Executive Licensing Panel - minutes

Centre 0363 (Bourn Hall Clinic Wickford)

Initial Inspection Report – Treatment and Storage Licence

Friday, 20 July 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Erin Barton Kathleen Sarsfield Watson	Director of Strategy and Corporate Affairs Policy Manager Communications Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Richard Chamberlain	Senior Governance Manager Temporary Committee Clerk

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. Bourn Hall Clinic Wickford is located at:

25 London Road
Wickford
Essex
SS12 0AW

1.2. The proposed Person Responsible (PR), Mrs Sarah Pallett, submitted an application for a treatment and storage licence in September 2017 to allow for the provision of fertility services.

1.3. The clinic will operate as part of the Bourn Hall corporate group that includes three other HFEA licensed centres: Bourn Hall Clinic (0100) in Cambridge; Bourn Hall Clinic (Colchester) (0188); and Bourn Hall (Norwich) Limited (0325). The group has a cohesive quality management system that is effectively implemented across all centres within the group. Taking this into consideration, this desk based assessment and on-site inspection has focused on local compliance with group policies and procedures, as well as the compliance of the centre's premises and facilities.

1.4. A desk based assessment was performed followed by an inspection on 24 May 2018.

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 24 May 2018.

2.3. The panel noted that at the time of the inspection on 24 May 2018, there were two major non-compliances relating to infection control and air quality and equipment validation. There was also one 'other' non-compliance concerning the Quality Management System (QMS). Since the inspection, the PR had implemented all the recommendations made in the report

2.4. The panel noted that the proposed PR, Mrs Sarah Pallett, 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.

2.5. The panel noted the suitability of the proposed Licence Holder (LH), Dr Arpita Ray

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

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 treatment and storage licence for a period of two years, subject to the implementation of the recommendations made in the report

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, Mrs Sarah Pallett, will discharge her duty under section 17 of the HFE Act 1990 (as amended). The panel agreed to appoint Mrs Sarah Pallett 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, Dr Arpita Ray. The panel agreed to appoint Dr Arpita Ray 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 the 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.

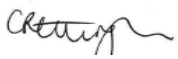
3.8. The panel referred to 'guidance on periods for which new or renewed licences can be granted' which states that an initial treatment/storage/non-medical fertility services licence would normally be granted for up to two years. This is because in granting an initial licence, there will be no history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

3.9. The panel agreed to grant the licence for treatment and storage for a period of two years with no additional conditions and looked forward to the PR working closely with the inspector for this new centre.

4. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

30 July 2018

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: 24 May 2018

Purpose of inspection: Initial licence inspection for 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: Susan Jolliffe (lead), David Gibbon and Janet Anderson Pearce (observing).

Date of Executive Licensing Panel: 20 July 2018

Centre name	Bourn Hall Clinic Wickford
Centre number	0363
Centre address	Bourn Hall Clinic Wickford 25 London Road Wickford Essex SS12 OAW
Proposed Person Responsible	Sarah Pallett
Proposed Licence Holder	Dr Arpita Ray

Contents

Section 1: Summary report

Brief description of the centre:
Bourn Hall Clinic Wickford is a new fertility treatment centre that will treat NHS and private patients in the Wickford area. The proposed Person Responsible (PR) has applied for a treatment and storage licence to allow the provision of fertility services.

The clinic will operate as part of the Bourn Hall corporate group that includes three other HFEA licensed centres: Bourn Hall Clinic (0100) in Cambridge; Bourn Hall Clinic (Colchester) (0188); and Bourn Hall (Norwich) Limited (0325). The group has a cohesive quality management system that is effectively implemented across all centres within the group. Taking this into consideration, this desk based assessment and on-site inspection has focused on local compliance with group policies and procedures, as well as the compliance of the centre's premises and facilities.

The proposed PR already holds the PR position at centre 0188. The proposed Licence Holder (LH) has not previously held the position of LH.

Centre's anticipated activity levels:

Type of treatment	Maximum number of proposed treatment cycles
In vitro fertilisation (IVF)	1500
Intracytoplasmic sperm injection (ICSI)	
Frozen embryo transfer (FET)	
Donor insemination (DI) and Partner insemination IUI	150

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓
Research	N/A

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) will be suitable upon completion of recommendations made in this report;
- the centre's proposed practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for an initial licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection, three areas of practice required additional work.

