Licence Committee - minutes

Centre 0356 European Sperm Bank UK Ltd

Initial licence

HFEA Level 2, 10 Spring Gardens, London SW1A 2BU
12 July 2018 at 10.00 am

Committee members	Andy Greenfield (Chair) Ruth Wilde Kate Brian	
Members of the Executive	Richard Chamberlain Catherine Burwood (Observer) Dee Knoyle (Observer)	Committee Secretary Senior Governance Manager Committee Secretary
Legal Adviser	Graham Miles	Blake Morgan LLP
Specialist Adviser		
Observers		

Declarations of interest:

- Members of the committee declared that they had no conflicts of interest in relation to this item.

The committee had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members

The following papers were considered by the committee:

- Initial Inspection Report with responses from the Person Responsible (PR)
- Application form
- CV of proposed Person Responsible
- CV of proposed Licence Holder
- Sperm Donor Contract
- Donor Information

1. Consideration of application

1.1. The committee noted that the application for a new storage licence was received from Bryan Woodward, the proposed PR of European Sperm Bank UK Ltd, of 48 Gray's Inn Road, London WC1X 8LT. It is a subsidiary of European Sperm Bank ApS based in Copenhagen, Denmark.

1.2. The proposed PR is currently PR of another HFEA licensed centre (X&Y Fertility centre 0353). Centre 0353, a treatment and storage centre, was granted a licence in November 2016. The proposed Licence Holder for centre 0356 is the corporate body European Sperm Bank (UK) Ltd and the Company's CEO - Annemette Arndal-Lauritzen - has agreed to be the emergency contact person.

1.3. The committee noted that the clinic was intending to employ an operating model that had not previously been used by a Licensed Centre in the UK. European Sperm Bank UK Ltd. will recruit sperm donors, procure, process and freeze their samples on the premises. These donor sperm samples will then be exported under General Direction 0006 to European Sperm Bank's headquarters in Copenhagen, Denmark. The samples will remain in Denmark until released from quarantine and distributed to centres for use in treatment. This would include centres in the UK and around the world.

1.4. The committee noted that the report covered the findings from the initial licensing inspection. There were a number of areas of practice that required improvement, including one critical, six major and four 'other' areas of non-compliance.

1.5. The committee also noted that the executive was satisfied that the PR had implemented their recommendations in relation to the non-compliances identified in the inspection visit and that he has the qualifications and experience to comply with section 16(2) (c) of the HF&E Act 1990 (as amended) and has discharged his duty under section 17 of the same Act.

1.6. In its recommendation to the Licence Committee, the Inspection team considered that it had sufficient information to recommend the granting of a storage licence for a period of two years without additional conditions.

1.7. The committee considered the revised Donor Contract and Donor Information, which had been amended by the PR in response to one of the major non-compliances, and decided that there were still some areas that need further clarification in order to ensure that sperm donors are: a) able to give fully informed consent; and b) not discouraged from exercising their right to withdraw consent by the use of financial penalties.

1.8. The particular areas that the committee would like the centre to address are outlined below:

- Provision of information for the donor on the number and range of countries that his sperm could be exported to, and giving him written information that the national/ESB limits for all these countries is available on request. The committee considered that a donor should know before consent whether he could potentially enable 10s, 100s or 1000s of donor-conceived children to be born worldwide and that currently the information given does not sufficiently explain the numbers of offspring that could be created from his donated sperm.
- Providing information for the donor on exactly what additional donor items might be required (in the Contract at 5.2) and inserting the fact that under UK law, ESB will not provide, to potential recipients, any donor items from which the donor could be identified.
- The committee considered that in this age of DNA testing direct to the consumer, it would be more reasonable to state that the donor has no right to request or be supplied with information on the identity of women using his donated sperm or donor-conceived children. The committee considered that it would not be reasonable to expect a donor to never engage with DNA-testing services in the future (see Donor Contract at 6.2 and 11.1).

- The committee expressed a preference for the centre to be more explicit (at 6.3) concerning what data ESB collects on donor-conceived children born worldwide and what information a donor would be entitled to receive on request e.g. whether a donor would be able to request information on the number, gender and year of birth of children conceived outside the UK. At section 7, the committee would like the centre to consider removing the requirement for one physical contact, as this is not a regular requirement in the UK. Instead, the donor should agree to have certain proscribed, identifiable information about him released on request to any donor-conceived adult offspring. The centre should consider explicitly stating what information can be released to adult donor offspring, as set out in the Code of Practice, 8th edition.
- The committee considered that the wording at 9.2 was ambiguous and that any information relevant to the withdrawal of consent should be provided here as part of the contract, so that a donor is fully aware of his rights. It is not clear here whether there is a financial penalty for withdrawing consent. The committee would like the centre to consider revising the information at 8, 9 and 10 to fully explain the difference between withdrawing consent and terminating the contract with explicit information on the financial penalties involved, if any.
- The committee noticed that at 12.3 the contract states that data may be distributed to donor children according to *national* law. The committee reminds the centre that the sperm samples can only be exported for use in treatment in the manner and circumstances in which it would be lawful to use them in the UK. Therefore, the contract should state that the data to be distributed are limited to what would be permissible under UK law.
- At 13, the committee felt that it was confusing for the donor to state that he has both received thorough counselling and been offered counselling by a BICA-accredited counsellor. The Code of Practice (8th edition), Section 3, states that the provision of counselling should be clearly distinguished from the normal relationship between clinical staff and patients or donors. The committee would encourage the centre to ensure that the donor can agree that he has received a suitable opportunity to receive proper counselling about the implications of donating his gametes. Also, at 13, the committee would encourage the centre to seek legal advice about whether this contract could be legally binding for the donor's heirs.

