Human Fertilisation and Embryology Authority

Minutes of the Executive Licensing Panel

Meeting held at HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF on
5 June 2015

Minutes – item no. 1

Centre 0332 (Oxford Heart Valve Bank) – Renewal Inspection Report

Members of the Panel:	**Juliet Tizzard** Director of Strategy & Corporate Affairs (Chair) **David Moysen** Head of IT **Hannah Verdin** Head of Regulatory Policy
Members of the Executive in attendance:	**Sam Hartley** Head of Governance & Licensing

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:

- HFEA protocol for the conduct of meetings of the Executive Licensing Panel
- 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)
- guidance for members of the 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 Direction 0008 (where relevant) and any other relevant directions issued by the Authority
- guide to Licensing
- compliance and enforcement policy
- policy on the publication of Authority and committee papers

Consideration of application

1. The panel considered the papers, which included an application form, renewal inspection report and licensing minutes for the past three years.

2. The panel noted that this is a storage only centre which provides ovarian tissue storage service for individuals who have a moderate to high risk of premature ovarian failure following chemotherapy or radiotherapy treatment.

3. The panel noted that the centre has been licensed by the HFEA since August 2013. The initial licence was granted for a period of two years and is due to expire on 4 August 2015.

4. The panel noted that the inspection team based their report on a Human Tissue Authority (HTA) onsite inspection that took place on 13 and 14 November 2014. The report found that the centre had met all HTA standards. At the time of the HFEA inspection report the Inspectorate identified one other area of non-compliance. The PR has provided evidence to the Inspectorate that the recommendation has been implemented.

5. The panel noted that the Inspectorate recommends the renewal of the centre's storage only licence for a period of four years without additional conditions.

Decision

6. 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.

7. 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 has discharged their duty under section 17 of the HFE Act 1990 (as amended).

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

9. The panel endorsed the Inspectorate's recommendation to renew the centre's storage only licence for a period of four years without additional conditions.

Signed: Date: 15 June 2015

Juliet Tizzard (Chair)

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. 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: 21 April 2015

Purpose of inspection: Renewal of a storage only licence

The centre has applied to add the following activities: none

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: Louise Winstone and Andy Leonard

Date of Executive Licensing Panel: 5 June 2015

Centre name	Oxford Heart Valve Bank
Centre number	0332
Licence number	L/0332/1/a
Centre address	Cardiovascular & Thoracic Surgery Division, Cardiac Unit, Level 0, John Radcliffe Hospital, Oxford University NHS Trust, Headington, Oxford, OX3 9DU, UK
Person Responsible	Mrs Jill Davies
Licence Holder	Mr Chandi Ratnatunga, Oxford University Hospitals NHS
Date licence issued	5 August 2013
Licence expiry date	4 August 2015
Additional conditions applied to this licence	none

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Oxford Heart Valve Bank (OHVB) has held a storage only licence with the HFEA since August 2013. The centre provides an ovarian tissue storage service for women and children who have a moderate to high risk of premature ovarian failure following chemotherapy or radiotherapy treatment. Ovarian tissue is procured in the main hospital operating theatres in the John Radcliffe Hospital, Oxford University Hospitals NHS Trust, under the auspices of a third party agreement (TPA). The tissue is then transported to the centre for processing and storage. Immature eggs can be harvested from the ovarian tissue during processing and if found, are transported to the Oxford Fertility Unit (OFU; HFEA licensed centre 0035) for processing and storage.

The OHVB is also licensed by the Human Tissue Authority (HTA) for the processing and storage of tissues and cells, including ovarian tissue.

The use of the HTA inspection report, in support of evidence of compliance at this inspection:

The HTA carried out an on site inspection of the OHVB, including the ovarian tissue storage service, on 13 and 14 November 2014. The report of that inspection has been made available to the HFEA. The HTA inspection report found that the centre fully met all HTA Standards. The Designated Individual, the Licence Holder, the premises and the practices were considered to be suitable and in accordance with the requirements of the legislation. This HTA report has been used as evidence of compliance with HFEA requirements where relevant. In this HFEA inspection report, the inspection team considers that the HTA inspection report provides suitable and appropriate evidence for compliance with HFEA requirements in most areas because:

- The HTA inspection directly reviewed the ovarian tissue storage service, which is the centre activity licensed by the HFEA.
- The HTA inspection was performed five months before this HFEA inspection, so findings are relatively current. The Person Responsible (PR) assured the HFEA inspection team that the practices and procedures used at the centre remain unchanged from those reviewed at the time of the HTA inspection.
- The regulatory requirements of the HTA and the HFEA have considerable commonality, as the European Union Tissues and Cells Directives (EUTCDs) are a major component of the regulatory frameworks of both organisations. Thus many HTA standards, with which the centre was fully compliant, are equivalent to HFEA standards.

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 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 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 practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of their 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 was one 'other' area of practice that required improvement.

The PR has provided evidence that the following recommendation has been implemented:

'Other' areas of non-compliance:

- the PR should ensure that the door to the cryostore room displays appropriate signs describing the potential health and safety risks to personnel entering.

Recommendation to the Executive Licensing Panel

The centre has no critical or major areas of concern.

The inspection team recommends the renewal of the centre's storage only licence for a period of four years without 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 ovarian tissue and oocytes and the patients to whom they relate, are compliant with HFEA requirements. This ensures that no mismatches occur between patients and stored ovarian tissue and oocytes when used in medical treatment.

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 notes 11)
The centre does not recruit donors; therefore this area of practice is not relevant to this inspection.

Payments for donors (Guidance note 13; General Directions 0001)
The centre does not recruit donors; therefore this area of practice is not relevant to this inspection.

