

HFEA Licence Committee Meeting

10 July 2014

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

Minutes – Item 1

Centre 0333 (Harley Street Fertility Clinic) – Initial Treatment and Storage (including Embryo Testing) Licence

Members of the Committee: Andy Greenfield (lay) (Chair) David Archard (lay) Debbie Barber (professional) Jane Dibblin (lay)	Legal Adviser: Tom Rider, Fieldfisher Committee Secretary: Lauren Crawford
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Declarations of Interest: members of the Committee declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the Committee:

- Inspection report
- Application form
- CV of proposed Person Responsible (PR) and references
- CV of proposed Licence Holder

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree); and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Background

1. The Committee noted that an initial application was received by the HFEA from the Harley Street Fertility Clinic for a treatment and storage (including embryo testing) licence.
2. The Committee noted that the Harley Street Fertility Clinic is located at:

134 Harley Street
London
W1G 7JY
3. The Committee noted that at the time of the inspection, the Inspectorate reported that there was one 'other' area of practice that required improvement and since the inspection the recommendation has been fully implemented.

Discussion

4. The Committee referred to its decision tree. It was satisfied that the appropriate application and fee had been submitted, and noted that the executive had received the supporting information required by General Direction 0008.
5. The Committee noted that the proposed PR (Dr Geetha Venkataraman) holds academic qualifications in the field of medicine and also has more than two years' practical experience which is directly relevant to the activity to be authorised by the licence as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii) (including acting in the capacity of PR). She has successfully completed the HFEA PR Entry Programme.
6. The Committee was satisfied that the proposed PR is suitable and will discharge her duty under section 17 of the HF&E Act 1990 (as amended).
7. The Committee was satisfied regarding the suitability of the proposed Licence Holder (LH), Mr Lawrence Ashford.
8. The Committee was satisfied that the licence application concerns treatment, storage or non-medical fertility services which relate to gametes or embryos intended for human application.
9. The Committee was satisfied that premises to be licensed (and those of relevant third parties) are suitable for the conduct of licensed activities based on evidence provided within the report.
10. The Committee referred to 'Guidance on periods for which new or renewed licences can be granted'. The Committee noted paragraph 4.2 of the guidance which states '[the Committee] will normally only grant an initial treatment/storage/non-medical fertility services licence for up to two years. This is because in granting an initial licence, there will be no history of compliance to support a longer licence'.

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

Decision

12. The Committee agreed to appoint Dr Geetha Venkataraman as the Person Responsible for Harley Street Fertility Clinic (Centre 0333) with immediate effect, in accordance with section 18A of the HFE Act 1990 (as amended).
13. The Committee agreed to appoint Mr Lawrence Ashford as the Licence Holder for Harley Street Fertility Clinic (Centre 0333) with immediate effect.
14. The Committee agreed to grant the centre's Treatment and Storage (including embryo testing) Licence for a period of two years with no additional conditions.

Signed:

Date: 23/07/2014

A handwritten signature in black ink, appearing to read 'AG', is written over the signature line.

Andy Greenfield (Chair)

Inspection Report



Purpose of the Inspection Report

This is a report of an assessment and inspection, carried out to determine whether an application for a new licence will meet essential requirements. The Authority's Licence Committee (LC) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 3 June 2014

Purpose of inspection: Issue of a licence to carry out Treatment (including embryo testing) and Storage.

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

Inspectors: Bhavna Mehta, Gill Walsh, Jason Kasraie, Heidi Birch and Sheila Pike

Date of Licence Committee: 10 July 2014

Centre name	Harley Street Fertility Clinic
Centre number	0333
Centre address	134 Harley Street. London W1G 7JY
Proposed Person Responsible	Geetha Venkataraman
Proposed Licence Holder	Lawrence Ashford

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Section 1: Summary report

Brief description of the centre:

The Harley Street Fertility Clinic is a private centre and the proposed Person Responsible (PR) has applied for a Treatment (including embryo testing) and Storage licence. The centre will be providing a full range of fertility services. The inspection team is satisfied that the activities to be carried out at the centre are necessary or desirable in order to provide licensed treatment services.

