Executive Licensing Panel - minutes

Centre 0352 (Future Health Biobank)

Interim Inspection Report

Friday, 20 July 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Erin Barton Kathleen Sarsfield Watson	Director of Strategy and Corporate Affairs Policy Manager Communications Manager
Members of the Executive	Richard Chamberlain Bernice Ash	Secretary Committee Secretary
External adviser		
Observers	Catherine Burwood	Senior Governance Manager

Declarations of interest

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

The panel had before it:

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

1. Consideration of the application

1.1. The panel noted that Future Health Biobank is located in the Faraday Building on Nottingham Science Park and had held a storage only licence since September 2016. The licence was varied in November 2017 to change the Person Responsible (PR) and the Licence Holder (LH).

1.2. The panel noted that the centre had also held a Human Tissue Authority (HTA) licence since 2006 to allow procurement, processing, testing, storage, distribution and import/export of human tissues and cells for human application. Many HTA standards, with which the centre had demonstrated compliance, are equivalent to HFEA standards, both sets of standards being derived from the European Union Tissues and Cells Directives. The HTA inspection was performed eight months prior to this HFEA inspection, so its findings are current. The PR advised that practices and procedures relevant to the HFEA licensed activities were unchanged from those reviewed at the HTA inspection.

1.3. The panel noted that the centre did not provide treatment services but offered gamete and embryo storage services to other HFEA licensed centres under long term service contracts or as part of a long-term contingency response to an emergency, but no such contracts had been made so far, therefore no gametes and embryos had yet been stored under the HFEA licence. However, procedures for ensuring effective consents to storage were in place and were discussed with the PR and were considered compliant with HFEA requirements.

1.4. The panel noted that the minutes of the approval of the centre's initial licence endorsed the inspectorate's recommendation to carry out an interim inspection during the first year of the licence, to monitor the centre's progress and performance. The executive sought to undertake an inspection at the centre in August/September 2017. However, centre staff advised that the centre had undertaken no licensed activity up to that time, nor was any planned. The executive judged an inspection at that time would be disproportionate and so delayed the interim inspection until the new business year.

1.5. The panel noted that the HTA undertook a routine inspection of the proposed centre in September 2017 and identified two major and nine minor shortfalls to HTA Standards. On this inspection, the Person Responsible (PR) advised that all but two of the shortfalls have been addressed and that actions are on-going to address these remaining two non-compliances. The HFEA inspector considers that the HTA inspection report provides suitable and appropriate evidence for compliance with HFEA requirements in many areas because:

- Many HTA standards, with which the centre has demonstrated compliance, are equivalent to HFEA standards, both sets of standards being derived from the European Union Tissues and Cells Directives.
- The HTA inspection was performed only eight months prior to this HFEA inspection, so findings are current. The PR advised that practices and procedures relevant to the HFEA licensed activities were unchanged from those reviewed at the HTA inspection.

1.6. The panel noted that the inspection took place on 24 April 2018 and not all interim inspection themes were relevant to this centre's storage only facility.

1.7. The panel noted that information about areas of non-compliance was limited due to the lack of storage business received, but that the inspector had noted non-compliance in two areas of the Quality Management System (QMS) of which recommendations had been completed or were to be completed by the time the PR's report was to be delivered on 24 July.

1.8. The panel noted that the inspectorate recommends the continuation of the centre's storage only licence.

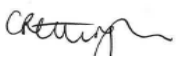
2. Decision

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

30 July 2018

Interim Licensing Report

Centre name: Future Health Biobank
Centre number: 0352
Date licence issued: 16 September 2016
Licence expiry date: 15 September 2020
Additional conditions applied to this licence: none
Date of inspection: 24 April 2018
Inspectors: Andrew Leonard
Date of Executive Licensing Panel: 20 July 2018

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 and must, by law, be inspected every two years. 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 a short notice interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. The focus of an interim inspection is:

- **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 with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

The inspector recommends the continuation of the centre's licence.

The Executive Licensing Panel is asked to note that this report makes two recommendations to address 'other' areas for improvement.

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

- The PR should ensure that SOPs are regularly reviewed and out of date content is updated appropriately.

