Executive Licensing Panel - minutes

Centre 0345 (Semovo, Leeds) Initial Inspection Report – Storage Only Licence

Friday, 18 November 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Paula Robinson (Chair) Ian Peacock Howard Ryan	Head of Business Planning Analyst Programmer Technical Report Developer
Members of the Executive	Dee Knoyle Siobhain Kelly	Secretary Interim Head of Corporate Governance
External adviser		
Observers		

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:

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

1. Background

1.1. Semovo, Leeds is located at:

Thorpe Park Clinic
4600 Park Approach
Leeds
West Yorkshire
LS15 8GB

1.2. Semovo is a registered company that aims to recruit sperm donors. The company was recently granted an HFEA storage only licence for Semovo, Liverpool, centre 0346.

1.3. The proposed Person Responsible (PR), Dr Falconer, also PR at Manchester Fertility, centre 0033, has applied for an HFEA storage only licence for Semovo, Leeds.

1.4. As part of the staged development of the clinic, the upper floor has recently been commissioned to provide additional clinical facilities. Semovo, Leeds will have access to two rooms, one room in which staff can meet with potential donors and for donors to produce their samples and a second room in which sperm will be frozen. Sperm samples will be frozen on the premises and transported to Manchester Fertility, centre 0033, on the same day, for storage and distribution under their licence. A storage only licence is required at Semovo, Leeds to cover the temporary storage of samples prior to transfer to Manchester Fertility, centre 0033.

1.5. The inspection report presents the findings of a desk based assessment of documentation submitted alongside the Semovo, Liverpool application, with an on-site inspection of the Leeds premises on 4 October 2016 and local agreements and protocols.

1.6. This inspection was based on the description of the service provided by the applicant and therefore the premises and practices were not assessed for their suitability for storage of sperm for longer periods of time. Documentation (such as patient information), processes and procedures are the same across the two Semovo sites, with the exception of a small number of premises specific agreements and local clinical protocols.

2. Consideration of application

2.1. The panel considered the papers which included an application form, inspection report, CV of the proposed Person Responsible (PR) and Licence Holder (LH).

2.2. The panel noted the findings of the desk based assessment and inspection carried out on 4 October 2016.

2.3. The panel noted that the proposed PR, Dr Deborah Falconer, holds academic qualifications in the field of medicine. The proposed PR also has more than two years' practical experience which is directly relevant to the activity to be authorised by the licence as required by the HFE Act 1990 (as amended) section 16(2)(c)(i) and (ii) (including acting in the capacity of PR). The proposed PR has successfully completed the HFEA PR Entry Programme.

2.4. The panel noted the suitability of the proposed LH, Mr Andrew Berkley.

2.5. The panel noted that the relevant building certificates for safe occupancy, fire and health and safety must be provided before commencing licensable activity.

2.6. The panel noted that at the time of the inspection on 4 October 2016 there were two major and one other area of non-compliances identified. Since the inspection the PR has committed to implementing the recommendations.

2.7. The panel noted that the inspectorate considered that there is sufficient information available to recommend:

- the appointment of the proposed PR;
- the appointment of the proposed LH;
- the grant of a storage only licence for a period of two years.

3. Decision

3.1. The panel referred to its decision tree.

3.2. The panel was satisfied that the appropriate application form was submitted.

3.3. The panel noted that the inspectorate had received the supporting information required by General Directions 0008 and was satisfied that the fee had been paid.

3.4. The panel was satisfied that the proposed PR, Dr Deborah Falconer will discharge her duty under section 17 of the HFE Act 1990 (as amended). The panel agreed to appoint Dr Falconer as the Person Responsible when the new licence comes into effect, in accordance with section 18A of the HFE Act 1990 (as amended).

3.5. The panel was satisfied with the suitability of the proposed LH, Mr Andrew Berkley. The panel agreed to appoint Mr Berkley as the Licence Holder when the new licence comes into effect.

3.6. The panel was satisfied that the premises to be licensed are suitable for the conduct of licensed activities and that the relevant building certificates for safe occupancy, fire and health and safety will be provided before commencing licensable activity.

3.7. The panel was satisfied that the licence application concerns treatment, storage or non-medical fertility services which relate to gametes or embryos intended for human application.