Donor assisted conception (Guidance note 20)
The centre does not treat people with donated gametes or embryos; therefore this area of practice is not relevant to 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 broadly 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 centre's third parties providing ovarian tissue procurement and oocyte storage services as well as laboratories conducting tests that impact on the quality and safety of gametes are suitable.

The centre is compliant with HFEA requirements to process ovarian tissue and any oocytes harvested as a result of this, in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or 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 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; Medicines management; Pre-operative assessment and the surgical pathway; Multiple births (Guidance note 7; General Directions 0003)
The centre does not provide fertility or other medical treatment and tissue procurement is undertaken in the main hospital theatres under third party agreement. Therefore these areas of practice were not considered relevant to this inspection.

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 ovarian tissue and any oocytes harvested, in licensed activity, based on the patient's medical history and therapeutic indications.

Transport and distribution of gametes and embryos (Guidance note 15; Directions 0009)
On the basis of the HTA inspection report and discussions with the PR and staff, the procedures in place for the safe transport of ovarian tissue and any immature oocytes harvested, 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 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 does not receive gametes from other centres and so this area is not relevant to this inspection.

Imports and exports (Guidance note 16; General Direction 0006)
The centre does not import or export gametes or embryos; therefore this area of practice is not relevant to this inspection.

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 establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

The HTA inspection report findings as well as observations on this inspection confirm that the centre has a QMS in place that is compliant with HFEA requirements.

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

Transport and satellite agreements (Guidance note 24; Directions 0010)
The centre does not have any transport or satellite agreements therefore this area of practice is not relevant to this inspection.

Equipment and materials (Guidance note 26)
On the basis of evidence provided by the HTA inspection report, discussions with staff and observations on inspection, equipment and material used at the centre to store tissues and cells is compliant with HFEA requirements.

All of the equipment and materials used in licensed activity is validated, designated for the purpose and is appropriately maintained in order to minimise any hazard to staff.

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

Process validation (Guidance note 15)
On the basis of the HTA inspection report and discussions on inspection, the inspection team concluded that the centre is 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 has not reported any adverse incidents (including serious adverse events and reactions) to the HFEA however, the PR is aware of the reporting requirements. There are systems in place to ensure that adverse events will be reported and investigated and that corrective or preventative measures will be put in place.

What the centre could do better

Safety and suitability of premises and facilities (Guidance note 25)
The door to the cryostore room does not notify personnel of the potential health and safety risks upon entering (SLC T17; recommendation 1).

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 more than two years of practical experience which is directly relevant to the activity authorised by the licence. The PR has completed the HFEA PR Entry Programme (PREP certificate T/1242/81).

Staff (Guidance note 2)
The centre has suitably qualified and competent staff, in sufficient number, to carry out

the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

As a storage-only centre, the centre is not required to have access to a nominated registered medical practitioner, within the UK, to advise on or oversee medical activities. It was clear to the inspection team however that there is a strong and positive interaction between the staff at the storage centre and the medical staff treating the patients from whom ovarian tissue is procured.

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 does not provide fertility treatment; therefore this area of practice is not relevant to this inspection.

Safeguarding
The centre does not provide fertility or other medical treatment and tissue procurement is undertaken in the main hospital theatres under third party agreement. Therefore this area of practice was not considered relevant to the inspection of this centre.

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)

These areas of practice are not applicable to this inspection.

2. The experience of patients

Patient feedback

What the centre does well
The centre does not itself provide fertility or other medical treatment so patient feedback to centre staff or the HFEA was not available.

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 does not provide licensed treatment to patients; therefore this area of practice is not applicable to this inspection.

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 providing consents to licensed treatment activities.

Gamete sharing arrangements (Guidance note 12; General Direction 0001); Surrogacy (Guidance note 14)
The centre does not offer gamete sharing services or surrogacy treatments therefore these areas of practice are not applicable to this inspection.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to client complaints. This is important to ensure that the centre uses client 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. OHVB is secure and paper and electronic patient records are stored securely with access limited to HFEA licensed staff.

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

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's procedures for providing information to patients are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients 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 procedures for obtaining HFEA related consent are compliant with HFEA requirements. This ensures that patients have provided all relevant consents before carrying out any licensed activity.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre does not provide any patient identifying information to the HFEA register, therefore this area of practice is not applicable to this inspection.

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
This area of practice is not applicable to 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 all relevant HFEA and HTA 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)
On the basis of evidence provided by the HTA inspection report, discussions with staff and observations on inspection the centre's procedures for ovarian tissue storage are compliant with HFEA requirements. These measures ensure that gametes and embryos will be stored appropriately to maintain their quality and safety.

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)
On the basis of the HTA inspection report and a review of patient records on inspection, the centre has procedures for records management that 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 is not required to submit information about ovarian tissue procurement activities to the Authority.

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

Section 3: Monitoring of the centre's performance

Following the initial inspection in May 2013, recommendations for improvement were made in relation to two major and one 'other' area of non-compliance.

The PR provided information and evidence that all recommendations have been addressed.

On-going monitoring of centre success rates

The centre does not provide treatment to patients so has no success rates to monitor through the risk tool.

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) The door to the cryostore room does not notify personnel of the potential health and safety risks upon entering.	The PR should ensure that the door to the cryostore room displays appropriate signs describing the potential health and safety risks to personnel entering, by the time that this report is considered by a licensing committee. The PR should notify the centre's inspector when this recommendation has been implemented.	The old sign has been removed and a new sign is already in place	The Executive acknowledges the PR's response. **No further action is required.**

Reponses from the Person Responsible to this inspection report