage conditions such as “DO NOT FREEZE”
h. in the case of all gametes and embryos, the following indication: “DO NOT IRRADIATE”, and
i. when a product is known to be positive for a relevant infectious disease marker, the following indication: “BIOLOGICAL HAZARD”.

If any of the information under the points above cannot be included on the primary container label, it must be provided on a separate sheet accompanying the primary container. The sheet must be packaged with the primary container in a manner that ensures that they remain together.

T108. The container/package must be secure and ensure that the gametes or embryos are maintained in the specified conditions. All containers and packages need to be validated as fit for purpose.

Receipt of gametes and/or embryos

T109. The centre must put in place, maintain and implement a procedure for the receipt of gametes and/or embryos from another centre or third party premises to ensure that:

a. the centre is provided with copies of all relevant consent forms signed by patients and donors when their gametes or embryos were first placed in storage and any renewal consent forms signed by patients and donors
b. the consignment of gametes and/or embryos is verified against SOPs and specifications. These must include information relating to the transport conditions, packaging, labelling, patient/donor documentation, and any other associated documentation and samples. These must also include the technical requirements and other criteria considered by the establishment to be essential for the maintenance of acceptable quality, and
c. the gametes and embryos received are quarantined until they, along with associated documentation, have been inspected or otherwise verified as conforming to requirements. The review of relevant patient/donor and procurement information and thus acceptance of the donation needs to be carried out by specified/authorised persons.

T110. The following data must be registered at the centre:

a. consent including the purpose(s) for which the gametes and/or embryos may be used and any specific instructions for disposal if the gametes or embryos are not used for the consented purpose
b. patient/donor identification and characteristics: age, sex and presence of risk
c. all required records relating to the procurement and the taking of the patient/donor history
d. gametes and embryos obtained and relevant characteristics
e. the results of laboratory tests and of other tests, and
f. a properly documented review of the complete patient/donor evaluation against the selection criteria by an authorised and trained person.

Third party relations

T111. The centre must establish a written agreement with those third parties who provide goods or services that influence the quality and safety of gametes and embryos, and in particular where:

a. the centre entrusts one of the stages of gamete or embryo processing to a third party
b. a third party provides goods or services that affect gamete or embryo quality and safety assurance, including the process of distribution, and
c. the centre distributes gametes or embryos processed by third parties.

T112. The centre must evaluate and select third parties on the basis of their ability to meet the requirements of these licence conditions and the guidance set out in the HFEA Code of Practice.

T113. Agreements with third parties must specify the terms of the relationship and responsibilities as well as the protocols to be followed to meet the required performance specification.

T114. The centre must ensure that the following core requirements are included in any third party agreement, namely:

a. full address and contact details of the third party, and nature of the service to be provided
b. identification of person(s) responsible for managing arrangement between the centre and the third party
c. provision setting out how often the agreement will be reviewed and by whom
d. summary of the responsibilities of the third party and agreed procedures with regard to each party's respective responsibilities,
e. any specific criteria that the service provided by the third party must meet, particularly in relation to quality and safety, and
f. description of how any test/diagnostic results are relayed to the commissioning centre, including sign off and confirmation that the result applies to the correct sample.

T115. The centre must keep a complete list of agreements referred to in licence condition T111 that they have established with third parties. Copies of these agreements must be made available to the Authority upon request.

T116. The centre must ensure that it is made a condition of any agreement with a third party, a satellite or a transport centre that the third party, satellite or transport centre will meet the requirements of the relevant licence conditions and the guidance set out in the HFEA Code of Practice.

T117. Where the third party procure gametes and/or embryos on behalf of a licensed centre, the third party agreement must require the procuring establishment to produce a report to the licensed centre which must include, but not be limited to, a record of the following:

a. where the procurement took place
b. patient/donor identification data including how and by whom identified
c. description and identification of the procured gametes/embryos including samples for testing
d. identification of the person responsible for the procurement process
e. date, time and location of procurement and SOP used

f. details of any incidents, including any serious adverse events and/or reactions, that occurred during the procurement process
g. where appropriate, the environmental conditions at the procurement facility, and
h. where appropriate, the identification/batch numbers for any reagents and transport media used.

Identification, investigation, reporting, recording and notification of serious adverse events and reactions

T118. The centre must establish, implement and comply with documented procedures to report, investigate, register and transmit information about serious adverse events and serious adverse reactions that occur on any premises to which a licence relates and any relevant third party premises.

T119. The documented procedures referred to in licence condition T118 must enable the centre to communicate to the Authority, without delay:

a. all relevant available information about suspected serious adverse events and reactions, and
b. the conclusion of the investigation to analyse the cause and ensuing outcome in relation to serious adverse events and reactions.

T120. The PR must notify the Authority of any suspected serious adverse events and serious adverse reactions by providing the information set out below and such other information as the Authority may specify in Directions:

a. identification of the centre
b. identification of the premises concerned
c. report identification
d. date of notification, and
e. date of serious adverse event/serious adverse reaction

In relation to serious adverse events the following information is also required:

f. an evaluation of the event by activity, (procurement, testing, transport, processing, storage, distribution or other) and specification of the source of error, (defect in gametes or embryos, equipment or material failure or defect), human error or other (to identify preventable causes), to be followed by a conclusion report including items (a) to (e) above

In relation to serious adverse reaction(s) the following additional information is also required:

g. date and place of procurement of gametes or application of gametes or embryos
h. unique donation identification number
i. date of suspected serious adverse reaction
j. details of gametes or embryos involved in the suspected serious adverse reaction, and
k. type of suspected serious adverse reaction(s).

