Executive Licensing Panel Minutes

Centre 0332 (Oxford Cell and Tissue Biobank)

Interim Inspection Report

Date:	27 July 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Clare Ettinghausen (Chair) Helen Crutcher Anna Coundley	Director of Strategy and Corporate Affairs Risk and Business Planning Manager Policy Manager
Executive:	Bernice Ash	Secretary
Observers	Catherine Burwood Julia Chain	Licensing Manager HFEA Chair (Induction)

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:

- 9th edition of the HFEA Code of Practice.
- Standard licensing and approvals pack for committee members.

1. Consideration of Application

1.1. The panel noted that The Oxford Cell and Tissue Biobank has held a storage only licence with the HFEA since 2013.

1.2. The panel noted that ovarian tissue is procured in hospitals throughout England and Wales, under the auspices of third party agreements with centre 0332. The tissue is transported to the centre for processing and storage. Immature eggs can be harvested from ovarian tissue during processing. These eggs used to be transported to Oxford Fertility (0035) for in vitro maturation and storage; this aspect of the service is currently suspended, but the Person Responsible (PR) does have long term plans to restart this under their licence and may process and store the immature eggs at centre 0332.

1.3. The panel noted that the centre also procures and stores testicular tissue for young boys who must undergo rapid medical treatment which may cause them to become infertile. This tissue is likely to be used in a transplantation approach, however, depending on the development of technology in this fast moving area, an in vitro approach to fertility preservation could feasibly be used in future.

1.4. The panel noted that a HFEA licence is not required for ovarian and testicular tissue processing and storage if the tissue will subsequently be used in a transplantation approach to fertility treatment: such activities are performed under the centre's licence from the Human Tissue Authority (HTA). However, the centre has a HFEA licence because of its plans to process and store immature eggs.

1.5. The panel noted that the regulatory requirements of the HTA and the HFEA have considerable commonality. The HTA last inspected this centre in February 2019 and found one minor shortfall; this was addressed immediately following the inspection visit.

1.6. The panel noted that, in March 2020, the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19). In response to UK measures to contain and mitigate the spread of the virus, new inspection methodologies were developed and implemented. These methods enable compliance to be reviewed through desk based assessment (DBA) and the use of virtual technology where available and appropriate. A risk based approach (RBA) can then be applied, balancing the risks of on-site inspection during the Covid-19 pandemic against those resulting from potential non compliances, identified during DBA, if not adequately investigated.

1.7. The panel noted that HFEA licensed premises must be inspected on site every two years in accordance with Schedule 3B paragraph (4)(1) of the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended). Whilst the current restrictions of the pandemic do not prohibit on-site inspection, the risks of doing so must be balanced against the need for the Authority to fulfil its legal duties.

1.8. The panel noted that the centre was last inspected in March 2019, therefore an on-site inspection should usually be conducted by March 2021. Following the DBA/RBA for this centre, it was concluded that any items of concern identified were of relatively low risk and could be reviewed effectively using virtual technology rather than on-site inspection. This removed the risks to staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

1.9. The panel noted that the DBA, followed by a short virtual inspection, was conducted on 1 June 2021 and this included videoconferencing with key members of staff. The centre's own

assessment of its service, the progress made in implementing the actions identified at the last inspection and on-going monitoring of the centre's performance was also taken into account.

1.10. The panel noted that at the time of the inspection, there were no recommendations for improvement.

1.11. The panel noted the centre is well led and provides a good level of patient support.

1.12. The panel noted that the inspection team recommends the continuation of the centre's storage only licence.

2. Decision

2.1. The panel was satisfied the centre was fit to have its storage only licence continued.

3. Chair's signature

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

Signature

Name

Clare Ettinghausen

Date

29 July 2021

Interim Licensing Report

Centre name: Oxford Cell and Tissue Biobank
Centre number: 0332
Date licence issued: 5 August 2019
Licence expiry date: 4 August 2023
Additional conditions applied to this licence: None
Date of inspection: 1 June 2021
Inspectors: Sara Parlett and Bernadette O'Leary
Date of Executive Licensing Panel: 27 July 2021

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years, although some centres have had their licence extended to five years due to the Covid-19 pandemic (five years being the maximum length of a treatment licence permitted by law). The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of an interim inspection, at the mid-point of the licence period.

In March 2020, the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19). In response to UK measures to contain and mitigate the spread of the virus, new inspection methodologies were developed and implemented.

These methods enable compliance to be reviewed through desk based assessment (DBA) and the use of virtual technology where available and appropriate. A risk based approach (RBA) can then be applied, balancing the risks of on-site inspection during the Covid-19 pandemic against those resulting from potential non compliances, identified during DBA, if not adequately investigated.

HFEA licensed premises must be inspected on site every two years in accordance with Schedule 3B paragraph (4)(1) of the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended). Whilst the current restrictions of the pandemic do not prohibit on-site inspection, the risks of doing so must be balanced against the need for the Authority to fulfil its legal duties.

This centre was last inspected in March 2019, therefore an on-site inspection should usually be conducted by March 2021. However, following the DBA/RBA for this clinic, it was concluded that any items of concern identified during the DBA were of relatively low risk and could be reviewed effectively using virtual technology rather than on-site inspection. This removed the risks to staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

This inspection was therefore carried out by desk based assessment followed by a short virtual inspection, which included videoconferencing with key members of centre staff.

The current foci for an interim inspection are:

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers, and the individuals who deliver that care.
- **Patient experience:** understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel (ELP) with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

Summary for licensing decision

The inspection team recommends the continuation of the centre's licence.

The centre is well led and provides a good level of patient support.

The ELP is asked to note that this report makes no recommendations for improvement.

Information about the centre

The Oxford Cell and Tissue Biobank has held a storage only licence with the HFEA since 2013.

