Executive Licensing Panel - minutes

Centre 0364 (Semovo Glasgow)

Initial Inspection Report – Storage Licence

Friday, 15 December 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Caylin Joski-Jethi Howard Ryan	Director of Strategy & Corporate Affairs Head of Intelligence Data Analyst
Members of the Executive	Bernice Ash	Secretary
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 Glasgow is located at:

Blythswood Health & Wellbeing
1 Blythswood Square
Glasgow
G2 4AD

1.2. The proposed Person Responsible (PR), Dr Deborah Falconer, submitted an application for a storage licence in November 2017. The centre will provide a storage only service.

1.3. The panel noted that Semovo is a registered company that aims to recruit sperm donors at various locations in the UK to alleviate the shortage of sperm from UK donors. Semovo Leeds (centre 0345) and Semovo Liverpool (centre 0346) have been licensed by the HFEA since 2016. Semovo's model is proving successful, with 12 donors currently in the process of donating at the Liverpool site and Semovo donor sperm being used by approximately 35 UK clinics.

1.4. Semovo Glasgow provides a range of occupational health and private medical services. The operational model will be the same as at Semovo Leeds and Liverpool: staff will meet with potential donors, donors will produce their sample and sperm will be frozen. Sperm will then be transported to Manchester Fertility (centre 0033) for storage and distribution under their licence.

1.5. A storage licence is required to cover this temporary storage of samples at Semovo Glasgow 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.

1.6. The panel noted that documentation (such as patient information), processes and procedures are the same across the three Semovo sites with the exception of a small number of premises-specific differences. Both Semovo Leeds and Semovo Liverpool were inspected for their initial licences in 2016. A further interim inspection was performed at both centres in 2017, where no non-compliances were noted. In view of the common structures and functioning of the centres within the group, the approach to this inspection was different to the standard initial inspection methodology. Activities common across the group, which had been found to be compliant in the course of the detailed review at the centres' recent initial and interim inspections, were not reviewed in detail. Instead local compliance with group policies and procedures was assessed.

2. Consideration of application

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

2.2. The panel noted the findings of the desk based assessment and inspection carried out on 30 November 2017.

2.3. The panel noted that the proposed PR, Dr Deborah Falconer, 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 Licence Holder (LH), Mr Andrew Berkley.

2.5. The panel noted the suitability of the premises for the conduct of licensed activities.

2.6. The panel noted that at the time of the inspection on 30 November 2017, there was one major area of practice requiring improvement, concerning equipment and materials. The PR had committed to implementing this recommendation.

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 licence for a period of two years, with no additional conditions.

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 Deborah 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 Andrew 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 based on evidence provided within the report.

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 storage licence for a period of two years with no additional conditions.

4. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

20 December 2017

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 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: 30 November 2017

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: Sara Parlett

Date of Executive Licensing Panel: 15 December 2017

Centre name	Semovo Glasgow
Centre number	0364
Centre address	Blythswood Health & Wellbeing 1 Blythswood Square Glasgow G2 4AD
Proposed Person Responsible	Dr Deborah Falconer
Proposed Licence Holder	Mr Andrew Berkley

Contents

Section 1: Summary report

Brief description of the centre:
Semovo is a registered company that aims to recruit sperm donors at various locations in the UK to alleviate the shortage of sperm from UK donors. Semovo Leeds (centre 0345) and Semovo Liverpool (centre 0346) have been licensed by the HFEA since 2016. Semovo's model is proving successful, with 12 donors currently in the process of donating at the Liverpool site and Semovo donor sperm being used by approximately 35 UK clinics.

A HFEA storage licence has been applied for by the proposed PR at Semovo Glasgow, to be held at Blythswood Health & Wellbeing, Glasgow, a clinic which provides a range of occupational health and private medical services. The operational model will be the same as at Semovo Leeds and Liverpool: staff will meet with potential donors, donors will produce their sample and sperm will be frozen. Sperm will then be transported to Manchester Fertility (centre 0033) for storage and distribution under their licence. The proposed Person Responsible (PR) is also PR at Manchester Fertility and the other two Semovo clinics.