The committee would encourage the centre to make the corresponding changes to the Donor Information to bring it in line with the Donor Contract.

The committee had regard to its decision tree. The committee considered that there was some further work to be done to ensure that both the Donor Contract and Donor Information are in line with UK law and practice. The Committee recommends that the centre work with the Executive to ensure that the written information is updated before sperm donors are recruited.

2. Decision

2.1. The committee decided to grant the new licence for storage for two years, with the expectation that the centre would engage with the Executive to address the committee's concerns.

3. Chair's signature

3.1. I confirm this is a true and accurate record of the meeting.

Signature

Name

Andy Greenfield

Date

1 August 2018

Initial Licence Report

Purpose of the Inspection Report

This is a report of an assessment and inspection, carried out to determine whether an application for a new licence will meet essential requirements. The Authority's Licence Committee uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 13 April 2018

Purpose of inspection: Application for a new storage licence

Inspection details: The report covers the findings from a desk based assessment of submitted documentation, the inspection visit and communications received from the centre since the time of the inspection.

Inspectors: Karen Conyers (lead) and Janet Kirkland

Date of Licence Committee: 12 July 2018

Centre name	European Sperm Bank UK Ltd.
Centre number	0356
Centre address	48 Gray's Inn Road, London, W1CX 8LT
Proposed Person Responsible	Bryan Woodward
Proposed Licence Holder	European Sperm Bank UK Ltd. named contact Annemette Arndal-Lauritzen

Contents

Section 1: Summary report 3

Section 2: Inspection findings 7

1. Protection of the patient and children born following treatment 7
2. The experience of patients 14
3. The protection of gametes and embryos 17
4. Information management 18

Areas of practice requiring action 19

Section 1: Summary report

Brief description of the centre:
European Sperm Bank UK Limited (Ltd.) is a subsidiary of European Sperm Bank ApS which is a private company located in Denmark. European Sperm Bank UK Ltd. is located in London and will recruit sperm donors, procure, process and freeze their samples on the premises. These donor sperm samples will then be exported under General Direction 0006 to European Sperm Bank's headquarters in Copenhagen, Denmark. The samples will remain in Denmark until released from quarantine and distributed to centres for use in treatment. This would include centres in the UK and around the world.

The proposed Person Responsible (PR), Bryan Woodward, is currently PR of another HFEA licensed centre (X&Y Fertility, centre 0353). Centre 0353 is a Treatment (Insemination using partner / donor sperm) and Storage centre which was granted a licence in November 2016. The centre was last inspected in June 2018, and the findings of this inspection are yet to be considered by a licensing committee.

The PR has applied for a HFEA storage licence for this new centre, European Sperm Bank UK Ltd., to undertake donor recruitment leading to procurement, processing and storage of donor sperm.

The proposed Licence Holder (LH) is the corporate body, European Sperm Bank UK Ltd., and the company's CEO Annemette Arndal-Lauritzen has agreed to be the emergency contact person.

Per Annex B of the Authority's Standing Orders, consideration of applications for initial licences has been delegated both to the Executive Licensing Panel and the Licence Committee. The operating model that this clinic plans to follow, if licensed, is a new model not previously employed in any UK clinic. This operating model presents different challenges because all the donor samples will be exported out of the UK for distribution and use across the world. On this basis, the executive requests that the Licence Committee considers this application.

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008, Standard Licence Conditions (SLCs) and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has been submitted by the individual designated to act as the PR;
- the PR's qualifications and experience comply with section 16(2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for an initial licence
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The Licence Committee is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including one critical, six major and four 'other' areas of non-compliance.

In view of these findings, the inspection team considered that it did not have sufficient information or assurance to conclude that the PR will be able to discharge his duty under section 17(a), (d) and (e) of the HF&E Act 1990 (as amended) to ensure that:

- staff are trained and competent for the tasks they will perform;
- the proposed practices are suitable; and
- the conditions of the licence are complied with.

