Executive Licensing Panel - minutes

Centre 0353 (X&Y Fertility)

Renewal Inspection Report

Thursday, 16 August 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Caylin Joski-Jethi (Chair) Anna Quinn Laura Riley	Head of Intelligence Scientific Policy Manager Head of Regulatory Policy
Members of the Executive	Richard Chamberlain	Temporary Committee Clerk
External adviser		
Observers	Catherine Burwood	Senior Governance Manager

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. Consideration of application

1.1. The panel considered the papers, which included a completed application form, a renewal inspection report, and licensing minutes for 18 November 2017.

1.2. The panel noted that X&Y Fertility of 144a New Walk, Leicester LE1 7JA, has held a Treatment (Insemination using partner / donor sperm) and Storage licence with the HFEA since November 2016.

1.3. The panel noted that the centre has not undertaken any licensed activities since it was first licensed in 2016 because demolition and building work in the vicinity, was creating dust, noise and disruption at the front and rear of the centre's premises, and that the Person Responsible (PR) considered it was not advisable to commence donor recruitment or insemination activities. The Inspector notes that the premises are safe and suitable but understands the PR's suspension of activities due to patient and donor recruitment which will unlikely to be 'optimal' until the building work is less disruptive than at present.

1.4. The panel noted that no licensed activities have been undertaken therefore no pregnancy outcomes or multiple pregnancies can be reported.

1.5. The panel noted that an inspection was carried out at the centre on 5 June 2018.

1.6. The panel noted that at the time of the inspection, there were no critical areas of non-compliance and three major areas of non-compliance regarding donor recruitment, assessment and screening, the QMS and staffing. There were also five other areas of non-compliance regarding infection control, third party agreements (TPAs), equipment and materials, process validation and patient information.

1.7. The panel noted that the PR has provided evidence that actions have been taken to implement recommendations and committed, where required, to audit the effectiveness of those actions within the required timescales for non-compliances relating to staffing levels, third party agreements and patient information.

1.8. The panel notes that the PR has given a commitment to fully implementing recommendations to ensure donor screening practice and supporting documents are compliant with best practice guidance. The PR has also given a commitment to audit standard operating procedures (SOPs) against current COP requirements and best practice guidance, and to develop an effective process for embedding regulatory change in the QMS and has given a commitment to fully implementing the recommendations relating to the 'other' non-compliances which include infection control, equipment and materials and process control.

1.9. The panel noted that the inspection found that significant improvement was required in order for the centre to reflect suitable practices. The centre has a QMS and the PR is encouraged to use it to best effect to monitor and improve the service.

1.10. The panel noted that the inspector will continue to monitor the centre's performance and the implementation of the report's recommendations within the required timescale i.e. on or before the date of opening the centre to patients.

1.11. The inspection team recommends the renewal of the centre's Treatment (Insemination using partner / donor sperm) and Storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

2. Decision

2.1. The panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

2.2. The panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

2.3. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR will discharge his duty under section 17 of the HFE Act 1990 (as amended).

2.4. The panel expected the PR to engage with inspectors to improve the QMS and to engage on other areas of non-compliance on or just before the time he expects to be open for treatment.

2.5. The panel commended the PR's cautious approach of waiting to open the centre when conditions around the premises have improved. The panel recognised this would be a much more suitable and high-quality environment in which patients would receive treatment.

2.6. The panel endorsed the inspectorate's recommendation of the renewal of the centre's Treatment (Insemination using partner / donor sperm) and Storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescale (i.e. on or before the opening of the centre for treatments).

3. Chair's signature

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

Signature

Name

Caylin Joski-Jethi

Date

3 September 2018

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies 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 a renewal of its existing licence. Licences are usually granted for a period of four years. 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: 5 June 2018

Purpose of inspection: Renewal of a licence to carry out Treatment (Insemination using partner / donor sperm) and Storage.

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Inspectors: Grace Lyndon (Lead) and Andrew Leonard

Date of Executive Licensing Panel: 16 August 2018

Centre name	X&Y Fertility
Centre number	0353
Licence number	L/0353/1/a
Centre address	144a New Walk, Leicester, LE1 7JA, United Kingdom
Person Responsible	Mr Bryan Woodward
Licence Holder	Mrs Melanie Proffitt
Date licence issued	28/11/2016
Licence expiry date	27/11/2018
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
X&Y Fertility is located in Leicester and has held a Treatment (Insemination using partner / donor sperm) and Storage licence with the HFEA since November 2016. The centre provides a basic range of fertility services including sperm storage, but does not create, use or store embryos.