Centre's anticipated activity levels:

Type of treatment	Maximum number of proposed treatment cycles
In Vitro Fertilisation (IVF)	800
Intracytoplasmic sperm injection (ICSI)	
Frozen embryo transfer (FET)	
Donor insemination (DI) and Partner insemination IUI(P)	50
Pre-implantation Genetic Diagnosis / Screening (PGD/S)	20
Other licensable activities	✓ or Not applicable (N/A)
Storage of gametes	✓
Storage of embryos	✓
Embryo testing	✓

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) 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 LC is asked to note that at the time of the inspection there was one area of practice that required improvement. Since the inspection visit, the following recommendation has been fully implemented:

- The proposed PR should ensure that the air quality is assessed and meets the requirements of Standard Licence Condition (SLC) T20.

Recommendation to the Licence Committee

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

1. Appointment of the proposed LH.
2. Appointment of the proposed PR.
3. Granting a Treatment (including embryo testing) and Storage licence for a period of two years with no additional conditions.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

1. Protection of the patient and children born following treatment

▶ Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)

The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre can do better

Nothing identified at this inspection.

▶ Donor selection criteria and laboratory tests

Screening of donors

Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)

The centre's 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.

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

Donor assisted conception (Guidance note 20)

A donor-conceived person is entitled to know details of their donor and any donor-conceived genetic siblings they may have. Parents of a donor-conceived child are able to access information on their child's donor (and about any donor-conceived genetic

siblings) from the HFEA or the clinic where they received treatment.

Therefore it is important that centres use donated gametes or embryos from identifiable donors. The centre's 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)

The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account to ensure 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 and/or embryos (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to processes gametes and/or embryos in an environment of appropriate air quality but this should be re-tested before commencing licensed treatments.

Laboratory accreditation (Guidance note 25)

The third party laboratories which will undertake the diagnosis and investigation of

patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

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

Infection control

The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

Medicines management

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

Pre-operative assessment and the surgical pathway

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

Multiple births (Guidance note 7; Directions 0003)

The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements. The single biggest risk of fertility treatment is a multiple pregnancy and implementation of a suitable strategy is expected to minimise the incidence of multiple births.

Procurement of gametes and embryos (Guidance note 15)

The centre's procedures are compliant with HFEA requirements to:

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

Transport and distribution of gametes and embryos (Guidance note 15; Directions 0009)

The centre's procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes / embryos sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or

embryos;

- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions.

Receipt of gametes and embryos (Guidance note 15)

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

Imports and exports (Guidance note 16; Directions 0006)

The centre's procedures for imports and exports of gametes and embryos are compliant with HFEA requirements.

Traceability (Guidance note 19)

The centre's procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability -

- to identify and locate gametes and embryos during any step from procurement to use for human application or disposal,
- identify the donor and recipient of particular gametes or embryos,
- to identify any person who has carried out any activity in relation to particular gametes or embryos, and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)

The centre has a QMS in place that is compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)

The centre's third party agreements are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; Directions 0010)

This section is not applicable to the centre as it does not have transport or satellite IVF arrangements with other centres.

Equipment and materials (Guidance note 26)

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

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

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

Process validation (Guidance note 15)

The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)

The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre will report all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre has processes in place to investigate all adverse incidents that may occur. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

To ensure that the centre remains compliant with HFEA requirements to processes gametes and/or embryos in an environment of appropriate air quality, this should be re-tested before commencing licensed treatments. SLC T20 **Recommendation 1**.

 **Staff engaged in licensed activity**

Person Responsible (PR)

Staff

What the centre does well

Person Responsible (Guidance note 1)

The proposed PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence (including acting in the capacity of PR). The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1243/81).