However, since the inspection the PR has provided evidence to confirm that all of the following recommendations have been fully implemented:

Critical non-compliance:

- **The PR should ensure provision of a 'proper' counselling service.**

Major areas of non-compliance:

- The PR should ensure that the laboratories used to undertake the diagnosis and investigation of donors or their gametes or any material removed from them are accredited by Clinical Pathology Accreditation (CPA) (UK) Ltd. or another body accrediting to an equivalent standard.
- The PR should ensure that the export of donor sperm samples to Denmark is compliant with General Direction 0006.
- The PR should ensure that written agreements are in place with third parties who provide goods or services that influence the quality and safety of gametes.
- The PR should ensure that CE marked medical devices are used where possible and that all critical equipment is validated and subject to routine monitoring.
- The PR should ensure that training and competency assessments are completed for all activities to be undertaken.
- The PR should ensure that donors are provided sufficient information on the nature and future use of their donations.

‘Other’ areas that require improvement:

- The PR should ensure the safety and suitability of the centre’s premises and facilities.
- The PR should ensure that the centre has access to an infection control lead to advise on infection control requirements.
- The PR should ensure that there are procedures in place in the event of clinical and non-clinical emergencies.
- The PR should ensure that processes are in place to protect donors and staff from harm where possible.

Recommendation to the Licence Committee

The inspection team considers that it has sufficient information to recommend the grant of a storage licence for a period of two years without additional conditions.

At the time of the inspection there were a number of areas of practice that required improvement, including one critical, six major and four ‘other’ areas of non-compliance. In view of this, the inspection team considered that there was insufficient evidence of compliance available to be able to recommend that a storage licence be granted. This conclusion was reached as a result of the following areas of non-compliance which are described in this report:

- The centre’s proposed practices in relation to the offer of a suitable opportunity for proper counselling to donors, and the provision of sufficient information to donors on the nature and future use of their donations are not suitable, and potentially undermine the effectiveness of the consent provided by the donors.
- The centre has not provided evidence of compliance with the requirements of General Direction 0006 for the export of the samples to Denmark.
- Training and competence assessments for staff in relation to critical activities such as the provision of information, consent and phlebotomy have not been completed.

The PR was provided with the inspection report on 17 May 2018, in which the executive set out the inspection team’s conclusions; that it was not in a position to recommend that the storage licence was granted. The PR was informed that recommendations for the following non-compliances must be fully implemented before the executive can recommend the granting of a licence:

Critical non-compliance:

- **The PR should ensure provision of a ‘proper’ counselling service.**

Major areas of non-compliance:

- The PR should ensure that the laboratories used to undertake the diagnosis and investigation of donors or their gametes or any material removed from them are accredited by CPA (UK) Ltd or another body accrediting to an equivalent standard.
- The PR should ensure that the export of donor sperm samples to Denmark is compliant with General Direction 0006.
- The PR should ensure that training and competency assessments are completed for all activities to be undertaken.
- The PR should ensure that donors are provided sufficient information on the nature and future use of their donations.

In response to the findings of the report, the PR provided evidence of implementation of recommendations in relation to all the non-compliances identified.

The executive is satisfied that all recommendations have been fully implemented and that the PR has fully discharged his duties under section 17.

Therefore, the inspection team now considers it has sufficient information to recommend the grant of a storage licence for a period of two years without additional conditions. An interim inspection will be completed during the first year as a useful indication of early performance and progress.

The inspection team also has sufficient information to recommend the appointment of the proposed PR and the appointment of the proposed LH, which is to be the corporate body with a nominated emergency contact person.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the donors and children born following treatment at this centre
2. The experience of donors at this centre
3. The protection of gametes and embryos at this centre
4. How this centre looks after important information

1. Protection of donors and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)
The centre's proposed procedures for double checking the identification of gametes and the donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes.

What the centre could do better
Nothing identified at this inspection.

Donor selection criteria and laboratory tests

Screening of donors
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
The centre's proposed procedures for screening donors are compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes.

Payments for donors (Guidance note 13; General Direction 0001)
It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused. The centre's proposed procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes.

Donor assisted conception (Guidance note 20)
The centre will not be carrying out treatments with donor gametes so this area of practice is not applicable to this inspection.

What the centre could do better
Nothing identified at this inspection.

Suitable premises and suitable practices
Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes
Transport and distribution of gametes
Receipt of gametes
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
It is important to ensure that all licensed activities are conducted in an appropriate environment that is fit for purpose. The centre's premises are suitable with the exceptions noted below.

The centre's proposed procedures are compliant with requirements to ensure that risks are taken into account to ensure donors and staff are in safe surroundings that prevent harm with the exceptions noted below.

The centre does not have any satellite facilities.

The centre is compliant with HFEA requirements to process gametes in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
Appropriate accreditation is important to assure the quality of the services provided. The centre's laboratories and/or third party laboratories which will undertake the diagnosis and investigation of donors or their gametes or any material removed from them, are partially compliant with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard.

Infection control (Guidance note 25)
The centre's proposed systems to manage and monitor the prevention and control of infection are broadly compliant with guidance.

Medicines management (Guidance note 25)
The centre will not be carrying out treatments so this area of practice is not applicable to this inspection.

Pre-operative assessment and the surgical pathway (Guidance note 25)
The centre will not be carrying out treatments so this area of practice is not applicable to this inspection.