The centre has not undertaken any licensed activities since it was first licensed in 2016, because demolition and building work in the centre's vicinity was creating dust, noise and disruption at the front and rear of the centre's premises. The centre has maintained compliance but the PR considered it was not advisable to commence donor recruitment or insemination activities. The building work is due to be completed by the end of 2018 and the PR plans to commence licensed activity on or before this time, when he considers the environment suitable.

The inspection team notes that the premises are safe and suitable but understands the PR's suspension of activities, as patient and donor recruitment is unlikely to be 'optimal' until the building work is less disruptive than at present.

Pregnancy outcomes[1]
Treatment outcomes and Multiple births[2] No licensed activities have been undertaken, therefore no pregnancy outcomes or multiple pregnancies can be reported.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.
[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

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 Person Responsible (PR);
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR has discharged 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 renewal of the centre's 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 a number of areas of practice that required improvement, including three major and five 'other' areas of non compliance.

Since the inspection visit, the PR has provided evidence that actions have been taken to implement the following recommendations and has committed, where required, to audit the effectiveness of those actions within the required timescales:

Major areas of non compliance:

- The PR should ensure that all staff are competent to undertake the tasks expected of them to deliver the licensed activities.

'Other' areas of non compliance:

- The PR should ensure that the centre has third party agreements (TPAs) with all service providers that are compliant with CoP requirements.
- The PR should ensure that all relevant information is available to patients in their patient information packs.

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

Major areas of non compliance:

- The PR should ensure that donor screening practice, and supporting documents, are compliant with regulatory requirements and best practice guidance.
- The PR should audit standard operating procedures (SOPs) against current CoP requirements and best practice guidance and develop an effective process for embedding regulatory change in the quality management system (QMS).

'Other' areas that requires improvement:

- The PR should take immediate actions to ensure that reasonably detailed records of the cleaning of the premises are documented.
- The PR should provide a list of all critical equipment to the centre's inspector, including the date of re-validation or the planned date by which re-validation will be completed.

- The PR should validate the air quality monitoring process, including the testing methodology used and the frequency of testing.

Recommendation to the Executive Licensing Panel

Significant improvement is required in order for the centre to reflect suitable practices. The centre has a QMS and the PR is encouraged to use it to best effect to monitor and improve the service provided.

The inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

The inspection team recommends the renewal of the centre's Treatment (Insemination using partner / donor sperm) and Storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

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 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 partially 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 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)
It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes

and embryos in treatment and the parents of donor-conceived children, are able to access non identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

The centre's procedures are compliant with HFEA requirements which ensure the donor-conceived and their parents will be able to receive all required donor-related information.

What the centre could do better

Screening of donors (Guidance note 11)
The centre's PR was not aware of recent guidance on screening donors, where necessary, for hepatitis A (Clinic Focus, August 2017) and it has not been incorporated into the centre's donor screening practice SOP, donor information or the centre's 'donor screening and release checklist'. This latter document has also not been revised to include consideration of the risk of Zika or Ebola virus infection, as per recent guidance issued by the HFEA (recommendations 1 and 8).

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. Suitable premises are important to ensure that all licensed activities are conducted in an environment that is fit for purpose. The inspection team notes that the exterior environment adjacent to the centre is an active building site and this has led to licensed activities not yet being undertaken at the centre.

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account so that patients and staff are in safe surroundings that prevent harm.

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

The centre is compliant with HFEA requirements to process gametes and embryos in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's laboratories and third party laboratories which 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 to be accredited 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 has systems in place to manage and monitor the prevention and control of infection that are broadly compliant with guidance.

Medicines management (Guidance Note 25)
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are compliant with guidance.

Prescription of intralipid 'off label'
Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
The centre is providing only insemination treatments and does not undertake surgical procedures so requirements related to pre-operative assessment and management of the surgical pathway are not relevant at this inspection.

Multiple births (Guidance note 7; General Direction 0003)
The centre is providing only insemination treatments, but such treatments still expose patients to the risks of multiple pregnancies and births if incorrectly applied. The single biggest risk of fertility treatment is a multiple pregnancy and birth. Thus it is important for centres providing insemination treatments to have a multiple births minimisation strategy. The centre's procedures are compliant with HFEA requirements to have a multiple births minimisation strategy and to conduct regular audits and evaluations of the progress and effectiveness of the strategy.

