Executive Licensing Panel - minutes

Centre 0356 (European Sperm Bank UK Ltd)

Interim Inspection Report

Tuesday, 4 June 2019

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Richard Sydee (Chair) Danielle Vincent Dina Halai	Director of Finance and Resources Communications Manager Scientific Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Nora Cooke-O'Dowd	Licensing Manager Head of Research and Intelligence

Declarations of interest

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

The panel had before it:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

1.1. The panel noted that the European Sperm Bank UK Limited (Ltd), located in London, has held a storage only licence with the HFEA since August 2018 and is a subsidiary of European Sperm Bank ApS, a private company located in Denmark. The centre recruits sperm donors, procuring, processing and freezing their samples on the premises. The donor sperm samples are exported under General Direction 0006 to European Sperm Bank's headquarters in Copenhagen, Denmark. The samples remain in Denmark until they are distributed to centres for use in treatment. This includes centres in the UK and around the world.

1.2. The panel noted that the inspection took place on 9 April 2019.

1.3. The panel noted that at the time of inspection there was one major area of non-compliance concerning the donor contract. Since the inspection, the Person Responsible (PR) has provided evidence to confirm that the recommendation made in the report has been fully implemented.

1.4. The panel noted that the inspectorate recommended the continuation of the centre's storage only licence.

2. Decision

2.1. The panel was satisfied the centre was fit to have its storage only licence continued.

3. Chair's signature

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

Signature

Name

Richard Sydee

Date

11 June 2019

Interim Licensing Report

Centre name: European Sperm Bank UK Ltd
Centre number: 0356
Date licence issued: 1 August 2018
Licence expiry date: 31 July 2020
Additional conditions applied to this licence: None
Date of inspection: 9 April 2019
Inspectors: Karen Conyers
Date of Executive Licensing Panel: 4 June 2019

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLCs).

This is a report of a short notice interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. The current foci for an interim inspection are:

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers, and the individuals who deliver that care.
- **Patient experience:** understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel (ELP) with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

The inspector recommends the continuation of the centre's licence.

The ELP is asked to note that this report makes a recommendation for improvement in relation to one major area of non-compliance.

Since the inspection visit, the Person Responsible (PR) has provided evidence to confirm that the recommendation has been fully implemented.

Major area of non-compliance:

- The PR should ensure that all donors complete the correct version of the centre's 'donor contract'.

Information about 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 recruits sperm donors, procuring, processing and freezing their samples on the premises. The donor sperm samples are exported under General Direction 0006 to European Sperm Bank's headquarters in Copenhagen, Denmark. The samples remain in Denmark until they are distributed to centres for use in treatment. This includes centres in the UK and around the world.

The centre has held a 'storage only' licence since August 2018. The PR, Bryan Woodward, is also currently PR of another HFEA licensed centre (X&Y Fertility, centre 0353).

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes: they are important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Pregnancy outcomes and multiple births

These inspection themes are not relevant as the centre does not offer treatment services.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur. The inspector was not able to observe any laboratory activities during the inspection but was able to discuss witnessing with staff. These discussions indicated that witnessing procedures are compliant with HFEA requirements.

Consent: To the storage of cryopreserved sperm

It is important that the centre has measures in place to ensure that sperm is stored in accordance with the consent of the donor. The centre stores donated sperm for a short period before being exported to the company's headquarters in Denmark. During the inspection, the centre's processes for taking consent to storage was discussed with staff. These activities indicate that the centre's processes for storing gametes line with the consent of the gamete providers are effective. As the centre has been active for about 6 months an audit of stored material has not yet been conducted.

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

The inspector considered that staffing levels in the clinic appeared suitable for the activities being carried out: donors attending for consultations are seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

Quality Management System (QMS)

It is important that centres audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following standard operating

procedures and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any necessary changes that are identified are made, as this supports continuous improvement. As centre has only been active for 6 months, it is not expected that audits of critical activity would have been undertaken, but these will be expected to be in place at the time of the renewal inspection which is to take place in early 2020.

The centre's QMS is managed centrally by the Quality Manager based at the company's headquarters in Denmark, and all staff at the centre are fully engaged in this process, for example by having remote teleconference meetings and electronic access to relevant documents.

The centre's QMS is partially compliant with requirements for the following reason.

- All donors sign an ESB 'donor contract' in addition to the HFEA MD consent form '*Your consent to donating your sperm*'. The donor contract is a detailed document which complements the HFEA MD consent form, setting out the specific aspects of the ESB donor programme such as the implications of the use of their samples in countries other than the UK. Centre staff informed the inspector that on reviewing the document about 2 weeks previously they had noted that the 'donor contract' provided to donors was not the final version as it did not include all the amendments that had been made in 2018 (see recommendation 1). The inspector was concerned why this error had not been noted until recently as the document would have been in use since September 2018. The inspector notes that these donated samples have not yet been used in treatment.

  Several changes had been made to the 'donor contract' in response to the recommendations made by Licence Committee following the consideration of the centre's application for a new storage licence in July 2018. These changes had been reviewed by the centre's inspector via email, and a number of versions were drafted during these communications. Once all requirements were addressed the centre's inspector confirmed that as all changes to the document recommended by Licence Committee had been made, licensed activity could commence at the centre. However, the version that was finalised and uploaded to the company's internal electronic systems had not included one change that had been requested by the Licence Committee: '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.' At the time the centre had confirmed that it agreed to the committee's request and would remove this statement from the 'donor contract'.