Multiple births (Guidance note 7; General Direction 0003)
The centre will not be carrying out treatments so this area of practice is not applicable to this inspection.

Procurement of gametes (Guidance note 15)
The centre's proposed procedures are compliant with HFEA requirements.

Transport and distribution of gametes (Guidance note 15; General Direction 0009)
The centre's proposed procedures for the transport, distribution and recall of gametes are compliant with HFEA requirements with the exception noted in the section 'Equipment and materials' below. It is important to ensure that all gametes sent to other licensed centres within or outside the UK are:

- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- shipped in a container/package which is validated, properly secured and ensures that the gametes are maintained in the specified conditions.

Receipt of gametes (Guidance note15)
The centre is not required to comply with this guidance note for the proposed activities.

Imports and exports (Guidance note 16; General Direction 0006)
The centre's proposed procedures for import and export of gametes are partially compliant with HFEA requirements.

Traceability (Guidance note 19)
The centre's proposed procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability:

- to identify and locate gametes during any step from procurement to use for human application or disposal,
- identify the donor of particular gametes,
- to identify any person who has carried out any activity in relation to particular gametes, and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS in place that is compliant with HFEA requirements with the exceptions noted below. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's third party agreements are partially compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre will not be carrying out treatments so this area of practice is not applicable to this inspection.

Equipment and materials (Guidance note 26)
The centre proposes to use equipment and materials that are partially compliant with HFEA requirements. Some of the equipment and materials used in licensed activity are designated for the purpose and will be appropriately maintained in order to minimise any hazard to donors and/or staff.

The centre is compliant with HFEA requirements to validate critical equipment with the exception noted below.

The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's proposed procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's proposed procedures for reporting adverse incidents are compliant with HFEA requirements. The centre will report adverse incidents (including serious adverse events and reactions) to the HFEA and will investigate all incidents that occur. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Safety and suitability of premises and facilities (Guidance note 25)
Two issues relating to the safety of the premises were noted at the time of inspection (see recommendation 8, CoP 25.4b and 25.17):

- The centre's most recent fire safety risk assessment included areas of 'high priority' where further actions were needed but there was no evidence that these had been completed.
- The inspection team noted that there was signage in the laboratory indicating the presence of liquid nitrogen but there was no further information advising what people should do in the event of an alarm sounding such as do not enter or the details of who should be contacted and how. The centre's dewars had not yet been filled with liquid nitrogen.

Laboratory accreditation (Guidance note 25)
The centre proposes to send samples for genetic analysis to laboratories in Spain and the USA. The laboratory in Spain is not accredited by CPA (UK) Ltd. or another body accrediting to an equivalent standard (see recommendation 2, SLC T21).

Infection control (Guidance note 25)
The centre does not have a person identified as an infection control lead to carry out such activities as reviewing the suitability of the flooring in clinical areas and developing suitable cleaning schedules (see recommendation 9, CoP 25.20).

Imports and exports (Guidance note 16; General Direction 0006)
The donor sperm samples will be exported to the centre's headquarters in Denmark where they will be quarantined and stored until use. At the time of inspection, the centre's proposed procedures did not include sufficient information to demonstrate compliance with the following requirements of General Direction 0006 Schedule 2 section 1 (see recommendation 3, General Direction 0006):

> (b) the person who provided the gametes has (and, in the case of an embryo, both persons who provided the gametes from which the embryo was created, have) given and not withdrawn consent in writing to the gametes or embryos being exported to the country in which the receiving centre is situated;
>
> (c) before giving consent, the person(s) has been given a written notice stating that the law governing the use of gametes and/or embryos and the parentage of any resulting child may not be the same in the country to which the gametes or embryos are to be exported as it is in the United Kingdom, and they have been given any further information which they may require; and
>
> (f) the gametes or embryos are not exported if they cannot be lawfully used in licensed treatment services in the United Kingdom in the manner or circumstances in which it is proposed that the gametes or embryos be used by the receiving centre.

Quality management system (QMS) (Guidance note 23)
The centre has not developed policies and procedures for a clinical emergency and a non-clinical emergency or business continuity plan (see recommendation 10, SLC T33b).

Third party agreements (Guidance note 24)
At the time of inspection, the centre did not have third party agreements in place with the laboratories that would be undertaking genetic analysis of donor samples and morphology assessments of semen samples (see recommendation 4, SLC T111).

Equipment and materials (Guidance note 26)
The centre's SOP describes the dilution of the medium for cryopreservation prior to use for freezing sperm. The inspection team noted that the centre has validated this methodology on the basis of scientific evidence and internal studies. However, the centre did not have a risk assessment, including risk control measures, in place for the use of a modified CE marked class III medical device (see recommendation 5, SLC T30 and MHRA guidance on 'Off-label use of a medical device' https://www.gov.uk/government/publications/medical-devices-off-label-use/off-label-use-of-a-medical-device).

The following items that the centre intends to use are not CE marked to the appropriate standard: specimen containers to collect the semen samples, plastic pipettes, and conical tubes (see recommendation 5, SLC T30).