Staff (Guidance note 2)

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

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

What the centre could do better

Nothing identified at this inspection.

▶ Welfare of the child and safeguarding**What the centre does well****Welfare of the child (Guidance note 8)**

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

Safeguarding

The 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 diagnosis and screening (Guidance notes 8 and 9);**

The centre's procedures for performing embryo testing will be compliant with HFEA requirements. This ensures that:

- no embryo is transferred to a woman where that embryo or material removed from it, or the gametes that produced it, has been subject to genetic testing unless expressly authorised by the HFEA;
- no information derived from tests conducted is used to select embryos of a particular sex for social reasons;
- no embryo is tested unless the statutory tests are met i.e. that the embryos is at a significant risk of having a serious genetic condition.

The centre will ensure that people seeking embryo testing are given suitable information, and have access to advice from a clinical geneticist and a counsellor.

What the centre could do better

Nothing identified at this inspection.

2. The experience of patients

▶ Treating patients fairly

Counselling

Egg sharing arrangements (Guidance note 12; Direction 0001)

Complaints

Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

The centre's procedures are compliant with the HF& E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)

The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

Egg sharing arrangements (Guidance note 12; Direction 0001)

The centre's procedures for egg sharing arrangements are compliant with HFEA requirements. This is important to ensure that:

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

Complaints (Guidance note 28)

The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)

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

What the centre could do better

Nothing identified at this inspection.

 Information
<p>What the centre does well</p> <p>Information (Guidance note 4; CH(11)02) The centre's procedures for providing information to patients are compliant with HFEA requirements. This ensures that the centre will give prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.</p>
<p>What the centre could do better</p> <p>Nothing identified at this inspection.</p>

 Consent and Disclosure of information, held on the HFEA Register, for use in research
<p>What the centre does well</p> <p>Consent (Guidance note 5) 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.</p> <p>Disclosure of information, held on the HFEA Register, for use in research (Directions 5) The centre's procedures for taking consent to disclosure to researchers are compliant with HFEA requirements.</p> <p>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 assisted reproductive therapies (ART) and those born following ART treatment.</p>
<p>What the centre could do better</p> <p>Nothing identified at this inspection.</p>

3. The protection of gametes and embryos

▶ Respect for the special status of the embryo

What the centre does well

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

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

What the centre could do better

Nothing identified at this inspection.

▶ Screening of patients Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)

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

Storage of gametes and embryos (Guidance note 17)

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

What the centre could do better

Nothing identified at this inspection.

4. Information management

▶ Record keeping Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)

The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32; Direction 0005)

The centre's procedures for submitting information, about licensed activities to the Authority, are compliant with HFEA requirements. This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

What the centre could do better

Nothing identified at this inspection.

Areas of practice requiring action

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

▶ Critical area of non compliance

A critical area of non-compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

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

▶ Major area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several “other” areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

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

 **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
1. To ensure that the centre remains compliant with HFEA requirements to process gametes and/or embryos in an environment of appropriate air quality, the air quality should be re-tested before commencing licensed treatments. SLC T20	The proposed PR should ensure that the air quality is assessed and meets the requirements of Standard Licence Condition (SLC) T20.	The air quality has been assessed again as requested. Please find the reports attached. All reports indicate Grade B air quality in the embryology laboratory and laminar flow cabinets, which is well above the SLC T20 requirement. Readings were also taken in the andrology laboratory and theatre (also attached), those indicate Grade C, which is again above the SLC T20 requirement. Finally, the certificate of	The proposed PR's comments are noted. No further action required.

		calibration for the instrument that was used to assess the air quality is also attached.	
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Reponses from the Person Responsible to this inspection report

With regards to laboratory accreditation for diagnostic semen analysis the report indicates that verbal assurance of the centre's enrollment in the UK NEQAS scheme was provided by the laboratory staff, please find attached documentation of the centre's enrollment in the UK NEQAS scheme.