A storage licence is required to cover this temporary storage of samples at Semovo, Glasgow 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 three Semovo sites with the exception of a small number of premises-specific differences. Both Semovo Leeds and Semovo Liverpool were inspected for their initial licences in 2016. A further interim inspection was performed at both centres in 2017, where no non compliances were noted. In view of the common structures and functioning of the centres within the group, the approach to this inspection was different to the standard initial inspection methodology. Activities common across the group and which had been found to be compliant in the course of the detailed review at the centres' recent initial and interim inspections were not reviewed in detail. Instead local compliance with group policies and procedures was assessed.

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 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 will discharge her 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 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 was one major area of non compliance resulting in the following recommendation:

- The warming oven and fridge must be validated before use.

The PR has committed to implementing this recommendation.

Recommendation to the Executive Licensing Panel

The inspection team considers that there is sufficient information available to recommend:

- the appointment of the proposed Licence Holder;
- the appointment of the proposed Person Responsible;
- the grant of a storage licence for a period of two years subject to the implementation of the recommendation in this report.

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 donors at this centre
3. The protection of gametes (sperm) 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 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 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 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)** 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 or embryos. 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 proposed procedures are compliant with HFEA requirements to ensure the donor conceived will be able to receive this information.

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 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 an appropriate environment that is fit for purpose.

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.

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

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

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

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

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

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre's proposed 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:

- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- 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 or embryos are maintained in the specified conditions.

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

Equipment and materials (Guidance note 26)
The centre proposes to 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 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 investigates 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

Equipment and materials (Guidance note 26)
A warming oven used for sperm samples has not yet been validated. A fridge, used to store reagents, has not yet been purchased or validated (SLC T24, recommendation 1).

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 compliant with HFEA requirements related to staffing, having 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.

The proposed Licence Holder is suitably qualified and experienced to undertaken the role.

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 proposed activities.

Safeguarding
The centre's proposed 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 proposed activities.

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

2. The experience of patients

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.

On the basis of discussions with centre staff and a review of documents in the course of the inspection it was possible to assess that the centre:

- will have respect for the privacy and confidentiality of donors in the clinic;
- will give donors sufficient, accessible and up-to-date information to enable them to make informed decisions;
- will provide donors with satisfactory facilities for their care;
- will have a mechanism in place to effectively respond to donor calls and queries in a timely manner.

What the centre could do better

Nothing identified at this inspection.

Treating donors 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 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 proposed counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to donors providing relevant consent.

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

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

Surrogacy (Guidance note 14)
These requirements are not relevant to the centre's proposed activities.

Complaints (Guidance note 28)
The centre's proposed 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 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
Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's proposed 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 proposed 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 proposed activities.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre's proposed 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' consents,

so that it only releases patient identifying information, to researchers, with the consent of the patient. 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.
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 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)** These requirements are not relevant to the centre's proposed activities. **Storage of gametes and embryos (Guidance note 17)** The centre's proposed procedures for storing gametes are compliant 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 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)** These requirements are not relevant to the centre's 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 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; 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 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
None noted			

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
1. Equipment and materials A warming oven used for sperm samples has not yet been validated. A fridge used to store reagents has not yet been purchased or validated. SLC T24.	The warming oven and fridge must be validated before use. When responding to this report, a timeframe for the validation of this equipment should be provided. Copies of these validations should be sent to the centre's inspector once available and before commencing licensed activities requiring the use of the equipment.	The warming oven is in the process of being validated. A small fridge will be purchased and validated. The validation reports will be provided to the HFEA prior to commencing licensed activities at the centre.	The executive acknowledges the PR's response and awaits the requested validations.

‘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
None noted.			

Further response from the Person Responsible to this inspection report
The Semovo team would like to thank the HFEA Inspectors for their understanding of Semovo's unique model with respect to donor sperm recruitment and supply.