The temperature of the fridge used for the storage of reagents for processing and freezing of sperm will be checked each working day but there is no mechanism to check whether there have been any deviation from required temperature ranges between these measurements (see recommendation 5, SLC T24). Centre staff explained that the supplier has confirmed that the reagents would be stable at room temperature for a day,

however the inspection team was concerned that if there was a temperature deviation over a weekend, staff would not be aware and no corrective actions could be taken.

The centre has a dry shipper that has been validated in Denmark but has not been re-validated after being relocated to the premises in London (see recommendation 5, SLC T24).

Staff engaged in licensed activity
Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The proposed PR has complied with HFEA requirements during the application process and in preparing the centre for licensed activity.

The proposed PR has academic qualifications in the field of biological sciences and more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme.

Staff (Guidance note 2)
The centre is partially compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services.

The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

Centre staff have access to a nominated registered medical practitioner in the UK to perform assessments of donors and who would be available in the event of a clinical emergency. The centre's specialist genetic consultant is based in Denmark and will review all the donor's medical and genetic information during the donor recruitment and assessment process. She is also available to discuss any findings with the donor if needed. The inspection team considers that this arrangement is suitable for the activities proposed.

What the centre could do better

Staff (Guidance note 2)
At the time of inspection, training and competency assessments had not been completed for staff undertaking the following activities: provision of information, consent, phlebotomy, infection control and safeguarding (see recommendation 6, SLC T15a).

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre will not be carrying out treatments so this area of practice is not applicable to this inspection.

Safeguarding
It is important that the centre's donors and staff are protected from harm where possible. The centre's proposed procedures are broadly compliant with safeguarding guidance.

What the centre could do better

Safeguarding
The centre has not established safeguarding processes and staff have not had training in safeguarding (see recommendation 11, CoP 25.33, 25.35 and 25.36).

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9); Embryo testing and sex selection (Guidance note 10)
The centre will not be carrying out treatments so this area of practice is not applicable to this inspection.

What the centre could do better
Nothing identified at this inspection.

2. The experience of donors

Donor feedback

What the centre does well
The centre has developed effective systems to seek donor feedback and has provided assurance that this feedback will be reviewed regularly and, where necessary, actions will be taken to address problems in the service communicated via donor feedback.

What the centre could do better
Nothing identified at this inspection.

Treating patients fairly
Counselling
Egg and sperm sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating donors fairly (Guidance note 29)
The centre's proposed procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's proposed procedures are compliant with requirements to ensure that prospective donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)
It is important to ensure that counselling support is offered to donors providing relevant consent. The centre's proposed counselling procedures are not compliant with HFEA requirements.

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre will not be carrying out treatments so this area of practice is not applicable to this inspection.

Surrogacy (Guidance note 14)
The centre will not be carrying out treatments so this area of practice is not applicable to this inspection.

Complaints (Guidance note 28)
It is important to ensure that the centre uses feedback and any complaints as an opportunity to learn and improve their services. The centre's proposed procedures are compliant with HFEA requirements to seek feedback from donors and to be responsive to complaints.

Confidentiality and privacy (Guidance note 30)
The centre's proposed procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current donors.

What the centre could do better

Counselling (Guidance note 3)
Schedule 3, 3(1) of the HF&E Act 1990 (as amended) requires that before seeking consent, a person must be given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps.

The centre has two counsellors who have a variety of experience in many areas of practice, however the inspection team was not able to confirm whether the counsellors had the required specialist competence in infertility counselling, or experience with counselling sperm donors. At the time of inspection, the centre's counsellors were not accredited by British Infertility Counselling Association (BICA) and did not have sufficient evidence to demonstrate equivalence to BICA accreditation (see recommendation 1, Schedule 3, 3(1) of the HF&E Act 1990 (as amended), SLC T14, SLCT15a and CoP 2.12). Soon after the inspection, the PR has informed the inspection team that the counsellors have joined BICA, but have not yet been able to start working towards BICA accreditation.

Without evidence of appropriate training, competence or accreditation, the inspection team is not assured that that the counselling service is fit for purpose or that **proper** counselling would be available, potentially undermining the effectiveness of consent provided by the sperm donors.

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
It is important that the centre gives prospective and current donors sufficient, accessible and up-to-date information to enable them to make informed decisions about their donation. The centre's proposed procedures for providing information to donors are partially compliant with HFEA requirements.

What the centre could do better

Information (Guidance note 4; CH(11)02)
Schedule 3, 3(1) of the HF&E Act 1990 (as amended) requires that before seeking consent, a person must be provided with such relevant information as is proper. The inspection team considered that the centre's 'donor information' and 'donor contract' does not provide sufficient information for donors in relation to their donation in this unique scenario where samples will be procured in the UK but used anywhere in the world, and that it also includes reference to some activities which are not permissible in the UK such as use of a baby photo of the donor (see recommendation 7, Schedule 3, 3(1) of the HF&E Act 1990 (as amended)), CoP 11.34).

