Executive Licensing Panel - minutes

Centre 0356 (European Sperm Bank UK Ltd)

Renewal Inspection Report

Tuesday, 16 June 2020

HFEA Teleconference Meeting

Panel members	Clare Ettinghausen (Chair) Joanne Anton Kathleen Sarsfield-Watson	Director of Strategy and Corporate Affairs Head of Regulatory Policy Communications Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing Manager

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 considered the papers, which included a completed application form, inspection report and licensing minutes for the last three years.

1.2. The panel noted that 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 donated semen on the premises. The donor samples are exported, under General Direction 0006, to European Sperm Bank's headquarters in Copenhagen, Denmark for long term storage. The samples remain in Denmark until they are distributed to centres world-wide for use in treatment.

1.3. An inspection was carried out at the centre on the 25 February 2020.

1.4. The panel noted that at the time of the inspection, there were two 'other' areas of non-compliance concerning donor assisted conception and the quality management system (QMS). Since the inspection, the Person Responsible (PR) has taken action to implement both of the recommendations made in the report, and these will all be fully completed within agreed timescales.

1.5. The panel noted that the centre suspended all donor recruitment and procurement activities on 20 March 2020, due to Covid-19. The centre has recently provided a Covid-19 self-assessment, for the commencement of procurement services, at a storage only centre, which the executive considered to be acceptable. The centre will be commencing donor recruitment and procurement activities some time in June.

1.6. The panel noted that the centre is well led and provides a good level of support to donors.

1.7. The panel noted that the inspection team recommends the renewal of the centre's storage only licence, for a period of four years, without additional conditions, subject to the recommendations made in this report being implemented within acceptable timescales.

2. Decision

2.1. The panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

2.2. The panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

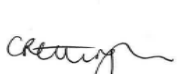
2.3. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR will discharge his duty under section 17 of the HFE Act 1990 (as amended).

2.4. The panel endorsed the inspectorate's recommendation to renew the centre's storage only licence, for a period of four years, without additional conditions, subject to outstanding actions being implemented within satisfactory timescales. The panel agreed that if no representations or any other information is received within 28 days, the final renewal licence should be issued.

3. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

22 June 2020

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) 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: 25 February 2020

Purpose of inspection: Renewal of a licence to carry out 'Storage only'.

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Inspector: Andrew Leonard

Date of Executive Licensing Panel: 16 June 2020

Centre name	European Sperm Bank UK Ltd
Centre number	0356
Licence number	L/0356/1/a
Centre address	48 Gray's Inn Road, London, WC1X 8LT, United Kingdom
Person Responsible	Mr Bryan Woodward
Licence Holder	European Sperm Bank UK Ltd. Named contact: Ms Annemette Arndale-Lauritzen
Date licence issued	1 August 2018
Licence expiry date	31 July 2020
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

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 donated semen on the premises. The donor samples are exported under General Direction 0006 to European Sperm Bank's headquarters in Copenhagen, Denmark for long term storage. The samples remain in Denmark until they are distributed to centres world-wide for use in treatment.

The centre has held a 'Storage only' licence since August 2018. This licence has not been varied since it was issued.

Pregnancy outcomes
Treatment services leading to pregnancies are not provided at this clinic.

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 designated an individual to act as the Person Responsible (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 renewal of the centre's licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection, the following two recommendations to address 'other' non compliances were made.

'Other' areas that requires improvement:

- The PR should ensure the centre records the sex of any child born as a result of the use of a donor's sperm in treatment, so this information can be provided to a donor on request.
- The PR should ensure that the centre's audits are robust and that audit reports document the implementation of all corrective and preventative actions and the date on which this occurs.

The PR has taken action to implement these recommendations and these actions will be completed within acceptable timescales.

Recommendation to the ELP

The centre has no critical or major of areas of non compliance.

The centre is well led and provides a good level of support to donors.

The inspection team recommends the renewal of the centre's 'Storage only' licence for a period of four years without additional conditions, subject to the recommendations made in this report being implemented within the prescribed timescales.

The inspector notes that the centre suspended all donor recruitment and procurement activities on 20 March 2020. The centre has recently provided a Covid-19 self assessment: For the commencement of procurement services at a storage only centre, which the executive considered to be acceptable. The centre will be commencing donor recruitment and procurement activities some time in June.

Centre 0356 has not been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018.

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 patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)
The centre's 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 prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
The centre's 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)
The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes. 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.

Donor assisted conception (Guidance note 20)
It is important that centres use donated gametes from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes in treatment and the parents of donor-conceived children, are able to access non identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived

genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

The centre's procedures are broadly compliant with HFEA requirements which ensure the donor-conceived and their parents will be able to receive all required donor-related information.