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, the centre keeps 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 procedures for the transport, distribution and recall of gametes and embryos

are compliant with HFEA requirements, notwithstanding the absence of a SOP describing the transport and distribution process. 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. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note15)
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 they are appropriately labelled and are accompanied by enough 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 procedures for import and export of gametes are compliant.

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;
- 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 that is partially 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 (TPA) (Guidance note 24)
The centre's TPAs are broadly compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has no transport or satellite relationships at present so this area of practice was not relevant at this inspection

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements and that are designated for the purposes for which they are used, and are appropriately maintained in order to minimise any hazard to patients and 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 partially 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 has undertaken no activities and therefore has had no incidents since the licence was granted in 2016. Reporting and investigating adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services they offer.

What the centre could do better

Infection control (Guidance Note 25)
The centre keeps records of the cleaning of the premises however the inspection team considered that the records should be more detailed, as they did not record the cleaning of specific areas (recommendation 4).

QMS (Guidance note 23)
The centre has a QMS which is partially compliant because:

- The QMS does not include a process to update staff guidance and patient information leaflets in response to regulatory change. This is required to ensure that patient information packs and staff SOPs are reviewed and modified so that regulatory changes are embedded in the centre's processes and compliance is maintained;
- SOPs are not present describing the procedures involved in applying a Single European Code to donated sperm samples which are to be distributed;
- SOPs have not been audited for compliance with current regulatory requirements and guidance.

Recommendation 2

Third party agreements (Guidance note 24)
TPAs have not been reviewed to ensure their compliance with all SLC requirements. In addition a TPA with one service provider was not present, while another needs to be revised to ensure its compliance (recommendation 5).

Equipment and materials (Guidance note 26)
The equipment was validated in 2016 but has not been used in any licensed activity, though it has been serviced. The inspection team considers it important that the equipment is re-validated before any licensed activity is undertaken. Equipment re-validation will ensure all equipment is operating according to specification and is suitable for use in licensed activity when it commences (recommendation 6).

Process validation (Guidance note 15)
The centre has not validated the following critical processes: air quality monitoring (recommendation 7).

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has complied with HFEA requirements.

The 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 partially 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

Staff (Guidance note 2)
Evidence of the recent assessment of the competence of staff was not available. It is noted that the centre is currently not active and some staff posts remain vacant. The PR described plans to recruit to these posts before licensed activity commences (recommendation 3).

Welfare of the child and safeguarding

What the centre does well

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

Safeguarding (Guidance Note 25)
The centre's 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 have procedures in place for performing embryo testing and therefore this area of practice was not relevant at this inspection.

2. The experience of patients

Patient feedback

What the centre does well
The centre has not been active since the licence was first granted in November 2016. Therefore no patients or donors were available to talk to on inspection and the centre and the HFEA have had no patient and donor feedback.

The PR described plans to collect patient and donor feedback when licensed activity commences.

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)
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 and sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre does not undertake procedures involving egg or sperm sharing arrangements so this area of practice was not relevant at this inspection.

Surrogacy (Guidance note 14)
The centre does not undertake procedures involving surrogacy arrangements so this area of practice was not relevant at this inspection

Complaints (Guidance note 28)
The centre has not been active since the licence was first granted in November 2016 so no complaints have been received. Discussions with the PR indicate that the centre has

procedures which are compliant with HFEA requirements and will, when the centre is active, seek patient feedback and be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

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

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients and / or donors are broadly 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

Information (Guidance note 4; Chair's Letter CH(11)02)
Written information and/or the centre's website did not discuss:

- the availability of the PBR (posthumous birth registration) consent form;
- the potential need for hepatitis A screening in donors;
- the availability of counselling for donors or users of donated sperm.

Recommendation 8.

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 patients and donors have provided all relevant consents before carrying out any licensed activity. However please see recommendation 3 re. staff competence.

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 the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

This centre was first licensed in November 2016, more than two years after 2014 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood.

Processes for recording legal parenthood consents were reviewed at this inspection and were considered compliant with HFEA requirements, albeit this is based on a review of the SOP and discussions with the PR, because the centre has not been active since the licence was first granted in 2016. Therefore, records of legal parenthood consenting could not be reviewed and no audit data was available.