Soon after the inspection the PR provided updated documents that do not include reference to a baby photo. However, the inspection team considers that these still do not provide sufficient information to donors, particularly in relation to the implications for the export and use of his donation outside the UK.

Consent
Legal parenthood
Disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5)
It is important that donors have provided all relevant consents before carrying out any licensed activity. The centre's proposed procedures for obtaining consent are not compliant with HFEA requirements for the reasons set out below.

Legal parenthood (Guidance note 6)
The centre is not required to comply with this guidance for the proposed activities.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
It is important to ensure that the HFEA holds an accurate record of donor's consents, so that it only releases patient identifying information, to researchers, with the consent of the donor. Information can be used by researchers to improve knowledge about the health of patients undergoing licensed fertility treatment and those born as a result of it.

The centre's proposed procedures for taking consent to disclosure to researchers are compliant with HFEA requirements.

What the centre could do better

Consent (Guidance note 5)
The inspection team considers that the centre's processes for seeking consent from donors is not compliant due to the issues identified in relation to the provision of information, offer of counselling, consent to export of sperm to Denmark, and requirements for training and competency of staff involved in these activities. These are described in the relevant sections in this report.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well
The centre will not be carrying out treatments so this area of practice is not applicable to this inspection.

What the centre could do better
Nothing identified at this inspection.

Screening of patients
Storage of gametes

What the centre does well

Screening of patients (Guidance note 15)
The centre will not be carrying out treatments so this area of practice is not applicable to this inspection.

Storage of gametes (Guidance note 17)
The centre's proposed procedures for storing gametes are compliant with HFEA requirements. These measures ensure that the gametes are stored appropriately to maintain their quality and safety. Furthermore, the centre will only store gametes in accordance with the consent of the gamete provider.

What the centre could do better
Nothing identified at this inspection.

Use of embryos for training staff (Guidance note 22)

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre will not be carrying out treatments so this area of practice is not applicable to this inspection.

What the centre could do better
Nothing identified at this inspection.

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's proposed procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The centre's proposed procedures for submitting information about licensed activities to the Authority are compliant with HFEA requirements. This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

What the centre could do better
Nothing identified at this inspection.

Areas of practice requiring action

The section sets out matters which the inspection team considers may constitute areas of non-compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, General Directions or the Code of Practice, and the recommended improvement actions are given, as well as the timescales in which these improvements should be carried out.

Critical area of non-compliance

A critical area of non-compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale	PR Response	Executive Review
1. Counselling The centre has two counsellors who have a variety of experience in many areas of practice, however the inspection team was not able to confirm whether the counsellors had the required specialist competence in infertility counselling, or experience with counselling sperm donors. At the time of inspection, the centre's counsellors were not accredited by BICA and did not have sufficient evidence	The PR should ensure the provision of a proper counselling service. The PR should ensure that the centre can access a suitably qualified counsellor to provide donors with an opportunity to receive proper counselling. The PR should ensure compliance with this requirement prior to this report being considered by a licensing committee.	We have now employed XXXX (BACP #XXX, BICA#XXX) to provide of a proper counselling service. XXXX is a suitably qualified counsellor and many years of experience in providing donors with an opportunity to receive proper counselling. This ensures compliance with this requirement.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has confirmed that the centre has now appointed a new counsellor who is BICA-accredited and will be responsible for providing the counselling service for the centre. The executive is assured that the centre can now access a

to demonstrate equivalence to BICA accreditation. Without evidence of appropriate training, competence or accreditation, the inspection team is not assured that the counselling service is fit for purpose or that **proper** counselling would be available, potentially undermining the effectiveness of consent provided by the sperm donors. Schedule 3, 3(1) of the HF&E Act 1990 (as amended), SLC T14, SLC 15a and CoP 2.12.			suitably qualified counsellor to provide donors with an opportunity to receive proper counselling. **No further action is required.**

Major area of non-compliance

A major area of non-compliance is a non-critical area of non-compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties;
- a combination of several 'other' areas of non-compliance, none of which on their own may be major but which together represent a major area of non-compliance.

Area of practice and reference	Action required and timescale	PR Response	Executive Review
2. Laboratory accreditation The centre proposes to send samples for genetic analysis to laboratories in Spain and the USA. The laboratory in Spain is not accredited by CPA (UK) Ltd. or another body accrediting to an equivalent standard. SLC T21.	The PR should ensure that the laboratories used to undertake the diagnosis and investigation of donors or their gametes or any material removed from them are accredited by CPA (UK) Ltd. or another body accrediting to an equivalent standard. The PR should review the laboratory to be used for the genetic analysis of samples or seek out an alternative, suitably accredited laboratory, to ensure compliance with this requirement prior to this report being considered by a licensing committee.	We can confirm that the laboratories used to undertake the diagnosis and investigation of donors or their gametes or any material removed from them are accredited by CPA (UK) Ltd or another body accrediting to an equivalent standard. The laboratory in Spain is no longer to be used. Rather, samples for genetic analysis will be sent directly to the USA, where the laboratory is accredited by Clinical Laboratory Improvement Amendments (CLIA), which	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The executive notes that the PR has confirmed that the laboratory in Spain will not be used for genetic analysis of samples from donors. The laboratory in the USA is accredited to an equivalent standard to that of CPA (UK) Ltd. **No further action is required.**

