Executive Licensing Panel - minutes

Centre 0353 (X&Y Fertility) Initial Inspection Report –

Treatment (insemination using partner/donor sperm) & Storage Licence

Friday, 18 November 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Paula Robinson (Chair) Ian Peacock Howard Ryan	Head of Business Planning Analyst Programmer Technical Report Developer
Members of the Executive	Dee Knoyle Siobhain Kelly	Secretary Interim Head of Corporate Governance
External adviser		
Observers		

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Background

1.1. X&Y Fertility is located at:

144a New Walk
Leicester
LE1 7JA

1.2. The proposed Person Responsible (PR), Dr Bryan Woodward, submitted an application for a treatment (insemination using partner/donor sperm) and storage licence in August 2016.

1.3. A full desk based assessment was performed followed by an inspection on 20 September 2016. Further information was provided by Dr Woodward after the inspection visit which has contributed to this report.

2. Consideration of application

2.1. The panel considered the papers which included an application form, inspection report, CV of the proposed Person Responsible (PR) and confirmation of acceptance of the role from the proposed Licence Holder (LH).

2.2. The panel noted the findings of the desk based assessment and inspection carried out on 20 September 2016.

2.3. The panel noted that the proposed PR, Dr Bryan Woodward, holds academic qualifications in the field of biological sciences. The proposed PR also has more than two years' practical experience which is directly relevant to the activity to be authorised by the licence as required by the HFE Act 1990 (as amended) section 16(2)(c)(i) and (ii) (including acting in the capacity of PR). The proposed PR has successfully completed the HFEA PR Entry Programme.

2.4. The panel noted the suitability of the proposed LH, Ms Melanie Proffitt.

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

2.6. The panel noted that at the time of the desk based assessment and inspection on 20 September 2016 there were no areas of non-compliance identified.

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 (insemination using partner/donor sperm) and storage licence for a period of two years.

3. Decision

3.1. The panel referred to its decision tree.

3.2. The panel was satisfied that the appropriate application form was submitted.

3.3. The panel noted that the inspectorate had received the supporting information required by General Directions 0008 and was satisfied that the fee had been paid.

3.4. The panel was satisfied that the proposed PR, Dr Bryan Woodward will discharge his duty under section 17 of the HFE Act 1990 (as amended). The panel agreed to appoint Dr Woodward 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, Ms Melanie Proffitt. The panel agreed to appoint Ms Proffitt as the Licence Holder when the new licence comes into effect.

3.6. The panel was satisfied that the premises to be licensed (and those of relevant third parties) are suitable for the conduct of licensed activities based on evidence provided within the report.

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

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

3.9. The panel agreed to grant the licence for treatment (insemination using donor/partner sperm) and storage for a period of two years with no additional conditions.

4. Chair's signature

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

Signature

Name

Paula Robinson

Date

28 November 2016

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 meets essential requirements. The Executive Licencing 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: 20 September 2016

Purpose of inspection: Initial application for a Treatment (insemination using partner/donor sperm) and Storage licence.

Inspection details: The report covers the findings from a desk-based assessment of submitted documentation, the inspection visit and communications received from the centre.

Inspectors: Grace Lyndon and Andy Leonard

Date of Executive Licencing Panel: 18 November 2016

Centre name	X&Y Fertility
Centre number	0353
Centre address	144a New Walk, Leicester, LE1 7JA
Proposed Person Responsible	Bryan Woodward
Proposed Licence Holder	Melanie Proffitt

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Section 1: Summary report

Brief description of the centre:
X & Y Fertility is located in central Leicester. The centre intends to provide services involving insemination with partner or donor sperm and storage of sperm to both private and NHS patients.

An initial licensing enquiry was received from Dr Bryan Woodward, the proposed Person Responsible (PR) on 31 July 2016 which was followed by an application for a Treatment (insemination using partner/donor sperm) and Storage licence in August 2016. A full desk based assessment was performed followed by an inspection visit on 20 September 2016. Further information was provided by Dr Woodward after the inspection visit which has contributed to this report.

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 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 the inspection and assessment activities have identified no areas of practice requiring improvement.

