Executive Licensing Panel - minutes

Centre 0346 (Semovo) Initial Inspection Report – Storage Only Licence

Wednesday, 24 August 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) David Moysen Trisram Dawahoo	Director of Strategy & Corporate Affairs Head of IT Digital Communications Manager
Members of the Executive	Dee Knoyle	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, centre 0346, is a registered company located at Pall Mall Medical, Liverpool which is a private medical practice:

Pall Mall Medical
5 St Paul's Square
Liverpool
L3 9SJ

1.2. The centre aims to recruit sperm donors on behalf of Manchester Fertility, centre 0033. The PR aims to recruit 10 donors within the first year of activity.

1.3. The centre will have the use of two rooms at Pall Mall Medical. One room will be used for staff to meet with potential donors and for donors to produce their samples and a second room will be used to process and freeze sperm. Sperm samples will be frozen on the premises and transported to centre 0033 for storage on the same day. A HFEA storage licence is required to cover the temporary storage of samples at centre 0346 prior to transfer to centre 0033. Therefore, the proposed Person Responsible (PR), Dr Deborah Falconer, who is also the PR for centre 0033, has applied for a HFEA storage only licence for centre 0346.

1.4. An inspection was carried out on 29 June 2016. This inspection was based on the service to be provided and therefore the premises and practices were assessed for suitability based on the storage of sperm for short periods of time.

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) and Licence Holder (LH).

2.2. The panel noted the report of the inspection carried out on 29 June 2016.

2.3. The panel noted that the proposed PR, Dr Deborah Falconer, holds academic qualifications in the field of biological sciences. 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 the suitability of the premises for the conduct of licensed activities.

2.6. The panel noted that at the time of the inspection on 29 June 2016, three major and one other area of non-compliance were identified. The panel noted in particular the non-compliance in relation to staff training. The panel noted that since the inspection the PR has addressed most of the non-compliances and has committed to implement the outstanding recommendation.

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

- the appointment of the proposed Person Responsible;
- the appointment of the proposed Licence Holder;
- the grant of a storage only licence for a period of two years, without additional conditions and subject to the recommendations made in this report being implemented.

2.8. The panel noted that the inspectorate also recommended that an interim inspection is carried out during the first year to monitor the centre's progress and performance.

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 (and those of relevant third parties) 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 endorsed the inspectorate's recommendation to grant a storage only licence for a period of two years, without additional conditions, subject to the recommendations made in this report being implemented. The panel expects that centre 0346 will not proceed with licensed activities until the major non-compliance relating to staff training and competency is completed and that the inspectorate is satisfied that its recommendation for this major area of non-compliance has been fully implemented.

3.10. The panel also endorsed the inspectorate's recommendation to carry out an interim inspection during the first year to monitor the centre's progress and performance.

4. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

25 August 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 licences 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: 29 June 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, Ms Janet Kirkland MacHattie

Date of Executive Licensing Panel: 24 August 2016

Centre name	Semovo, Liverpool
Centre number	0346
Centre address	Pall Mall Medical, 5 St Paul's Square, Liverpool, L3 9SJ
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 on behalf of Manchester Fertility (centre 0033). The proposed Person Responsible (PR), Dr Falconer, is also PR at Manchester Fertility.

A HFEA storage licence has been applied for to be held at Pall Mall Medical, Liverpool, a private medical practice. Semovo will have use of 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 processed and frozen. Sperm samples will be frozen on the premises, and on the same day will be transported to Manchester Fertility for storage under their licence. A storage licence is required to cover the temporary storage of samples at Pall Mall Medical, Liverpool prior to transfer to Manchester Fertility. The inspection was based on the description of the service to be 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.

The PR aims to recruit 10 donors within the first year of activity.

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) 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 were three major areas of non compliance and one 'other' area of practice.

The PR has provided a commitment to implementing the following recommendation:

Major area of non compliance:

- Staff must be trained and assessed as competent in all activities, and relevant policies including those at Pall Mall Medical that are relevant to their role.

The following recommendations have been fully implemented:

Major areas of non compliance:

- The dry shipper must be validated before use to store and transport donated sperm.
- Potential donors must have an opportunity to receive proper counselling before their consent is sought.

'Other' areas that requires improvement:

- A third party agreement with a laboratory that will test blood samples from potential donors should describe how any test/diagnostic results will be relayed to the commissioning centre, including sign off and confirmation that the result applies to the correct sample.

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. 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
Nothing identified at this inspection.