The PR has committed to implement the following recommendation and actions to do so have been started but are not yet completed:

- The PR should implement a process to ensure that changes to HFEA requirements and guidance published in Clinic Focus articles, are considered by the PR and are, where necessary, embedded in the centre's practices

Information about the centre

Future Health Biobank is located in the Faraday Building on Nottingham Science Park and has held a 'storage only' licence since September 2016. The licence was varied in November 2017 to change the Person Responsible (PR) and the Licence Holder (LH).

The centre has held a Human Tissue Authority (HTA) licence since 2006, to allow procurement, processing, testing, storage, distribution and import/export of human tissues and cells for human application. The centre processes and stores relevant material derived from the human body for use in scheduled purposes; thus the centre is also regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA). The centre's quality management system (QMS) is certified to ISO standard 9001:2008, and is in the process of transitioning to ISO standard 9001:2015.

The company does not provide treatment services but uses its cryostorage expertise to offer gamete and embryo storage services to other HFEA licensed centres, under long term service contracts or as part of a planned contingency response to an emergency. The centre has however not yet developed any such contracts for the provision of storage services, so no gametes and embryos have yet been stored under the HFEA licence. The PR clarified during the inspection that the centre is keen to develop this area of activity.

The inspection team notes that the minutes of the ELP's approval of the centre's initial licence endorsed the inspectorate's recommendation to carry out an interim inspection during the first year of the licence, to monitor the centre's progress and performance. The executive sought to undertake an inspection at the centre in August/September 2017, however centre staff advised that the centre had undertaken no licensed activity up to that time, nor was any planned. The executive judged an inspection at that time would be disproportionate and so delayed the interim inspection until the new business year.

Details of inspection findings

The ELP is asked to note that not all interim inspection themes were relevant to the inspection of this 'storage only' facility.

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

The HTA undertook a routine inspection of the proposed centre in September 2017 and identified two major and nine minor shortfalls to HTA Standards. On this inspection, the PR advised that all but two of the shortfalls have been addressed and that actions are on-going to address these remaining two non compliances. The HFEA inspector considers that the HTA inspection report provides suitable and appropriate evidence for compliance with HFEA requirements in many areas because:

- Many HTA standards, with which the centre has demonstrated compliance, are equivalent to HFEA standards, both sets of standards being derived from the European Union Tissues and Cells Directives.
- The HTA inspection was performed only eight months prior to this HFEA inspection, so findings are current. The PR advised that practices and procedures relevant to the HFEA licensed activities were unchanged from those reviewed at the HTA inspection.

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 and multiple births

These inspection themes are not relevant as the centre does not offer treatment services.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur.

The proposed witnessing procedures were discussed with the PR during the inspection because no licensed material has yet been stored at the centre. The centre operates a business model where they will take receipt of locked storage dewars from other HFEA licensed centres (the 'primary' centres) and then store them in a compliant manner. Both receipt and subsequent dispatch of dewars will be witnessed. Under this business model, the centre will not access samples within the dewars. All such manipulation will be the responsibility of staff from the primary centres, who will visit the proposed centre but will operate to their own witnessing procedures.

The proposed centre is compliant with HTA requirements related to witnessing, suggesting that if any manipulation of individual samples were to be necessary, it will be done in a compliant manner.

Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures and to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

No gametes or embryos have yet been stored at the centre, however procedures for ensuring effective consents to storage are in place were discussed with the PR and were considered compliant with HFEA requirements. The HFEA licensed centre sending cryopreserved material to Future Health Biobank will retain consent to storage documentation and remain responsible for the monitoring of storage consent expiry dates. The centre will ensure that stored gametes and embryos have effective consent by regularly reviewing the dewar stock sheets, which will include the storage consent expiry dates for each sample, to ensure all samples are within their consented storage period.

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 centre does not currently store HFEA licensed material, but staffing levels were discussed with the PR. She described the current level of staffing and proposed changes related to recent changes to the organisational structure. The inspector considered that staffing levels in the centre appeared suitable to support any storage activity arising at short notice due to an emergency at another HFEA licensed centre.