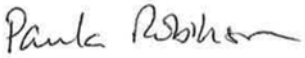
3.8. The panel referred to 'guidance on periods for which new or renewed licences can be granted' which states that an initial treatment/storage/non-medical fertility services licence would normally be granted for up to two years. This is because in granting an initial licence, there will be no history of compliance to support a longer licence.

3.9. The panel agreed to grant the licence for storage only for a period of two years with no additional conditions, subject to the non-compliances being implemented within the prescribed timescales.

4. Chair's signature

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

Signature



Name

Paula Robinson

Date

28 November 2016

Initial Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre will comply 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 their first licence. Initial licenses are usually granted for a period of two years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 4 October 2016

Purpose of inspection: Application for a HFEA 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.

Inspectors: Dr Douglas Gray, Mrs Gill Walsh

Date of Executive Licensing Panel: 18 November 2016

Centre name	Semovo, Leeds
Centre number	0345
Centre address	Thorpe Park Clinic, 4600 Park Approach, Leeds, West Yorkshire, LS15 8GB
Proposed Person Responsible	Dr Deborah Falconer
Proposed Licence Holder	Mr Andrew Berkley

Contents

Section 1: Summary report

Brief description of the centre and the inspection:
SEMOVO is a registered company that aims to recruit sperm donors at a number of locations. The ELP has recently granted a storage licence following a similar application for SEMOVO in Liverpool.

A HFEA storage licence has been applied for to be held at the Thorpe Park Clinic, Leeds, a mixed NHS and private medical practice. As part of the staged development of the clinic, the upper floor has recently been commissioned to provide additional clinical facilities. SEMOVO will have access to two rooms in which staff can meet with potential donors and for donors to produce their samples, and a second room in which sperm will be frozen. Sperm samples will be frozen on the premises, and on the same day will be transported to Manchester Fertility (0033) for storage and distribution under their licence. The proposed Person Responsible (PR), Dr Falconer, is also PR at Manchester Fertility.

A storage licence is required to cover the temporary storage of samples at the Thorpe Park Clinic prior to transfer to Manchester Fertility. This inspection was based on the description of the service provided by the applicant and therefore the premises and practices were not assessed for their suitability for storage of sperm for longer periods of time.

Documentation (such as patient information), processes and procedures are the same across the two SEMOVO sites with the exception of a small number of premises specific agreements and local clinical protocols. This inspection report presents the findings of a desk based assessment of documentation submitted alongside the SEMOVO Liverpool application, with an on-site inspection of the Leeds premises and local agreements and protocols.

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 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 PR;
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR will discharge her duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) will be suitable upon completion of recommendations made in this report;
- the centre's proposed 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 ELP is asked to note that at the time of the inspection there were two major areas of non compliance and one 'other' area of practice.

Major areas of non compliance:

- The warming oven and fridge must be validated before use.
- Confirmation that the relevant building certificates for safe occupancy, fire and health and safety are in place must be provided before commencing licensable activity.

'Other' areas that requires improvement:

- The risks of not routinely conducting a physical examination of potential sperm donors should be considered and measures identified to mitigate any such risk.

The PR has committed to implementing all three recommendations.

Recommendation to the Executive Licensing Panel

The inspection team has sufficient information to recommend the grant of a storage licence for a period of two years without additional conditions subject to the recommendations made in this report being implemented. An interim inspection will be completed during the first year as a useful indication of early performance and progress.

The inspection team has sufficient information to recommend the appointment of the proposed LH and appointment of the proposed PR.

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 will ensure 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 with one exception. 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)
A donor-conceived person is entitled to know details of their donor and any donor-

conceived genetic siblings they may have. Parents of a donor-conceived child are able to access information on their child's donor (and about any donor-conceived genetic siblings) from the HFEA or the clinic where they received treatment.

Therefore it is important that centres use donated gametes or embryos from identifiable donors. The centre's procedures are compliant with HFEA requirements to ensure the donor conceived will be able to receive this information.

What the centre could do better

Screening of donors (Guidance note 11)
Donors will have a consultation with a qualified medical practitioner but will not routinely undergo a physical examination for the presence of genital warts or herpes as recommended by professional body guidelines (Code of practice 11.22; recommendation 3).

Suitable premises and 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)
It is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose. The premises will be suitable upon completion of recommendations made in this report.

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account to ensure 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 will undertake the diagnosis and investigation of donors' samples are compliant with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

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

Medicines management
The centre is not required to comply with this guidance for the proposed activities.