T121. The centre must thereafter notify the Authority of the conclusion of the investigation into the serious adverse event/serious adverse reaction by providing at least the information set out below and any such other information as the Authority may specify in Directions:

a. identification of the centre
b. identification of the premises concerned
c. report identification
d. date when the serious adverse event/serious adverse reaction was confirmed
e. date of the serious adverse event/serious adverse reaction, and
f. corrective measures taken

In relation to serious adverse reaction(s) the following additional information is also required:

g. date when the serious adverse reaction was confirmed
h. unique donation identification number
i. confirmation of the type of reaction(s) or a change in the type of reaction(s)
j. clinical outcome, if known:
    i. complete recovery
    ii. minor sequelae
    iii. serious sequelae, or
    iv. death
k. root cause analysis
l. outcome of investigation and final conclusions, and
m. recommendations for preventive and corrective actions.

T122. The centre must ensure that an accurate, rapid and verifiable procedure is in place, which will enable it to recall from distribution any product that may be related to a serious adverse event or reaction.

Multiple births

T123. **This licence condition has been removed.**

Mitochondrial donation

T124. a. No clinic may carry out either the process of pronuclear transfer* (PNT) or maternal spindle transfer* (MST) or part of either process, unless express provision has been made on the clinic's licence permitting it to undertake either or both processes.

b. Neither PNT nor MST may be carried out under third party, satellite or transport agreements.

c. No clinic may provide treatment using gametes or embryos which have been created using PNT or MST unless express provision has been made on the clinic's licence permitting the clinic to undertake either or both processes.

*Wherever reference is made in this licence to PNT or MST, or to the process of PNT or MST, it is to be treated as a reference to the process described in Regulation 4 or Regulation 7 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015.

T125. PNT and MST must only be carried out on premises of clinics that are licensed to undertake mitochondrial donation ('MD'). These processes must not be carried out on the premises of a

clinic that is operating under a third party, satellite or transport agreement with a clinic that holds a licence to undertake MD.

T126. Donors of gametes for use in MST and or PNT must be screened for pathogenic mitochondrial DNA mutations, and an assessment of the risk of transmission of any mitochondrial disease in the donor's family must be carried out, after consent is obtained. Complete information on the associated risk and on the measures undertaken for its mitigation must be clearly communicated and explained to the recipient.

T127. a. No alterations may be made to the nuclear or mitochondrial DNA of an egg created by means of the application of MST.

b. No alterations may be made to the nuclear or mitochondrial DNA of an embryo created by means of the application of PNT, and no cell may be added to an embryo created by means of the application of PNT other than by the division of the embryo's own cells.

T128. In the case of treatment involving mitochondrial donation, the clinic must ensure that it only carries out the process of PNT or MST for a particular, named patient once the Authority has issued a determination that:

- there is a particular risk that any egg extracted from the ovaries of the named woman, or any embryo created by the fertilisation of an egg extracted from the ovaries of the named woman, may have mitochondrial abnormalities cause by mitochondrial DNA, and

- there is a significant risk that a person with those abnormalities will have or develop a serious mitochondrial disease.

T129. Only those embryologists assessed as competent by the Authority to undertake PNT, MST or both, and named on the front of this licence, are permitted to undertake those processes or any part thereof.

Annex A – Additional conditions

1. The following specific additional conditions apply to this licence and have been agreed by the Licence Committee granting this licence:
    a. None.

Annex B – Schedule of definitions

Creation of embryos in vitro: the collection and mixing of eggs and sperm; the injection of sperm into an egg, in a laboratory, to achieve fertilisation outside the body.

Distribution of embryos: any authorised processes by which embryos are transported or delivered.

Distribution of gametes: any authorised process by which gametes are transported or delivered.

Keeping embryos: any authorised process by which embryos are maintained prior to their use, storage or in the course of carriage.

Placing any permitted embryo in a woman: the insertion of an embryo into the uterus; the transfer of a one cell zygote to either fallopian tube.

Processing gametes: any authorised operation involved in the preparation or manipulation of gametes

Procuring embryos: any authorised process by which embryos are made available.

Processing embryos: any authorised operation involved in the preparation, manipulation or packaging of embryos.

Procuring gametes: any authorised process by which gametes are made available.

Keeping gametes: any authorised process by which gametes are maintained prior to their use, storage or in the course of carriage.

Storage of embryos: keeping embryos that have been cryopreserved or preserved by any other authorised method.

Storage of gametes: keeping sperm/testicular tissue that has been cryopreserved or preserved by any other authorised method; keeping eggs/ ovarian tissue that has been cryopreserved or preserved by any other authorised method.

Embryo testing: removing and testing material from an egg or an embryo for a specific genetic disorder which has been authorised by the Authority; to ensure an egg or an embryo contain the correct number of chromosomes (euploidy) and not more or less than normal (aneuploidy).

Use of Embryos for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques: The use of embryos for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques.

Use of Gametes: the introduction of sperm into the vagina, cervix or uterus; transferring sperm and eggs to the fallopian tubes for fertilisation in the body.