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 prescribed 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 centre has yet to undertake any licensed activity so no audits against HFEA requirements could be reviewed. The effectiveness of the centre's QMS was assessed by reviewing: the recent HTA inspection report and corrective actions taken by the PR; the draft version of the annual review of the QMS; a storage audit; SOPs for proposed HFEA regulated activities. These activities confirm that the centre has a QMS in place that is compliant with HFEA requirements.

The effectiveness of the clinic's processes for implementing learning was also considered. If a clinic is to achieve continuous improvement and encourage a learning culture then it is important that it acts to review practices when guidance is issued by the HFEA or other bodies. The inspector was not satisfied that the PR acts upon guidance issued in the Clinic Focus articles and disseminates the information to the rest of the team. This is because the PR and key staff have not signed up to receive Clinic Focus emails (Recommendation 1).

Medicines management

It is important that clinics follow best practice for medicines management to protect patients and ensure that medicines are stored, administered and disposed of in the correct way.

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

Infection Control

It is important that clinics have suitable arrangements in place so that patients experience care in a clean environment and to prevent patients and staff acquiring infections.

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 and/or embryos are approved for the provision of fertility treatment, to ensure the safety of gametes, embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The centre only stores gametes and embryos as they are supplied in vessels and media by other HFEA licensed centres.

Patient experience

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

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 compliant with HFEA requirements with one exception:

- Two standard operating procedures (SOPs 333v1 and 334v2) have not been reviewed recently and contain contact details for a staff member who is no longer employed at the centre (Recommendation 2).

Compliance with recommendations made at the time of the last inspection

Following the new licence inspection on 19 July 2016, no recommendations for improvement were made.

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.

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 carried out.

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 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	Inspection team's response to the PR's statement
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 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.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
None			

‘Other’ areas of practice that requires improvement

Other areas of practice that require improvement are any area 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.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1) **Quality management system** The PR and key staff have not signed up to receive Clinic Focus emails, therefore the inspector was not satisfied that a system is in place to ensure that the centre acts upon guidance issued in Clinic Focus articles and disseminates the guidance to the team. The inspector notes that few Clinic Focus articles are relevant to storage only centres and this shortfall has not yet led to non compliant practice.	The PR should implement a process to ensure that changes to HFEA requirements and guidance, published in Clinic Focus articles, are considered by the PR and are, where necessary, embedded in the centre’s practices. The PR should review past Clinic Focus articles at https://portal.hfea.gov.uk/knowledge-base/clinic-focus/ to ensure that changes to guidance have, where necessary, been implemented in the QMS. The results of this review and actions taken to implement this recommendation should be reported to the centre’s inspector by 24 July 2018.	The PR has signed up to Clinic Focus. Full review of the newsletter will take place monthly and be documented during the laboratory audit performed by the PR. Review of past Clinic Focus articles from the time the licence was granted (Sept 2016) will be included in the laboratory audit to be completed in June 2018 to ensure any changes in guidance are actioned.	The inspection team notes the PR’s response which suggests that actions are being taken to implement this recommendation. The inspection team looks forward to receiving the PR’s report on the 24 July 2018, but notes that the inspection report is to be presented to the ELP on 20 July 2018, just before this deadline. The inspection team considers that this recommendation – which will be followed up by the centre’s inspector - is to address an ‘other’ non compliance only, and advises that questions regarding its completion should not impact on a decision regarding the continuation of the licence.

2) **Quality management system** Two SOPs (333v1 and 334v2) have not been reviewed recently and contain contact details for a staff member who is no longer employed at the centre (SLC T33b; CoP Guidance 31.9).	The PR should ensure that SOPs are regularly reviewed. The two SOPs in question should be updated appropriately, e.g. to include contact details for a relevant member of current staff. The revised SOPs should be provided to the centre's inspector with the PR's response to this report.	Change Request CR0981 is open for the Department Manager to review and update both documents before 29th June 2018. The SOP update will remove the name of the staff member in favour of the job title of the person responsible. The current QMS procedure is for a bi-annual audit of all SOPs.	The inspection team notes the PR's response which indicates that actions have been taken to implement this recommendation. No further actions are required

Additional information from the Person Responsible