As is noted elsewhere in this report, staff competence to lead and advise patients through the legal parenthood consenting process has not been documented (recommendation 3). Furthermore, the PR had no knowledge of the PBR posthumous birth registration consent form, released in August 2017, and information about it has not been included in the patient information or in the centre's legal parenthood consent SOP (recommendations 2 and 8).

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 ART and those born following ART treatment.

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 activities do not involve the creation, manipulation or storage of embryos, therefore requirements related to this area of practice were not relevant at this inspection.

Screening of patients and 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.

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. The storage of gametes 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.

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

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre does not create, use, or store embryos therefore this area of practice was not relevant to this inspection.

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

4. Information management

Record keeping and 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.

The HFEA register audit team found no evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

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

Section 3: Monitoring of the centre's performance

Following the initial inspection in 2016, no recommendations for improvement were made.

On-going monitoring of centre success rates

No licensed activities have been undertaken at the centre, therefore no pregnancy outcomes or multiple pregnancies have been reported or could be monitored.

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 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.

A critical area of non compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

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.

A major area of non compliance is identified in the report by a statement that an area of practice is partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Donor recruitment, assessment and screening The PR was not aware of recent guidance on considering the risk of hepatitis A infection in sperm donors (Clinic Focus, August 2017) and the guidance has not been incorporated into the centre's donor screening SOP or information leaflets. The centre's screening and release checklist for donors has also not been updated to include consideration of the risks of hepatitis A virus, Zika	The PR should review current screening requirements and guidance and ensure that the centre's proposed screening practice, and materials to support it, are compliant. The PR should provide the updated SOP and donor screening and release checklist to the centre's inspector by 5 September 2018.	The PR has reviewed the current screening requirements and can confirm that the proposed screening practice, and materials to support it, are compliant. An updated SOP and donor screening/release checklist will be provided accordingly.	The Executive acknowledges the PR's response to this recommendation and awaits the updated screening SOP and donor screening and release checklist, which should be provided by 5 September 2018. **Further action required.**

virus or Ebola virus, as per recent guidance issued by the HFEA. SLC T52 CoP Guidance 11.22			
2. QMS The QMS is non compliant because: • The QMS does not include a process to update staff guidance and patient information leaflets in response to regulatory changes; • SOPs are not present describing the procedures for applying a Single European Code to a donated sperm sample to be distributed; • SOPs have not been audited for compliance with current regulatory requirements; • The SOP for the legal parenthood consenting process has no reference to the PBR posthumous birth registration consent form.	The PR should take immediate action to address non compliances in the QMS. A plan to implement this recommendation, with a timescale for implementation, should be submitted to the HFEA with the PR's response to the report. The PR should provide confirmation by 5 September 2018 that all non compliances have been addressed.	The communication SOP has been updated to highlight that staff guidance and patient information leaflets is regularly checked against all HFEA communication. This will ensure that the patient information and all SOPs are compliant with the latest legilsation. A new SOP has been developed to describe how the SEC will be applied to a donated sperm sample that will be distributed, and for transporting sperm to other centres. A full audit of all SOPs against the Code of Practice is underway. The final audit with a summary of any changes to SOPs will be provided by 5 September 2018.	The Executive accepts the PR's commitment to fulfil this recommendation and the documents already sent to provide evidence of compliance. Further confirmation is required that all SOPs have been audited for compliance with current regulatory requirements ,by 5 September 2018. **Further action required.**

SLCs T32, T33b and T36		A new SOP for legal parenthood consenting, which now includes reference to the PBR form, has been developed.	
3. Staff Evidence of the recent assessment of the competence of staff was not available. It is noted that the centre is not currently active and some staff posts remain vacant. The PR described plans to recruit to these posts before licensed activity commences. SLCs T12 and T15a.	The PR should ensure that all staff are competent to undertake the activities expected of them, and that evidence of this is provided to the centre's inspector by 5 September 2018 or by the time licensed activity commences, whichever is earlier. The inspection team notes, in particular, that competence to deliver processes around informing and consenting patients and donors must be considered. Any new staff recruited must undertake an induction process, receive any necessary training and be assessed as competent for the activities they will perform.	All staff will have satisfactory competency assessments completed for the activities they undertake prior to performing any activities. The competence of the PR to deliver processes around informing and consenting patients and donors has since been assessed by an independent clinic. Full evidence will be provided prior to any licensed activity taking place. New staff will undertake an induction process, necessary training and have their competency assessed prior to undertaking any activities. This is described in the induction, competence and CPD policy.	The Executive thanks the PR for his response and commitment to ensure competence assessments are performed before activity commences. No further action required.