		accredits US labs to an equivalent standard. No unaccredited labs will be used. This ensures compliance with this requirement.	
3. Export The donor sperm samples will be exported to the centre's headquarters in Denmark where they will be quarantined and stored until use. At the time of inspection, the centre's proposed procedures did not include sufficient information to demonstrate compliance with all the requirements of General Direction 0006 Schedule 2 section 1. General Direction 0006.	The PR should ensure that the export of donor sperm samples to Denmark is compliant with General Direction 0006. The PR should ensure compliance with this requirement prior to this report being considered by a licensing committee.	The donor information, donor contract and SOPs have been reviewed and amended to ensure each section of GD0006 Schedule 2 section 1 has been incorporated into the donor information, contract and SOPs. An audit to demonstrate this compliance has been provided. The export of donor sperm samples to Denmark is compliant with General Direction 0006. This ensures compliance with this requirement.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided the revised 'donor information' and 'donor contract', and an audit which demonstrates compliance with the relevant requirements of General Direction 0006. **No further action is required.**
4. Third party agreements At the time of inspection, the centre did not have third party agreements in place for the laboratories that would be undertaking genetic analysis	The PR should ensure that written agreements are in place with third parties who provide goods or services that influence	Written agreements are now in place with third parties who provide goods or services that influence the quality and safety of	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation.

of donor samples and morphology assessments of semen samples. SLC T111.	the quality and safety of gametes. The PR should ensure that the agreements are in place prior to the commencement of licenced activity.	gametes, and copies have been supplied as evidence. These include TPAs with Cooper Genomics (in the US) for genetic analysis and The Doctors Laboratory (TDL in London) for morphology assessments of semen samples. This ensures compliance with this requirement.	The PR has provided the third party agreements noted in the report. **No further action is required.**
5. Equipment The centre's SOP describes the dilution of the medium for cryopreservation prior to use for freezing sperm. The inspection team noted that the centre did not have a risk assessment, including risk control measures, in place for the use of a modified CE marked class III medical device. The following items that the centre intends to use are not CE marked to the appropriate standard: specimen containers used to collect the semen samples, plastic pipettes, and conical tubes.	The PR should ensure that CE marked medical devices are used where possible and that all critical equipment is validated and subject to routine monitoring. The PR has provided the centre's inspector with a copy of the risk assessment and risk control measures that are in place for the use of modified sperm freezing medium. However, the inspection team will seek further clarification from the PR with regards to the information provided in this risk assessment.	CE marked medical devices are used where possible and all critical equipment is validated and subject to routine monitoring. Further clarification has been provided to all questions raised about the risk assessment and risk control measures that are in place for the use of modified sperm freezing medium. Clarification includes supporting declarations from XXXXX, the manufacturer of the sperm freezing medium and data to show that the freezing method has led to	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided the requested clarification and evidence of compliance with all the recommendations in relation to equipment that are noted in the report. **No further action is required.**

The temperature of the fridge used for the storage of reagents for processing and freezing of sperm will be checked each working day but there is no mechanism to check whether there has been any deviation from required temperature ranges between these measurements. The centre has a dry shipper that has been validated in Denmark but has not been re-validated after being relocated to the premises in London. SLCT30, SLC T24 and MHRA guidance on 'Off-label use of a medical device'.	The PR should ensure that the areas of non-compliance identified (use of non-CE marked medical devices, fridge temperature monitoring, revalidation of dry shipper) are completed prior to the commencement of licenced activity.	conception of over 25000 healthy families. All CE marked medical devices are used where possible, including the specimen containers used to collect the semen samples, plastic pipettes, and conical tubes. All critical equipment is validated and subject to routine monitoring. This includes recording the max-min temperature of the fridge to demonstrate if any deviation should occur. The dry shipper is re-validated before and after each shipment between London and Denmark. This ensures compliance with this requirement.	
6. Staff At the time of inspection, training and competency assessments had not been completed for staff undertaking the following	The PR should ensure that training and competency assessment are completed for all activities to be undertaken.	Training and competency assessment are completed for all activities to be undertaken.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation.