What the centre could do better

Donor assisted conception (Guidance note 20)
The centre does not currently require the treatment centres it supplies with donor sperm, to inform it regarding the sex of any child born through use of the donor sperm in treatment, though pregnancies and births are notified. Thus it cannot easily provide donors with information, if requested, about the sex of the persons born as a result of their donation (HF&E Act 1990 (as amended), 31ZD (3); see recommendation 1).

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 and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
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)
The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account so that donors and staff are in safe surroundings that prevent harm.

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

Laboratory accreditation (Guidance note 25)
The centre's third party laboratories which undertake the diagnosis and investigation of donors' samples, are compliant with HFEA requirements to be accredited by UKAS, the

national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control (Guidance Note 25)
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

Medicines management (Guidance Note 25)
These requirements are not relevant to the centre's activities.

Prescription of intralipid 'off label'
These requirements are not relevant to the centre's activities.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
These requirements are not relevant to the centre's activities.

Multiple births (Guidance note 7; General Direction 0003)
These requirements are not relevant to the centre's activities.

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

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

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes;
- 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;
- the container/package is secure and ensures that the gametes are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note15)
These requirements are not relevant to the centre's activities.

Imports and exports (Guidance note 16; General Direction 0006)
The centre does not import gametes so it was not necessary to review against import-relevant HFEA requirements at this inspection.

The centre exports gametes and these activities are undertaken in a manner compliant with HFEA requirements.

Traceability (Guidance note 19)
The centre's 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;
- to 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 establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services. The centre has a QMS that is broadly compliant with HFEA requirements.

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

Transport and satellite agreements (Guidance note 24; General Direction 0010)
These requirements are not relevant to the centre's activities.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

The centre is compliant with HFEA requirements to validate critical equipment. 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 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 procedures for reporting adverse incidents are compliant with HFEA requirements. No adverse incidents have occurred at the centre since it was licensed, but discussions with centre staff demonstrated that any adverse incident would be appropriately managed. 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

QMS (Guidance note 23)
Minor concerns were noted in the centre's audits:

- Some process audits did not include direct observation of practice against the centre's procedures (SLC T36).
- The donor screening audit did not review donor age or whether a full medical history was documented and reviewed. These are important requirements and should be audited against to ensure the audit is robust (SLC T36).

- Reports of some process audits did not document whether corrective and preventative actions had been implemented and on which date this occurred (SLC T36).

It is acknowledged that all donor records reviewed on inspection recorded medical histories and that the donors were less than 45 years old, and also that all corrective actions noted in audit reports have been implemented.

See recommendation 2.

Staff engaged in licensed activity

Person Responsible (PR)
Leadership
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has complied with HFEA requirements.

The PR has academic qualifications in the field of biological sciences and has 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.

The PR is also currently PR of another HFEA licensed centre (X&Y Fertility, centre 0353). Centre 0353 is also a storage centre and it has since 2018 had a very low level of activity. The inspector considered that the PR's role at centre 0353 had not undermined his performance as the PR at centre 0356, nor will it do so in the future.

Leadership
The centre is compliant with HFEA guidance regarding effective leadership.

Good leadership improves patient care and is encouraged by the HFEA. A PR should have the necessary authority and autonomy to carry out the role. The PR should ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about patient care. The PR is legally accountable for the overall performance of the centre and should establish clear responsibilities, roles and systems of accountability to support good governance, including ensuring that appropriate action is taken following all forms of feedback from the HFEA or patients.

Staff (Guidance note 2)
The centre is 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.

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

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
These requirements are not relevant to the centre's activities.

Safeguarding (Guidance Note 25)
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's donors and staff are protected from harm where possible.

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

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)
These requirements are not relevant to the centre's activities.

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

2. The experience of patients

Donor feedback

What the centre does well

During the inspection visit, no donors were available to speak to the inspectors.

The centre has good systems to seek feedback from both donors and centres that are using donor samples in treatment and to respond to that feedback. Feedback received by the centre to date has been generally positive and two minor concerns have been responded to appropriately.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- has respect for the privacy and confidentiality of donors in the clinic;
- gives donors sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides donors with satisfactory facilities for their care.

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 patients fairly (Guidance note 29)

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

Counselling (Guidance note 3)

The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to donors providing relevant consent.

Egg sharing arrangements (Guidance note 12; General Direction 0001)

These requirements are not relevant to the centre's activities.

Surrogacy (Guidance note 14)

These requirements are not relevant to the centre's activities.

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

Confidentiality and privacy (Guidance note 30)
The centre's 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
Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

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

Consent and disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that donors have provided all relevant consents before carrying out any licensed activity.

Legal parenthood (Guidance note 6)
These requirements are not relevant to the centre's activities.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre's procedures for taking consent to disclosure to researchers are compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of donors' consent, so that it only releases the donor's identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

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

3. The protection of gametes and embryos

Respect for the special status of the embryo
What the centre does well These requirements are not relevant to the centre's activities.
What the centre could do better Nothing identified at this inspection.