The centre provides an ovarian tissue storage service for women and children who are to undergo chemotherapy or radiotherapy and are at risk of premature ovarian failure.

Ovarian tissue is procured in hospitals throughout England and Wales, under the auspices of third party agreements with centre 0332. The tissue is transported to the centre for processing and storage.

Immature eggs can be harvested from ovarian tissue during processing. These eggs used to be transported to Oxford Fertility (0035) for in vitro maturation and storage. This aspect of the service is currently suspended, but the PR does have long term plans to start it again under their licence and may process and store the immature eggs at centre 0332.

The centre also procures and stores testicular tissue for young boys who have to undergo rapid medical treatment which may cause them to become infertile. This tissue is likely to be used in a transplantation approach, however, depending on the development of technology in this fast moving area, an in vitro approach to fertility preservation could feasibly be used in future.

A HFEA licence is not required for ovarian and testicular tissue processing and storage if the tissue will subsequently be used in a transplantation approach to fertility treatment: such activities are performed under the centre's licence from the Human Tissue Authority (HTA). However, the centre has a HFEA licence because of its plans to process and store immature eggs.

The regulatory requirements of the HTA and the HFEA have considerable commonality. The HTA last inspected at this centre in February 2019 and found one minor shortfall that was addressed immediately following the inspection visit.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes: they are important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Pregnancy outcomes

This inspection theme is not relevant as the centre does not offer treatment services.

Multiple births

This inspection theme is not relevant as the centre does not offer treatment services.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches and that identification errors do not occur. The inspection team was able to discuss witnessing practices with staff and reviewed the centre's latest witnessing audit. These activities indicated that witnessing procedures are compliant with HFEA requirements.

Consent: To the storage of cryopreserved material

The storage of ovarian and testicular tissue containing immature gametes is an important service offered by this clinic. It enables patients to preserve their fertility prior to undergoing medical treatment such as radiotherapy. It is important that the centre has measures in place to ensure that this material is stored in accordance with the consent of the gamete providers.

On inspection, consent practices were discussed with staff and the centre's consent audit was reviewed. These activities indicate that the centre's processes for obtaining consent are compliant with HFEA requirements.

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

The inspection team considered that staffing levels are suitable for the storage related activity. The centre has a large multidisciplinary team encompassing consultant paediatricians, surgeons, tissue bank coordinators and laboratory technicians.

Quality Management System (QMS)

It is important that centres audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following standard operating procedures and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any necessary changes that are identified are made, as this supports continuous improvement.

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: witnessing, consent and CE marking.

The centre's procedures for auditing and acting on the findings of audits are compliant with requirements.

We also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture then it is important that they act to review their practices when guidance is issued by the HFEA or other bodies. Due to the unique services provided by the clinic, limited HFEA guidance applies to their activities. However, the inspection team is assured that any such information, including via Clinic Focus publications, is reviewed by the PR and centre staff and applied where appropriate. For example the 'emotional support for patients' resources available on our website were used by the clinic to inform their patient support protocols and to provide staff training.

Medicines management

This inspection theme is not relevant as the centre does not offer treatment services.

Prescription of intralipid 'off label'

This inspection theme is not relevant as the centre does not offer treatment services.

Infection Control

This inspection theme is not relevant as the centre does not offer treatment services.

Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes are approved for the provision of fertility treatment, to ensure the safety of gametes and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The CE mark status of a sample of medical devices was reviewed in the course of the inspection. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

Patient support

New HFEA guidance strengthens support provided by staff at all levels to patients, so as to improve their emotional experience of care. All clinics should have a policy outlining how appropriate psychosocial support from all staff is provided to patients, donors and their partners, before, during and after treatment. All staff should understand their responsibilities and be provided with appropriate training, information and functional aids to assist them. Patient feedback should be collected to enhance the patient support procedures.

Although this HFEA guidance is focussed on centres providing IVF treatment, the guidance has been considered by this clinic and applied as appropriate. The centre's patient support procedures are compliant with HFEA guidance.

Patient feedback

The centre does not provide treatment services so patient feedback to the HFEA was not available. The centre is committed to getting feedback on the service. The centre's own most recent patient/parent survey responses from January to April 2021 were reviewed and provided very positive feedback.

Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

Compliance with HFEA standard licence conditions

Information submitted by the centre in their self assessment questionnaire, the pre-inspection assessment and observations during the visit to the centre, indicate that the centre is fully compliant with HFEA requirements.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2019, recommendations for improvement were made in relation to one major area of non compliance.

The PR subsequently provided information and evidence that the recommendation was fully implemented.

On-going monitoring of centre success rates

This inspection theme is not relevant as the centre does not offer treatment services.

Provision of information to the HFEA

This inspection theme is not relevant as the centre does not offer treatment services.

Legal parenthood

This inspection theme is not relevant as the centre does not offer treatment services.

Leadership

The centre is compliant with HFEA guidance regarding effective leadership.

Good leadership improves patient care and is encouraged by the HFEA. A PR should have the necessary authority and autonomy to carry out the role. The PR should ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about patient care. The PR is legally accountable for the overall performance of the centre and should establish clear responsibilities, roles and systems of accountability to support good governance, including ensuring that appropriate action is taken following all forms of feedback from the HFEA or patients.

Annex 1

Areas of practice that require the attention of the Person Responsible

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 made.

Critical areas 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 child who may be born as a result of treatment services. A critical 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 identified.			

‘Major’ areas 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 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;
- which can comprise 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
None identified.			

‘Other’ areas of practice that require improvement

‘Other’ areas of practice that require improvement are any areas of practice in which failings occur, which cannot be classified as either a critical or major area of non compliance, but which indicate 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
None identified.			

Additional information from the Person Responsible