HFEA Licence Committee Meeting

13 March 2014

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 2

Centre 0338 (Centre for Reproductive Health) – Initial Treatment and Storage Inspection Report

Members of the Committee: Andy Greenfield (lay) (Chair) Bishop Lee Rayfield (lay) Debbie Barber (professional) Jane Dibblin (lay)	Legal Adviser: Rosalind Foster, Browne Jacobson Committee Secretary: Lauren Crawford Also in Attendance: Sam Hartley, Head of Governance and Licensing

Declarations of Interest: members of the Committee declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the Committee:

- Inspection report
- Application form (appropriately signed).
- CV of proposed Person Responsible and references
- CV of proposed Licence Holder
- CQC reports

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree); and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation

- Indicative Sanctions Guidance
- HFEA Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Background

1. The Committee noted that an initial application was received by the HFEA from the Centre for Reproductive Health for a treatment and storage licence.

2. The Committee noted that the **Centre for Reproductive Health** is located at:

   Daresbury Park
   Warrington
   Cheshire
   WA4 4GE

3. The Committee noted that at the time of the inspection, the Inspectorate reported that there were a number of areas of practice that required improvement including two 'major' and one 'other' areas of non-compliance.

4. The Committee noted that since the inspection visit, the PR (Person Responsible) has provided evidence that one of the 'other' recommendations has been fully implemented and that he has given a commitment to fully implement the remaining 'major' recommendations which are:

- The PR should confirm the critical equipment that is still to be delivered, installed, commissioned and validated and submit validation documents for the dry shipper and cryopreservation dewars, for approval by the HFEA's Executive before commencing licensed treatments.
- The PR should provide evidence of the installation and testing of the cryopreservation dewar alarms, including a confirmation that the autodial system works and that it will continue to work in the event of a power failure before commencing licensed treatments.

Discussion

5. The Committee referred to its decision tree. It was satisfied that the appropriate application and fee had been submitted, and noted that the executive had received the supporting information required by General Direction 0008.

6. The Committee noted that the proposed PR (Mr James Armatage) holds academic qualifications in the field of medicine and 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 HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii). He has successfully completed the HFEA PR Entry Programme.

7. The Committee was satisfied that the proposed PR is suitable and will discharge his duty under section 17 of the HF&E Act 1990 (as amended). Two references have been supplied along with this application.

8. The Committee was satisfied regarding the suitability of the proposed Licence Holder (LH), Mr Simon Shepherd.

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

10. The Committee was satisfied that 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. It noted that the centre will not be storing any gametes until the suitability of the storage facilities has been reviewed by the HFEA.

11. The Committee referred to 'Guidance on periods for which new or renewed licences can be granted'. The Committee noted paragraph 4.2 of the guidance which states '[the Committee] will normally only grant an initial treatment/storage/non-medical fertility services licence 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'.

12. The Committee noted the Inspectorate's recommendation to grant the centre's licence for a two year period without additional conditions and to also appoint the proposed PR and LH.

Decision

13. The Committee agreed to appoint as Mr James Armatage the Person Responsible for Centre for Reproductive Health (Centre 0338) with immediate effect, in accordance with section 18A of the HFE Act 1990 (as amended).

14. The Committee agreed to appoint Mr Simon Shepherd as the Licence Holder for Centre for Reproductive Health (Centre 0338) with immediate effect.

15. The Committee agreed to grant the centre's licence for a period of two years with no additional conditions.

Signed: Date: 27/03/2014

Andy Greenfield (Chair)

Inspection 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 Licence Committee (LC) 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: 14 February 2014

Purpose of inspection: Issue of a licence to carry out Treatment and Storage

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: Bhavna Mehta, Tony Knox, Andy Glew, Jenny Clifford, Debra Bloor

Date of Licence Committee: 19 March 2014

Centre name	Centre for Reproductive Health
Centre number	0338
Centre address	Daresbury Park, Warrington, Cheshire, WA4 4GE
Person Responsible	Mr James Armatage
Licence Holder	Mr Simon Shepherd

Contents

Section 1: Summary report

Brief description of the centre:
The Centre for Reproductive Health is a private centre and the proposed Person Responsible (PR) has applied for a Treatment and Storage licence. The centre will be providing a full range of fertility services. The inspection team is satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

Centre's anticipated activity levels:

Type of treatment	Number of treatment cycles
In Vitro Fertilisation (IVF)	2000
Intracytoplasmic sperm injection (ICSI)	
Frozen embryo transfer (FET)	
Donor insemination (DI) and Partner insemination IUI(P)	1000

Other licensable activities	✓ or Not applicable (N/A)
Storage of gametes	✓
Storage of embryos	✓
Embryo testing	NA

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 his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for an initial licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The LC is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including two major and one 'other' areas of non-compliance.

Since the inspection visit, the following recommendations have been fully implemented:

'Other' areas that require improvement:

- The PR should review the parenthood requirements and ensure that the centre's process is compliant with requirements before any treatments are provided with donor sperm.