Screening of patients and Storage of gametes and embryos
What the centre does well **Screening of patients (Guidance note 17)** These requirements are not relevant to the centre's activities. **Storage of gametes and embryos (Guidance note 17)** The centre's 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 only stores gametes in accordance with the consent of the gamete providers.
What the centre could do better Nothing identified at this inspection.

Use of embryos for training staff
What the centre does well **Use of embryos for training staff (Guidance note 22)** These requirements are not relevant to the centre's activities.
What the centre could do better Nothing identified at this inspection.

4. Information management

Record keeping and Obligations and reporting requirements
What the centre does well **Record keeping and document control (Guidance note 31)** The centre's 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 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.

Section 3: Monitoring of the centre's performance

Following the interim inspection in April 2019, recommendations for improvement were made in relation to one major non compliance. This concern was resolved before the inspection report was considered by the licensing committee.

On-going monitoring of centre success rates

Treatment services that result in success rates monitored by the HFEA are not provided at this clinic.

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 required are given, as well as the timescales in which these improvements should be carried out.

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 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.

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
No issues identified		N/A	

Major areas 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 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
No issues identified		N/A	

Other areas of practice that require improvement

'Other' areas of practice that require improvement are any areas of practice 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
1. Donor assisted conception The centre does not currently require the treatment centres it supplies with donor sperm, to inform them regarding the sex of any child born through use of the donor sperm in treatment. Thus, it cannot easily provide donors with information, if requested, about the sex of the persons born as a result of their donation (HF&E Act 1990 (as amended), 31ZD (3)). This non compliance is graded as an 'other' because this information would be provided by the treatment centres to the HFEA register.	To provide the best support to donors, the centre should record the sex of any child born as a result of the use of the donor's sperm in treatment. The PR should inform the inspector of the actions taken to implement this recommendation, with supporting evidence, by 25 August 2020. The PR should inform the inspector of the actions taken to implement this recommendation, with supporting evidence, by 25 August 2020. This deadline is considered reasonable given the current suspension of services due to the COVID-19 pandemic, however the inspector will liaise with the	The European Sperm Bank currently uses an online system whereby clinics report pregnancy details. However, this system does not record the sex of any child born. To ensure complaince, an upgrade to the online reporting system has been scheduled for 2020 which will include the record of the sex of any child born. Until the system supports these requirements ESB will continue to assist donors in obtaining the information via clinic reporting to the HFEA.	The inspector notes the proposed actions to be taken, which will address the concerns identified. The actions will be completed in 2020, potentially outside of the deadline of 25 August 2020. The inspector has discussed this with the PR and considers the proposed timescale acceptable, given the difficulties created by the Covid-19 emergency and that the actions are part of a larger project to update the reporting systems across ESB centres, which will provide a robust solution to our concerns. Furthermore, information on the sex of donor conceived children is not being 'lost', since it remains available from the HFEA register, having

	PR to consider a more appropriate timescale should the PR require it.		been reported by treatment centres to the HFEA. **Further actions are required**
2. QMS Minor concerns were noted in the centre's audits: • Some process audits do not include direct observation of practice against the centre's procedures (SLC T36). • The donor screening audit did not review donor age or whether a full medical history was documented and reviewed. These are important requirements and should be audited against to ensure the audit is robust (SLC T36). • Reports of some process audits did not document whether corrective and preventative actions had been implemented and on which date this occurred (SLC T36).	The PR should ensure that: • the centre's audits are robust and include observation of practice and review against all relevant regulatory requirements. • audit reports (or a non conformance log) document the implementation of all corrective and preventative actions and the date on which this occurs. The PR should inform the inspector of the actions taken to implement this recommendation, with supporting evidence, by 25 August 2020. This deadline is considered reasonable given the current suspension of services due to the COVID-19 pandemic, however the inspector will liaise with the PR to consider a more	Audits of observation of practice against all relevant regulatory requirements will be conducted for centre staff. Audits will be undertaken once practice is resumed post-pandemic. Audits forms now include details of the corrective and preventive action and the dates when these have been completed and by whom. An example of an audit will be provided to demonstrate the revised practice.	The inspector notes the PR's comments and that actions have been taken to implement the recommendation. The actions remain to be finalised, due to the COVID-19 emergency and the centre's suspension of activity. The PR has though indicated that the centre will be able to provide audit reports by 25 August 2020 in evidence of the full implementation of this recommendation. The inspector considers this to be a reasonable timeframe, given the suspension of service and that the donor recruitment and procurement activities will commence again sometime in June. The inspector looks forward to receiving the audit reports and will liaise with the PR to ensure effective implementation of the recommendation.

It is acknowledged that all donor records reviewed on inspection recorded medical histories and that the donors were less than 45 years old, and also that all corrective actions noted in audit reports have been implemented.	appropriate timescale should the PR require it.		**Further actions are required**

Reponses from the Person Responsible to this inspection report
I agree with this report.