activities: provision of information, consent, phlebotomy, infection control and safeguarding. SLC T15a.	The PR should ensure that the issues noted at the time of inspection are undertaken and completed prior to the commencement of licenced activity. A copy of the competency assessments should be provided to the centre's inspector prior to this report being considered by a licensing committee.	These include the following activities: provision of information, consent, phlebotomy, infection control and safeguarding. Further training and competency assessments have been completed for provision of information and consents following the updates of our donor information and donor contract. Copies of all competency assessments have been provided.	The PR has provided the requested training and competency assessments for the areas of practice noted in the report. **No further action is required.**
7. Provision of information The inspection team considered that the centre's 'donor information' and 'donor contract' does not provide sufficient information for donors in relation to their donation in this unique scenario where samples will be procured in the UK but used anywhere in the world. Schedule 3, 3(1) of the HF&E Act 1990 (as amended)), CoP 11.34.	The PR should ensure that donors are provided sufficient information on the nature and future use of their donations. The PR should ensure compliance with this requirement prior to this report being considered by a licensing committee.	The donor information and in-house donor contract has been reviewed and updated to ensure donors are provided sufficient information on the nature and future use of their donations. This includes the scenario where samples will be procured in the UK but used anywhere in the world. The revised donor information and donor	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided the updated 'donor information' and 'donor contract' documents which include information relating to the use of their donations anywhere in the world.

		contract have been supplied.	**No further action is required.**

‘Other’ areas of practice that require improvement

An ‘other’ area of practice that requires improvement is any area of practice which cannot be classified as either a critical or major area of non-compliance, but which constitutes a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale	PR Response	Executive Review
8. Safety and suitability of premises and facilities Two issues relating to the safety of the premises were noted at the time of inspection: • The centre’s most recent fire safety risk assessment included areas of ‘high priority’ where further actions were needed but there was no evidence that these had been completed. • The inspection team noted that there was signage in the laboratory indicating the presence of liquid nitrogen but there was no further information advising what people should do in the event of an alarm sounding such as do not enter or the details of who should be	The PR should ensure the safety and suitability of the centre’s premises and facilities. The PR should provide evidence that actions arising from the fire risk assessment have been completed when responding to this report. The PR should ensure there is sufficient safety signage and information for staff and visitors in relation to hazards such as liquid nitrogen, and confirm that this has been completed prior to the use of liquid nitrogen.	The safety and suitability of the centre’s premises and facilities has been ensured. Evidence has been provided that actions arising from the fire risk assessment have been completed including fire drills. Sufficient safety signage and information in relation to hazards such as liquid nitrogen for all staff and visitors has been put in place to advise what people should do in the event of an alarm sounding.	The executive acknowledges the PR’s response and his commitment to fully implementing this recommendation. The PR has provided the report of a further fire safety risk assessment that was carried out on 25 June 2018, and the executive notes that no ‘high priority’ actions were identified. The PR has confirmed that safety signage and information for staff and visitors in relation to hazards such as liquid nitrogen in now in place. **No further action is required.**

contacted and how. The centre's dewars had not yet been filled with liquid nitrogen. CoP 25.4b and 25.17.			
9. Infection control The centre does not have a person identified as an infection control lead to carry out such activities as reviewing the suitability of the flooring in clinical areas and developing suitable cleaning schedules. CoP 25.20.	The PR should ensure that the centre has access to an infection control lead to advise on infection control requirements. The PR should confirm that the non-compliance identified have been addressed within three months of commencing licensed activity.	XXXX is now fully trained in infection control and has been appointed as the infection control lead to advise on infection control requirements. An external company has since been contracted to assess the premises. Where there were gaps, these have now been addressed. A re-assessment now demonstrates that the premises has an acceptable infection control status.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has confirmed that a member of staff has been trained and appointed as infection control lead, and that an external infection control advisor has assessed the centre's premises and confirmed that these are suitable for the activities to be carried out there. **No further action is required.**
10. QMS The centre has not developed policies and procedures for a clinical emergency and a non-clinical	The PR should ensure that there are procedures in place in the event of clinical and non-clinical emergencies.	Policies and procedures are now in place to cover clinical and non-clinical emergencies. A business	The executive acknowledges the PR's response and his commitment to fully

emergency or business continuity plan. SLC T33b.	The PR should confirm that these procedures have been developed prior to the commencement of licenced activity or recruitment of donors.	continuity plan has also been developed. Evidence of all documentation has been supplied.	implementing this recommendation. The PR has provided the requested procedures. **No further action is required.**
11. Safeguarding The centre has not established safeguarding processes and staff have not had training in safeguarding. CoP 25.33, 25.35 and 25.36.	The PR should ensure that processes are in place to protect donors and staff from harm where possible. The PR should ensure compliance with this requirement prior to the commencement of licenced activity or recruitment of donors.	Safeguarding processes have been developed and documented to protect donors and staff from harm where possible. Staff have had training in safeguarding and certificates have been supplied. XXXX has been appointed as the Safeguarding Lead. All staff have passed DBS checks.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has confirmed that the centre has a designated safeguarding lead, that they have developed and implemented safeguarding processes in the centre, and that staff have been trained in this area of practice. **No further action is required.**

Further response from the Person Responsible to this inspection report
We are grateful for the highlighting of areas where we could improve. We hope we have satisfactorily addressed all concerns raised. We note that the ESB London model is being considered as a new operating model not previously employed in any UK clinic, since samples will be exported out of the UK for distribution. We hope that our model and our stringent transparent controls are acceptable.