Since the inspection the PR has implemented all three recommendations:

Major areas of non compliance:

- Confirmation that the air quality testing results comply with regulatory requirements, must be provided before commencing licensed activity.
- Confirmation that all critical equipment has been validated must be provided before commencing licensed activity.

Other area of non compliance:

- The standard operating procedure (SOP) for non-clinical emergencies is in draft, and should be finalised and shared with staff at the centre.

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 treatment and storage licence for a period of two years subject to the implementation of the recommendations in this report.

The inspection team considers the recommendations proportionate, on the understanding that the outstanding work should all be completed by the time the report is considered by a licensing committee.

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

The centre's proposed procedures are compliant with requirements to ensure that risks are taken into account to ensure patients and staff are in safe surroundings that prevent harm.

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

The centre has not yet performed final air quality testing to demonstrate compliance with HFEA requirements to process gametes and/or embryos in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or 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.

Infection control (Guidance note 25)
The centre's proposed systems to manage and monitor the prevention and control of infection are compliant with guidance. However, the final microbiological testing of relevant areas of the premises to confirm this has not yet been carried out.

Medicines management (Guidance note 25)
The centre's proposed arrangements for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines are compliant with guidance.

Prescription of intralipid 'off label'
Intralipid is a sterile liquid soybean and egg yolk based fat emulsion which is licensed as an intravenous nutritional supplement for adults and children. Some healthcare professionals consider intralipid therapy may be beneficial to a particular subset of women having IVF. Intralipid is not however licensed for use in fertility treatment and if prescribed in this context, it represents 'off-label' use. Healthcare professionals' responsibilities when prescribing a medicine off-label may be greater than when prescribing a medicine for use within the terms of its licence.

In April 2015, the President of the Royal College of Obstetricians and Gynaecologists, published concerns regarding the evidence base for the use of intralipid in IVF treatment, in terms of its safety and efficacy. In July 2015, the HFEA published guidance to centres regarding the prescribing of intralipid (or other 'off label' therapies) to patients. This guidance required centres to take responsibility for prescribing the medicine and for overseeing the patient's care by:

- reviewing and recording the information provided to patients about intralipid therapy to ensure that the reasons for prescribing it 'off-label' are explained, including that there is currently little evidence to support its use in fertility treatment;
- recording the reasons for prescribing intralipid in the patient's records and;
- ensuring that patients who are prescribed intralipid are properly monitored and followed up.

The proposed process for administering and monitoring patients during intralipid infusion was reviewed and considered to be suitable.

Written information provided to patients offered intralipid therapy is compliant with guidance.

Pre-operative assessment and the surgical pathway (Guidance note 25)
The centre's proposed policies and procedures 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; General Direction 0003)
The centre's proposed procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and

effectiveness of the strategy. The single biggest risk of fertility treatment is a multiple pregnancy.

Procurement of gametes and embryos (Guidance note 15)
The centre's proposed 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, the centre proposes to keep a record of this in the gamete provider's records.

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 and embryos are compliant with HFEA requirements. This is important to ensure that all gametes and embryos 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 note 15)
The centre's proposed 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 they are appropriately labelled and have enough accompanying information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; General Direction 0006)
The centre's proposed procedures for import and export of gametes and embryos are compliant with HFEA requirements.

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 and embryos during any step from procurement to use for human application or disposal,
- to 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 apart from one SOP still in draft: the SOP for non-clinical emergencies (business continuity plan) is yet to be signed off and shared with staff. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

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

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre is not planning satellite or transport arrangements; therefore, this area of practice is not applicable to this inspection.

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 and/or staff.

The centre has not yet validated its 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 or embryos 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 investigate 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

Infection control and air quality (Guidance note 25)
The clinical and laboratory areas have been tested for microbiological cleanliness and air quality.

Following installation of the remaining equipment, a final deep clean will take place where microbiological and air quality testing will be performed (SLC T17 and T20; recommendation 1).

Equipment and materials (Guidance note 26)
Equipment is in the process of being validated (SLC T24; recommendation 2).