Pre-operative assessment and the surgical pathway
The centre is not required to comply with this guidance for the proposed activities.

Multiple births (Guidance note 7; General Direction 0003)
The centre is not required to comply with this guidance note for the proposed 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.

Receipt of gametes and embryos (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 proposed PR has confirmed that they do not anticipate importing or exporting gametes.

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 and recipient 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. 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 compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre is not required to comply with this guidance note for the proposed activities.

Equipment and materials (Guidance note 26)
The centre will use 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 will be appropriately maintained in order to minimise any hazard to patients, donors and/or staff.

The centre is partially 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. 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

Premises (Guidance note 25)
On the day of inspection, the commissioning of the upper floor was complete although the deep clean has not yet taken place. The relevant certification confirming safe building occupancy, fire and health and safety was not available, nor is there an agreement in place between SEMOVO and the owners of the premises setting out respective responsibilities, and staff had not received an induction to the premises. (recommendation 1).

Equipment and materials (Guidance note 26)
A warming oven used for sperm samples, and fridge used to store reagents have not been validated (recommendation 2).

Staff engaged in licensed activity

Person Responsible (PR)

Staff

What the centre does well

Person Responsible (Guidance note 1)
The proposed 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.

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 scientist, within the UK, to advise on and oversee 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)
The centre is not required to comply with this guidance for the proposed activities.

Safeguarding
The centre's procedures are compliant with safeguarding guidance. This ensures that the 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)
The centre is not required to comply with this guidance for the proposed activities.

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

2. The experience of patients

Patient feedback

What the centre does well
No feedback is available on which to make an assessment.

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 patients and 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 counselling procedures are compliant with HFEA requirements.

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre is not required to comply with this guidance for the proposed activities.

Surrogacy (Guidance note 14)
The centre is not required to comply with this guidance for the proposed activities.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient 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 patients and 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)
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)
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 patients' consent, so that it only releases the patients identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing treatment and those born following treatments.

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 The centre is not required to comply with this guidance for the proposed activities.
What the centre could do better Nothing identified at this inspection.

Screening of patients **Storage of gametes and embryos**
What the centre does well **Screening of patients (Guidance note 17)** The centre is not required to comply with this guidance for the proposed 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 (Guidance note 22)
What the centre does well **Use of embryos for training staff (Guidance note 22)** The centre is not required to comply with this guidance for the proposed activities.
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 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.

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 Direction 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 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 for action	PR Response	Executive Review
none			

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 may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Premises Evidence of final building sign-off (including an occupancy certificate) is still required. The premises are yet to have a deep cleaning, and staff require an induction to the premises. There is also no agreement in place with the owners of the premises setting out respective responsibilities. SLC T17	Copies of the building sign off, agreement with the owners, confirmation that a deep clean and staff induction have taken place, should be provided once available and before commencing licenced activity.	We are working with the premises providers to ensure all requested documents and confirmations are available. We will provide to the HFEA as soon as possible and before commencing licensed activity.	We await the requested documents to be provided before commencing licensable activity.
2. Equipment A warming oven and fridge have not been validated. SLC T24; General Directions 0008	The warming oven and fridge must be validated before use. When responding to this report, a timeframe for the validation of these equipment	The warming oven validation is in progress and will be provided to the HFEA within the next two weeks. The fridge is not yet in	We are satisfied with the PR's proposed timeframe and await the requested validations.

	should be provided. Copies of these validations should be sent to their inspector once available and before commencing licensed activities requiring the use of the equipment.	operation. We will not use it for storing 'sperm freeze' until donors are recruited and accepted onto the programme. We will therefore commence the fridge temperature validation as soon as we are licensed and provide the report to the HFEA before the fridge is used for storing 'sperm freeze'.	

Other areas of practice that requires improvement

Areas of practice that require improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
3. Donor Screening Donors will not routinely undergo a physical examination for the presence of genital warts or herpes as recommended by professional guidelines. Code of practice 11.22	The risks of not following professional guidelines should be considered and measures identified to mitigate any such risk. A summary of the assessment should be provided by 4 January 2017.	The risk assessment is in progress and a summary will be provided by 4 January 2017.	We await the assessment.

Reponses from the Person Responsible to this inspection report
The Semovo team would like to thank the HFEA inspectors for considering Semovo's HFEA licence application for our second donor recruitment location and understanding our novel model and licensing requirements.