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)
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 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 broadly 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 broadly 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

Third party agreements (Guidance note 24)
A third party agreement with a laboratory that will test blood samples from potential donors does not clearly describe how any test/diagnostic results will be relayed to the commissioning centre, including sign off and confirmation that the result applies to the correct sample (recommendation 4).

Equipment and materials (Guidance note 26)
A dry shipper to be used when samples are transported to Manchester Fertility has not been purchased or validated (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 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 broadly 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

Staff (Guidance note 2)
Staff responsible for processing and freezing semen will also provide information to potential donors. Their competency framework does not include an assessment to suitably cover the provision of information (see recommendation 2).

Whilst staff have comprehensive access to training in infection control, and the management of a needle stick injury via Manchester Fertility, there was no formal training in, or links with, the policies in operation at Pall Mall Medical, Liverpool (see recommendation 2).

The inspectors noted that despite having recently completed fire training at Pall Mall Medical, Liverpool, Semovo staff did not know the location of fire the extinguishers (see recommendation 2). Staff were also unable to confirm the date the fire extinguishers were last checked.

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 broadly 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

Counselling (Guidance note 3)
Schedule 3, 3(1) of the HF&E Act 1990 (as amended) requires that before seeking consent, a person must be given a suitable opportunity to receive proper counselling. Whilst potential donors will be offered counselling before their consent is sought, the centre's proposed standard process would mean that counselling was not received until after consents are sought (recommendation 3).

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. Equipment A dry shipper to be used when samples are transported to Manchester Fertility has not been purchased or validated. SLC T24; General Directions 0008	The PR should ensure that the dry shipper is validated before use to store and transport donor sperm. When responding to this report the PR should provide a timeframe for the purchase and validation of the shipper. A statement confirming validation of the shipper should be sent to their inspector once available and before commencing licensed activities.	Since the inspection, the dry shipper has been validated and the validation report has been provided to the HFEA.	A suitable validation for the dry shipper has been received. No further action is required.
2. Staff Staff competency frameworks do not include an assessment for the provision of information.	The PR should provide a description of how they intend to address observations noted in this section when responding to this report.	Competency framework has been revised to include provision of information and has been provided to HFEA.	A revised competency framework has been received and suitably covers the provision of information and requires no further action.

There was no formal training in, or links with, infection control and needle stick injury policies in operation at Pall Mall Medical, Liverpool. Semovo staff did not know the location of fire the extinguishers and were unable to confirm the date the fire extinguishers were last checked. SLC T12 and T15	Confirmation of appropriate training and assessment of competency should be provided to their inspector once available and before commencing licensed activities.	Prior to the inspection, the Semovo team had requested a suite of Pall Mall Medical policies, including infection control. This request has been resubmitted and acknowledged by Pall Mall Medical. Once the policies are received, the Semovo Reproductive Technologist will receive training in Pall Mall policies, including infection control and needle stick injury. We will ensure that this takes place before commencing licensed activities and confirmation will be provided to the HFEA in due course. The Semovo team had received fire and health & safety training from Pall Mall Medical prior to the inspection. The Semovo team are now aware of the location of the fire extinguishers. The training did not cover the dates the fire extinguishers were last checked as this is the responsibility of the premises provider – Pall Mall Medical.	We await confirmation that training in local policies has been received. We are satisfied with the PR's assurances in relation to fire extinguishers and require no further action.
3. Counselling	The PR must ensure that	It is Semovo policy for all	The PR has provided

Potential donors may not receive counselling until after their consent is sought. Schedule 3, 3(1) HF&E Act 1990 (as amended).	potential donors have an opportunity to receive proper counselling before their consent to donation is sought. The PR should provide a description of how they intend to address this recommendation when responding to this report.	potential donors to receive counselling from a BICA-accredited counsellor prior to being accepted as a donor. This is over and above the legal requirement and the practice adopted by other sperm donor recruitment centres. The Semovo team have reviewed the assessment and screening process since the inspection. Consent will now be sought routinely after counselling is received. SOPs and process maps have been revised reflecting the change.	assurance that potential donors will have a suitable opportunity to receive counselling before their consent is sought, supported by an amended SOP/policy. No further action is required.

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
4. Third Party Agreements A third party agreement with a laboratory that will test blood samples from potential donors did not clearly describe how any test/diagnostic results will be relayed to the commissioning centre, including sign off and confirmation that the result applies to the correct sample. SLC T114(f)	A revised TPA incorporating this requirement was received by the executive 01 July 2016 and therefore no further action is required.		

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