Interim Licensing Report

Centre name: **Fisher Bioservices UK**
Centre number: **0300**
Date licence issued: **01/08/2009**
Licence expiry date: **31/07/2014**
Additional conditions applied to this licence: **None**
Date of inspection: **22/01/2013**
Inspector: **Douglas Gray**
Date of Executive Licensing Panel: **15/03/2013**

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 an 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. For 2012-14 the focus of an interim inspection is:

- **Quality of service**: the quality of service provided by a centre, including its success rates and performance in reducing multiple births – the biggest single risk of IVF.
- **Patient experience**: it is considered crucial that the experiences of service users feed into any evaluation of a centre's performance.

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

This report has enabled the inspector to form a conclusion on the continuation of the centre's licence. The inspector recommends the continuation of the centre's licence.

The ELP is asked to note that a recommendation for improvement in relation to one 'other' area of non-compliance has been made:

- The Person Responsible (PR) should ensure that access to stored licensed material is controlled. This includes ensuring that access controlled doors are operating as intended.

Since the inspection, the PR has confirmed that access controlled doors are operating as intended. Suitable security measures have been proposed should the centre accept gametes or embryos into storage.

Information about the centre

Fisher Bioservices UK is located in Bishops Stortford, Essex and has held a HFEA storage licence since August 2008. The centre is a storage facility for tissues and cells and holds a Human Tissue Authority (HTA) license, and is regulated by the Medicines and Healthcare products Regulatory Agency (MHRA) as a Good Manufacturing Practice (GMP) facility.

The centre also provides a disaster recovery service for the emergency transfer of cryopreserved cells and tissues which extends to the storage of gametes and embryos. At the time of this inspection, the PR confirmed that no gametes or embryos have ever been stored at the centre.

Details of Inspection findings

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

Quality of Service

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

Outcomes[1]

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

Multiple births[2]

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

Witnessing

This inspection theme is relevant because placing gametes or embryos into, and removing from cryopreservation are critical witnessing steps. The proposed procedures for ensuring witnessing of relevant critical steps were considered compliant with HFEA requirements. There was however no observation of witnessing practices, or review of witnessing records during this inspection as no gametes or embryos have ever been stored at the centre.

Consent: Disclosure to researchers

This inspection theme is not relevant as the centre does not seek consent decisions from patients. Consent to disclosure documentation will be retained by the client.

[1] The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems.
[2] The HFEA use a conversion factor of 1.27 to convert the multiple live birth rate (MLBR) target to a multiple clinical pregnancy rate (MCPR) target. The 2010/11 MLBR target of 20% is calculated as equivalent to a MCPR of 25%: the 2011/12 MLBR target of 15% is calculated as equivalent to a 19% MCPR.

Consent: To the storage of cryopreserved material

The client will retain consent to storage documentation. The centre will ensure that stored gametes and embryos have effective consent by auditing their client's consent documentation annually or more frequently if required. The proposed procedures for ensuring effective consent to storage is in place were considered compliant with HFEA requirements following the last inspection. However, no gametes or embryos have ever been stored at the centre.

Staffing

Staffing levels observed during the inspection appeared suitable for the proposed storage related activity. It is particularly noteworthy that the centre has a dedicated quality team.

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

From the information submitted by the centre in their self assessment questionnaire and from observations during the visit to the centre, the inspector identified one non-compliance;

- Two access controlled doors were found to be open (the external reception door, and one internal door) (see recommendation 1). However, additional levels of access restriction would have to be compromised before unauthorised access to storage areas could be gained.

Compliance with recommendations made at the time of the last inspection

Following an interim inspection in 2011 recommendations for improvement were made in relation to three areas of major non-compliance and one 'other' area of non-compliance.

The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales, with the following exception:

- The centre must establish procedures for ensuring that access to confidential identifying information (labelling on cryopreserved material, for example) would only be disclosed in circumstances permitted by law (SLC T43).

  Following the last inspection, the PR committed to controlling access to storage vessels designated for gametes and embryos using lockable units and a segregated area. These measures have not yet been implemented and are not likely to be until a HFEA licensed centre client is identified. Access control was discussed during the

inspection and in particular what measures could be put in place should material be transferred to the centre for storage in a disaster recovery situation. The PR has committed to controlling access to storage containers using other methods than those initially proposed at the time of the last inspection which can be implemented quickly, should the centre accept gametes or embryos at short notice (see recommendation 1).

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.

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	Inspection team's response to the PR's statement
1. The PR has not yet implemented measures to ensure that access to stored licensed material is controlled. Section 33A, HF&E Act 1990 (as amended).	The PR should ensure that access to stored licensed material is controlled. This includes ensuring that access controlled doors are operating as intended. This should be implemented before licensed material is accepted for storage. The PR should ensure SOPs adequately describe procedures for controlled access, paying particular	Corrective action: Doors identified that were not closing properly were the dispatch door and the main door into the repository. This was due to the door mechanism being too loose. Within the week the facility manager had corrected all the door issues. Preventative Action: In relation to the acceptance of HFEA material in event of a client disaster.	We consider the PR's proposal regarding temporary access measures as suitable. We request that the PR forwards to their inspector a copy of their SOP once completed.

	attention to temporary access control measures should gametes or embryos be accepted for storage at short notice. The PR should forward the amended SOP to their HFEA inspector by 22 April 2013.	As a temporary solution all HFEA material will be stored in the mezannine ambient. This room is access controlled and if required can be restricted on site to trained personnel. The Liquid nitrogen tanks will be manually filled. Once HFEA material enters the site, the plan for implementing a electronically access controlled cage will be re-assessed. Meanwhile an SOP on HFEA requirements and what to do if we have an emergency request will be completed. Completion date: 15th April 2013.	

Additional information from the Person Responsible

HFEA Executive Licensing Panel Meeting

15 March 2013

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

Minutes – Item 2

Centre 0300 – (Fisher Bioservices UK) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Mark Bennett – Director of Finance and Facilities (Chair) Ian Peacock – Analyst Programmer Matthew Watts – Regulatory Policy Manager	Rebecca Loveys

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of 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 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 Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that this is a storage only centre and that it has held a storage licence from the HFEA since 2008.

2. The Panel noted that the centre's current licence is due to expire on 31 July 2014.

3. The Panel noted that, at the time of the inspection, no gametes or embryos had ever been stored at the centre. The Panel noted that the facility is also regulated by the Human Tissue Authority and the Medicines and Healthcare Regulatory Authority.

4. The Panel noted that the Inspectorate identified no critical, no major and one other area of non-compliance. The one non-compliance related to access control, which the Person Responsible (PR) had since reported as resolved.

5. The Panel noted that there are few storage only centres, and that the business continuity / resilience of such centres is key to their planned role in disaster recovery for other clinics.

6. The Panel suggested that, before or during the centre's next inspection, evidence of a 'walk-through' or 'live test' (without gametes but with a dewar, say) is provided for the Inspectorate.

7. The Panel noted that such a test of the centre's procedures would require approval of the PR and requested the Inspectorate to discuss this with the PR.

Decision

8. The Panel agreed to the inspectorate's recommendation to continue the centre's licence with no additional conditions.

Signed:
Mark Bennett (Chair)

Date: 26 March 2013