Quality management system (QMS) (Guidance note 23)
The SOP for non-clinical emergencies (business continuity plan) is in draft, and has not been finalised and shared with staff at the centre (SLC T33b; recommendation 3).

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 nursing 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. The PR is also currently PR at Bourn Hall Clinic (Colchester). The PR has given appropriate assurance to the inspection team that the PR roles at both clinics can be covered sufficiently. The PR described that staffing and resources will be monitored to ensure they are commensurate with the activities to be provided to ensure an effective and safe service.

Staff (Guidance note 2)
The centre is compliant with HFEA requirements. The centre has 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 proposed procedures to ensure that they take into account before treatment is provided, 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, are compliant with HFEA requirements.

Safeguarding
The centre's proposed procedures are compliant with safeguarding guidance. This ensures that the centre's patients 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 does not carry out embryo testing and therefore this area of practice is not relevant to this inspection.
What the centre could do better Nothing identified at this inspection.

2. The experience of patients

Patient feedback

What the centre does well

The centre has developed effective systems to seek patient 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 patient 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 patients in the clinic;
- will give patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- will provide patients with satisfactory facilities for their care;
- will have a mechanism in place to effectively respond to patient calls and queries in a timely manner.

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 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 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 proposed counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent, including consent to legal parenthood.

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

The centre's proposed 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) (where relevant).

Surrogacy (Guidance note 14)
The centre's proposed procedures for treatment involving surrogacy are compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

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 proposed 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 proposed procedures for providing information to patients and donors 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 proposed procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Legal parenthood (Guidance note 6)
Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for

the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about its effectiveness and, in some cases, it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

The centre's proposed procedures for collecting legal parenthood consent are compliant with HFEA requirements.

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 patients' 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

The centre's proposed 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 only take place on licensed premises;
- only permitted embryos are used in the provision of treatment services;
- embryos are not selected for use in treatment for social reasons;
- embryos are not created by embryo splitting;
- embryos are only 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 are only 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 proposed 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 proposed procedures for storing gametes and embryos are compliant 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

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's proposed procedures for using embryos for training staff are compliant with HFEA requirements. Embryos will only be used for the purpose of training staff in those activities expressly authorised by the Authority.
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 proposed 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 identified.			

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. Infection control and air quality The clinical and laboratory areas have been tested for microbiological cleanliness and air quality. A further deep clean has taken place in June 19th and microbiological and air quality testing performed on 22nd June. SLCs T17 and T20.	The PR should provide the lead inspector with a copy of the summary of the microbiological and air quality testing results, confirming the premises are suitably clean and that processing of gametes/embryos will take place in an environment that complies with the air quality requirements of SLC T20. This must occur prior to commencing licensed activity.	The microbiological and air quality testing is scheduled for the 22nd June 2018. Therefore we should receive the results by the 6th July 2018. We will forward the results from this testing when we receive them.	The PR has confirmed that the air quality results meet regulatory requirement. No further action required.
2. Equipment validation Equipment is in the process of being validated. SLC T24.	The PR should provide the lead inspector with confirmation of the validation of all equipment. This must occur prior to commencing licensed activity.	The equipment validation is currently in progress. Included with this response is a table of all equipment and the status. We will	The PR has confirmed that all equipment has now been validated. No further action required.

	Equipment validation is due to take place the week commencing 11 June 2018, with the exception of the equipment monitoring system which can only be performed once the equipment to be monitored has itself been fully validated.	provide a further update by the 6th July 2018.	

‘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
3. **Quality management system (QMS) (Guidance note 23)** The SOP for non-clinical emergencies (business continuity plan) is in draft and has not been finalised and shared with staff at the centre. SLC T33b.	The PR should submit the final version of the business continuity plan, together with evidence of how staff will be made aware of the policy, when responding to this report.	Included with this response is the final version of the business continuity plan. The Business Continuity Plan is issued through our document management system (Workbench). All staff recieve a task via this system to read and acknowledge the document. All members of the emergency response team will also receive a hard copy of the document	The PR has provided the final version of the business continuity plan and how staff will be made aware of the SOP when responding to this report. No further action required.
Further response from the Person Responsible to this inspection report			