The PR has given a commitment to fully implement the following recommendations:

Major areas of non-compliance:

- The PR should confirm the critical equipment that is still to be delivered, installed, commissioned and validated and submit validation documents for the dry shipper and cryopreservation dewars, for approval by the Executive before commencing licensed treatments.
- The PR should provide evidence of the installation and testing of the cryopreservation dewar alarms, including a confirmation that the autodial system works and that it will continue to work in the event of a power failure before commencing licensed treatments.

Recommendation to the Licence Committee

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

1. Appointment of the proposed LH.

2. Appointment of the proposed PR.

3. Granting a Treatment and Storage licence for a period of two years with no

additional conditions.

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 embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre can do better

Nothing identified at this inspection.

Donor selection criteria and laboratory tests

Screening of 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 and/or embryos. The centre are planning to offer egg sharing treatment and will be using donor sperm received from HFEA licensed centres or imported from abroad but are not planning to recruit sperm donors.

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 suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre is registered with the Care Quality Commission (CQC) for the provision of treatments not licensed by the HFEA. Under the terms of this registration, the CQC inspected the premises and reported that they were considered suitable for activities including surgical procedures. As the centre will be registered with both the CQC and the HFEA, to avoid regulatory overlap, the HFEA Executive has taken assurance from the CQC inspection report and subsequent registration approval in relation to the suitability of premises.

The premises of laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to processes gametes and/or embryos

in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The third party laboratories which will undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, 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.

The centre's own laboratories will carry our diagnostic semen analysis. Although not accredited by CPA (UK) Ltd, the centre has appropriate premises to carry out the testing; be using validated methodology for semen analysis; have a quality management system in place; have staff suitably qualified to interpret the test results, and provided verbal assurance that the laboratory, when operational, will participate in the National External Quality Assessment Scheme (or its equivalent) for semen diagnosis. On this basis, the centre is considered to have a status equivalent to that conferred by CPA (UK) Ltd in relation to diagnostic semen assessment.

As stated above, the centre is also registered with the CQC and to avoid regulatory overlap, the HFEA Executive has taken assurance from the CQC inspection report and subsequent registration approval in relation to the following three requirements. The CQC report confirms that:

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 has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are compliant with guidance.

Pre-operative assessment and the surgical pathway
The centre has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

Multiple births (Guidance note 7; Directions 0003)
The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements. The single biggest risk of fertility treatment is a multiple pregnancy and implementation of a suitable strategy is expected to minimise the incidence of multiple births.

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

- document the justification for the use of the patient's gametes (or embryos created with their gametes) in treatment, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, to keep a record of this in the gamete provider's records.

Transport and distribution of gametes and embryos (Guidance note 15; Directions 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are broadly compliant with HFEA requirements. This is important to ensure that all gametes / embryos 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 or embryos;
- 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;
- The container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions.

Receipt of gametes and embryos (Guidance note 15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if the gametes and embryos are appropriately labelled and has enough information to permit the gametes and embryos be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; Directions 0006)
The centre's procedures for imports and exports of gametes and embryos are compliant with HFEA requirements.

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability -

- to identify and locate gametes and embryos during any step from procurement to use for human application or disposal,
- identify the donor and recipient of particular gametes or embryos,
- to identify any person who has carried out any activity in relation to particular gametes or embryos, and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos 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; Directions 0010)
The centre has systems in place to manage satellite activities that are compliant with HFEA requirements. This is important to ensure that activities performed by satellite

clinics on behalf of the licensed centre are suitable and meet the HFEA requirements.

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

The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

The centre is broadly compliant with HFEA requirements to validate critical equipment.

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 or embryos 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. The centre will report all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre has processes in place to investigate all adverse incidents that may 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

At the date of the inspection, the centre was expecting delivery of a dry shipper, cryopreservation dewars and alarms and have planned to install, commission and validate this equipment within six weeks from the date of the inspection. SLC T24 **Recommendation 1.**

The cryopreservation dewars are not appropriately monitored or alarmed. The alarms have not been tested or checked to ensure that the autodial system is working. SLC T24 **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 medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence (including acting in the capacity of PR). The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1247/81).

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

What the centre could do better

Nothing identified at this inspection.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures for taking into account the welfare of the child are compliant with HFEA requirements. This is important to ensure that the centre takes into account the welfare of any child who may be born as a result of the licensed treatment, and of any other child who may be affected by that birth before treatment is provided.

Safeguarding
The CQC reviewed these requirements as part of their inspection and the report confirms that the centre's procedures are compliant with safeguarding requirements. This will ensure that the centre patients and staff are protected from harm where possible.

What the centre could do better

Nothing identified at this inspection.