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.

An 'other' area of non compliance is identified in the report by a statement that an area of practice is 'broadly' compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
4. Infection control The centre keeps records of the cleaning of the premises however the inspection team considered that they should be more detailed, because they did not record the cleaning of specific areas. SLC T26.	The PR should take immediate actions to ensure that reasonably detailed records of the cleaning of the premises are documented, so that the cleaning of specific areas can be reviewed. The PR should advise the centre's inspector of the actions taken when responding to this report.	Whilst records of cleaning are present, more detailed records are now being produced, so that cleaning of specific areas is documented. Evidence has been provided to the inspector.	The Executive acknowledges the new measures the centre has put into place regarding the cleaning of premises, however, further review of the cleaning log may be required to ensure the documentation of appropriate infection control measures after each patient and not necessarily just at the end of each day. **Further action required**.
5. Third party agreements TPAs have not been reviewed to ensure their compliance with all SLC requirements. In addition, a TPA with one service provider was not present, while another needs	The PR should ensure that the centre has TPAs with all service providers and that the TPAs are all compliant with relevant HFEA CoP requirements. A plan to implement this	Whilst all TPAs had been reviewed, they will be re-reviewed to ensure compliance with all SLC requirements. A plan has been sent to the inspector.	The Executive acknowledges the PR's commitment to implement this recommendation though would dispute that the TPAs had been effectively reviewed

to be revised to ensure its content is compliant. SLCs T111-T116.	recommendation should be forwarded to the centre's inspector with the PR's response to this report. The plan should be implemented by 5 September 2018.		already. No further action required.
6. Equipment and materials The equipment was validated in 2016 but has not been used since in any licensed activity, though it has been serviced. The inspection team considers it important that the equipment is re-validated before any licensed activity is undertaken. Equipment re-validation will ensure all equipment is operating according to specification and is suitable for use in licensed activity when it commences. SLC T24. This non compliance has been graded as an 'other', rather than a major, because the centre has not been active since it was first licensed so has not used any unvalidated equipment in licensed activity.	The PR should provide a list of critical equipment to the centre's inspector, including the date of re-validation or the planned date by which re-validation will be completed, with the response to this inspection report. The inspection team envisage that the re-validation process should be completed by 5 December 2018 or by the commencement of licensed activity, whichever is sooner. The PR should notify the centre's inspector when the re-validation process is completed, so that validation documents for selected pieces of equipment can be reviewed.	A list of critical equipment will be provided along with the re-validation date, and supporting documentation provided. This will be provided in accordance with required timeline.	The Executive thanks the PR for his response and is looking forward to receiving the list of critical equipment so that a sample of the revalidation documents can be selected for review. **Further action required**

7. Process validation The centre has not validated the following critical processes: air quality monitoring SLC T72 This non compliance has been graded as an 'other', rather than a major, because the centre has not been active since it was first licensed so has not used any unvalidated processes in licensed activity.	The PR should validate the air quality monitoring process, including the testing methodology used and the frequency of testing. The validation documentation should be provided to the centre's inspector by 5 September 2018, or by the time the centre commences licensed activity, whichever is sooner.	Air quality monitoring takes place via use of settle plates and particle counts. Full validtion of these methods and the frequency of the tests will be provided in accordance with required timeline.	The Executive awaits the validation documents. **Further action required**
8. Patient information Written information and/or the centre's website do not discuss: • the use of the PBR posthumous birth registration consent form; • hepatitis A screening; • the availability of counselling for donors or users of donated sperm; SLC T60	The PR should ensure that all necessary information is available to patients in the written information provided to them as well as on the centre's website. Appropriate changes should be made and a summary document describing the changes provided to the centre's inspector by 5 September 2018.	A new information sheet has been produced to specifically address legal parenthood. This includes information about use of the PBR form. The written information for donors has been updated to include hepatitis A screening. The centre's website now includes a section on support counselling for all clients and donors. Written information on our counselling service is already embedded in our	The Executive acknowledges the new patient information taking into account the PBR form and the Hepatitis A screening. No further action required.

		written information. However, two new information sheets specifically for counselling for donors and for users of donated sperm have been produced.	

Reponses from the Person Responsible to this inspection report
We are grateful for comments received by the inspectors. We hope our improvement actions demsontrate continued compliance to the HFEA Code of Practice as we continuously aim to improve the quality of our service.