Recommendation to the Executive Licensing Panel

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

- The appointment of the proposed LH.
- The appointment of the proposed PR.
- The granting of a Treatment (insemination using partner/donor sperm) and Storage licence for a period of two years.

An interim inspection will be completed during the first year as a useful indication of early performance and progress.

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) at this centre
4. How this centre looks after important information

1. Protection of the patient and children born following treatment

▶ **Witnessing and assuring patient and donor identification**
What the centre does well **Witnessing (Guidance note 18)** The centre's proposed procedures for double checking the identification of gametes and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes.
What the centre could do better Nothing identified at this inspection.

▶ **Donor selection criteria and laboratory tests** Screening of donors prior to procuring, processing gametes and embryos Payments for donors Donor assisted conception
What the centre does well **Screening of donors (Guidance note 11)** The centre's proposed procedures for screening donors are compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes. **Payments for donors (Guidance note 13; Directions 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. 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 from identifiable donors.

The centre's procedures are compliant with HFEA requirements to use identifiable donors and thus to ensure the donor conceived will be able to receive all required 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'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 laboratories conducting tests that impact on the quality and safety of gametes are suitable.

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which will undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes 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
The centre has a system in place which will manage and monitor the prevention and control of infection in a manner compliant with guidance.

Medicines management
This area is not applicable to this centre as no medications will be kept on site for patients.

Pre-operative assessment and the surgical pathway
The centre has indicated on their application that they would like to undertake Surgical Sperm Retrieval (SSR). However, this procedure will not commence until the IUI service has been developed and TPAs are in place. The centre will liaise with their inspector before any proposed activities are undertaken.

Multiple births (Guidance note 7; General Direction 0003)
The centre's proposed procedures are compliant with HFEA multiple births minimisation strategy requirements pertaining to centres providing insemination services. The single biggest risk of fertility treatment is a multiple pregnancy.

Procurement of gametes (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 in treatment, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, the centre will keep a record of this in the gamete provider's records.

Transport and distribution of gametes (Guidance note 15; General Direction 0009)
The centre's proposed procedures for the transport, distribution and recall of gametes are compliant with HFEA requirements. This is important to ensure that all gametes sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- appropriately packaged in validated containers, secured and maintained under the specified conditions.

Receipt of gametes (Guidance note15)
The centre's proposed procedures for the receipt of gametes are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes from other centres if the gametes are appropriately labelled and has enough information to permit the gametes 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 importing gametes 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 during any step from procurement to use for human application or disposal,
- identify the donor and recipient of particular gametes,
- to identify any person who has carried out any activity in relation to particular gametes, and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS in place that is compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

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

Satellite agreements (Guidance note 24; General Direction 0010)
This section is not relevant as the centre will not have satellite agreements.

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

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

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

Process validation (Guidance note 15)
The centre's proposed procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's proposed procedures for reporting adverse incidents are compliant with HFEA requirements. The centre will report all 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
Nothing identified at this inspection

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's proposed processes for ensuring suitably qualified and competent staff provide licensed activities are compliant with HFEA requirements. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively. The centre's staff are registered in accordance with the appropriate professional and/or statutory bodies.

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 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 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)
This section is not relevant as the centre will not be performing preimplantation genetic screening, embryo testing or sex selection when it commences activities.

2. The experience of patients

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 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 and prior to consenting to legal parenthood.

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
This area is not applicable to this centre.

Surrogacy (Guidance note 14)
This area is not applicable to this centre.

Complaints (Guidance note 28)
The centre's proposed 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 will give 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;6)
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 any licensed activity is undertaken.

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' 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 will not create, process or store embryos, therefore this area is not applicable.
What the centre could do better Nothing identified at this inspection.

Screening of patients **Storage of gametes**
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 (Guidance note 17)** The centre's proposed 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 will 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 (Guidance note 22)
What the centre does well **Use of embryos for training staff (Guidance note 22)** This area is not applicable to this centre.
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 planned 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 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, 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 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 may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None identified			

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
None Identified			

Reponses from the Person Responsible to this inspection report
I am in full agreement with the content of this report.