  During the inspection the inspector reviewed a recently updated 'donor contract' and the PR confirmed that once this document has been approved via the document control process all donors will be contacted and asked to sign the correct version of the 'donor contract'. The PR did not anticipate any difficulty in contacting all 23 donors that have been recruited. Centre staff confirmed that this issue had been reported internally as a non-conformance, in accordance with their company's QMS.

We also considered whether the centre's processes for implementing learning are effective. If a centre is to achieve continuous improvement and encourage a learning culture, then it is important that they act to review their practices when guidance is issued by the HFEA or

other bodies. The centre's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- leadership
- information provision
- counselling
- consent
- screening
- data protection and confidentiality
- the use of CE marked medical devices
- the content of the centre's website

The centre has been effective in ensuring compliance with guidance issued by the HFEA. Prior to the inspection, the inspector noted that the centre's website included a reference to a doctor's group that is not used by the centre. This link was removed during the inspection; therefore, no further recommendation is considered necessary.

Medicines management

It is important that clinics follow best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way. This inspection theme is not relevant as the centre does not offer treatment services.

Infection Control

It is important that clinics have suitable arrangements in place so that donors experience care in a clean environment and to prevent donors and staff acquiring infections. During the inspection, we reviewed infection control practices and found them to be compliant with guidance.

Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for the provision of fertility treatment, to ensure the safety of gametes, embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The CE mark medical devices in use at the centre were reviewed during the inspection. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

This inspection theme is not relevant as the centre does not offer treatment services. No donors were available during the inspection to speak with the inspector.

Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

Compliance with HFEA standard licence conditions

Information submitted by the centre in their self-assessment questionnaire, the pre-inspection assessment and observations during the visit to the centre, indicate that the centre is compliant with HFEA requirements.

Compliance with recommendations made at the time of the last inspection

Following the new licence inspection on 13 April 2018, recommendations for improvement were made in relation to one critical, six major and four 'other' areas of non-compliance. The PR provided information and evidence that all of the recommendations were fully implemented before the application was considered by Licence Committee.

On-going monitoring of centre success rates

This inspection theme is not relevant as the centre does not offer treatment services.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. This information is held in the HFEA Register. The centre does not offer treatment service but is compliant with requirements to submit relevant data about the donors which is required for the HFEA Register.

Legal parenthood

This inspection theme is not relevant as the centre does not offer treatment services.

Annex 1

Areas of practice that require the attention of the Person Responsible

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, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be made.

Critical areas 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 child who may be born as a result of treatment services. A critical non-compliance requires immediate action to be taken by the Person Responsible.

A critical area of non-compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive review
None identified on this inspection.		Agreed	

‘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 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;
- which can comprise a combination of several ‘other’ areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

A major area of non-compliance is identified in the report by a statement that an area of practice is partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive review
‘Donor contract’ 1. All donors sign an ESB ‘donor contract’ in addition to the HFEA MD consent form ‘Your consent to donating your sperm’. Centre staff informed the inspector that about 2 weeks previously they had noted that the ‘donor contract’ provided to donors was not the final version as it did not include all the amendments that had been made in 2018.	The PR should ensure that all donors complete the correct version of the centre’s ‘donor contract’. The PR should provide a copy of the correct ‘donor contract’ that is to be signed by donors to the centre’s inspector when responding to this report. The PR has confirmed that the centre will be contacting all donors and asking them to sign the correct ‘donor contract’. The PR should provide an update on progress with completing this action	All donors complete the correct version of our donor contract. A copy of the correct ‘donor contract’ has been supplied to the inspector. All donors who signed the older version of the contract have been contacted and have now signed the correct version.	The executive acknowledges the PR’s response and his commitment to fully implementing this recommendation. The PR has provided the updated donor contract and has confirmed that all donors have now signed this document. The PR has also provided the summary reports of the centre’s audit of all HFEA MD consent forms and investigation into why the centre’s document control

The inspector was concerned why this error had not been noted until recently as the document would have been in use since September 2018. SLC T34.	when responding to this report. The PR should also undertake an audit of all HFEA MD consent forms for donors recruited at the centre to provide assurance that these have been completed correctly. A summary report of the findings of the audit should be provided to the centre's inspector when responding to this report. The PR should investigate why the centre's document control processes had failed in this instance, and why the use of the incorrect document was not identified until March 2019. A summary of the findings of these investigations including corrective actions and the timescales for implementation should be provided to the centre's inspector when responding to this report.	An audit of all MD forms has been undertaken and a summary report has been supplied to the inspector to provide assurance that these are being completed correctly. An investigation has been undertaken into why the document control processes failed on this one occasion. A summary of the findings, and CAPA with timescales has been supplied to the inspector.	processes had failed in this instance. The investigation concluded that incorrect approval of the final version was due to 'multiple email revisions between the HFEA and ESB staff.' The PR has confirmed that the correct version of the 'donor contract' is now in use. **No further action is required.**

‘Other’ areas of practice that requires improvement

Areas of practice that require improvement are any area of practice in which failings occur, which cannot be classified as either a critical or major area of non-compliance, but which indicate a departure from statutory requirements or good practice.

An ‘other’ area of non-compliance is identified in the report by a statement that an area of practice is ‘broadly’ compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive review
None identified on this inspection.		Agreed	

Additional information from the Person Responsible
No additional information supplied.