2. The experience of patients

Treating patients fairly
Counselling
Egg sharing arrangements (Guidance note 12; Direction 0001)
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)
The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

Egg sharing arrangements (Guidance note 12; Direction 0001)
The centre's procedures for egg sharing arrangements are compliant with HFEA requirements. This is important to ensure that:

- care is taken when selecting egg providers donating for benefits in kind
- egg providers are fully assessed and medically suitable, and
- the benefit offered is the most suitable for the egg provider and recipient(s).

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; CH(11)02)
The centre's procedures for providing information to patients are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and 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)
The centre's procedures for obtaining consent are broadly compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Disclosure of information, held on the HFEA Register, for use in research (Directions 5)
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 ART and those born following ART treatment.

What the centre could do better

The centre does not have a process in place to follow to ensure that where a woman being treated withdraws her consent to a nominated second parent being the legal parent, or consents to a different person being the legal parent of any child born, that the nominated second parent is informed of the change in writing. **Recommendation 3.**

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities.

- licensed activities will only take place on licensed premises;
- only permitted embryos will be used in the provision of treatment services;
- embryos will not be selected for use in treatment for social reasons;
- embryos will not be created by embryo splitting;
- embryos will only be created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman and
- embryos will only be stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

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's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Storage of gametes and embryos (Guidance note 17)
The centre's procedures for storing gametes and embryos are partially compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre will only store gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

What the centre could do better

At this time of the inspection, the alarms associated with the cryopreservation dewars had

not been installed or validated. SLC T24 **See recommendation 1.**

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

Critical 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. At this time of the inspection, cryopreservation dewars and their associated alarms had not been delivered, installed, commissioned or validated. The centre was also awaiting delivery and validation of a dry shipper. T24	In responding to this report, the proposed PR should confirm when the critical equipment is expected to be delivered, installed. commissioned and validated. The proposed PR should submit validation documents for the dry shipper and cryopreservation dewars before commencing licensed treatments. Treatments should not be undertaken until the documents have been approved as suitable by the Executive. In responding to this report, the PR should provide written assurance that this recommendation will be met.	4 x MVE XC47/10 dewars have been ordered from Airproducts plc and are due to be delivered on 25th February. Liquid nitrogen is already stored on site therefore the dewars can be filled and monitored from delivery date. Ongoing monitoring and validation will be by weekly liquid level measurement. Dewars will be regarded as suitable for purpose if losses over each 7 day period are consistent and within the manufacturers specifications. Dry shipper is due same date. Validation will be by temperature logging over and beyond manufacturers stated safe holding time. I can confirm that no treatments will take place until a licence has been granted and the documents regarding	The proposed PR's comments are noted and the validation documents should be sent to the lead inspector as soon as available.

		this recommendation has been completed and approved by the HFEA Executive	
2. At the time of the inspection, the cryopreservation dewars were not appropriately monitored or alarmed. The alarms have not been tested or checked to ensure that the autodial system is working SLC T24.	The proposed PR should provide evidence of the installation and testing of the cryopreservation dewar alarms, including a confirmation that the autodial system works and that it will continue to work in the event of a power failure before commencing licensed treatments.	Installation and testing, of the dewar alarms is due to commence week of 24th February. Alarm consists of Planer DATAcentre wireless system for each dewar. Validation documentation including testing of the autodial system in the event of a power failure will be available at completion of install, due 28th february. UPS systems and a generator have already been installed.	The proposed PR's comments are noted. The PR should confirm that the alarm and autodial systems work and that they will continue to work in the event of a power failure before commencing licensed treatments.

Other areas of practice that requires improvement

Areas 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 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. The centre does not have a process in place to follow to ensure that where a woman being treated withdraws her consent to a	The PR should review the parenthood requirements and ensure that the centre's process is compliant with requirements before any	A number of documents have been edited to ensure statutory requirements are met. These documents have been submitted to Bhavna Mehta.	The documents listed have been reviewed. The centre is compliant with this requirement. The centre has a process in

nominated second parent being the legal parent, or consents to a different person being the legal parent of any child born, that the nominated second parent is informed of the change in writing. SLC T65	treatments are provided with donor sperm.	They are, Quality Protocol, QAP008: Withdrawl and variation of consent, Patient information sheets, PAI021: HFEA-A guide to withdrawing and varying consent, PAI022: HFEA-A guide to filling in form WC and Clinical checklist form CLF015, IVF and ICSI checklist.	place to follow to ensure that where a woman being treated withdraws her consent to a nominated second parent being the legal parent, or consents to a different person being the legal parent of any child born, that the nominated second parent is informed of the change in writing. No further action required.

Reponses from the Person Responsible to this inspection report

The entire team at the Reproductive Health Group enjoyed the inspection visit on Friday 14th February. Debra Bloor was very complementary about the building and the facilities. There was plenty of time for discussion which we found extremely useful and stimulating. In particular, we were delighted to discuss the issue of confidentiality with 3rd parties having remote access to data sets amongst other issues. I very much hope that the remainder of the application process will progress smoothly and may I thank the HFEA team for their commitment and diligence in processing our application for the licence committee meeting on 19th March.