Interim Inspection Report

Date of Inspection: 1 March 2011
Purpose of inspection: Interim inspection of storage licence
Length of inspection: 5 hours
Inspectors: Miss Allison Cummings and Mrs Sara Parlett

Inspection details:
The report covers the pre-inspection analysis, the visit and information received between 20 January 2009 and 13 May 2011.

Date of Executive Licensing Panel: 13 May 2011.

Purpose of the Inspection report
The purpose of the inspection is to assess whether centres are complying with the HF&E Act 1990 (as amended), the HF&E Act 2008 and the Code of Practice to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence interim inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Authority's Executive Licensing Panel which makes the decision about the continuation of the centre's licence.

Centre details

Centre Name	Fisher Bioservices UK
Centre Number	0300
Licence Number	L0300/2/b
Centre Address	Unit 1 Woodside Bishop's Stortford Hertfordshire CM23 5RG
Telephone Number	01279 713320
Person Responsible	Colin Grant
Licence Holder	Robert Jones
Date Licence issued	01/08/2009
Licence expiry date	31/07/2014
Additional conditions applied to this licence	none

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Report to Executive Licensing Panel

Recommendation to the Executive Licensing Panel:

The Executive Licensing Panel is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including three major areas of non-compliance and one other area of non-compliance.

Since the inspection visit, the Person Responsible (PR) has confirmed that the following recommendation has been fully implemented:

Other areas of practice that requires improvement:

- The PR should establish quality indicators for witnessing.

The PR has given a commitment to fully implement the following recommendations:

Major non-compliance:

- The PR should ensure that there are robust systems in place to ensure that cryopreserved material is not stored without written consent;
- The PR should establish a witnessing protocol for double checking the identification of samples and the patients or donors to whom they relate at all critical points of the laboratory process;
- 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.

The inspector considers that, overall, there is sufficient information available to recommend the continuation of the centre's licence years without additional conditions but this recommendation is made subject to the full implementation of these recommendations prior to any cryopreserved material being accepted for storage.

Details of Inspection findings

Brief description of the centre and its licensing history:

Fisher Bioservices UK was initially licensed by the HFEA as a storage only centre on 24 July 2008. It had its first renewal inspection on 20 January 2009 and a licence was granted for five years with no additional conditions, taking effect from 1 August 2009.

The PR completed the PR Entry Program (PREP) in 2008 and is suitably qualified and experienced for the role.

The centre is licensed to store human tissue by the Human Tissue Authority (HTA), Medicines and Healthcare products Regulatory Agency (MHRA) and has a quality management system (QMS) in place which is ISO certified (ISO 9001:2008).

Prior to this inspection, the PR confirmed that they have not stored gametes or embryos since being licensed in 2008.

The Executive Licensing Panel is asked to note that requirements related to the following themes were not relevant to this inspection and have not been commented on:

- costed treatment plans;
- legal parenthood;
- multiple births;
- consent to disclosure;
- gamete and embryo donation, reimbursement, information provision and screening;
- validation of critical processes;
- welfare of the child (in relation to basic partner services only);
- embryo testing.

Activities of the Centre:

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓
Research	n/a

1. Focus of inspections for 2010-12

Consent to storage
What the centre does well. Since the centre does not currently store gametes and embryos, inspectors discussed the procedures for ensuring that there is effective consent for stored material. The PR reported that he did not anticipate holding copies of written consent to storage: any licensed centre entering into an agreement with the storage facility would remain responsible for contacting patients and communicating changes to consent. Licence Condition T110 requires that information, including consent, is "registered" at the centre: the PR provided a copy of a template which a centre commissioning storage would be required to complete. A completed template would register consent (including the expiry date), patient identification and the results of screening tests. This is compliant with the requirements of T110 as far as they are applicable to storage of samples. The PR described a proposed bring forward system in the course of the inspection; the PR described how the expiry of the consented storage period registered at the centre would be recorded on a database and that the database would be reviewed to ensure that centre's commissioning storage would be contacted in advance of the expiry date.
What they could do better. There is currently no standard operating procedure documenting the process to be followed to alert the centre to the end of the consented storage period. This is non-complaint with T33(b).

Validation of critical equipment
What the centre does well. **Validation of critical equipment** The PR confirmed that critical equipment is validated, including the liquid nitrogen storage unit and shippers planned for use in the transportation stage. The validation documentation for one liquid nitrogen vessel was reviewed.
What they could do better.

Witnessing
What the centre does well. The PR has a framework in place to train staff and to assess their competence to carry out witnessing prior to storing material.
What they could do better. Although staff were able to describe the steps involved in double checking the identification of samples at critical points, these have not been documented in a witnessing protocol. This is non-compliant with T33(b) The PR has not established quality indicators relevant to witnessing (T35). With no gametes or embryos in storage it has not been possible or relevant to audit witnessing practice.

2. Changes / improvements since the last inspection on 20 January 2009

Area for improvement	Action required	Action taken as evidence during this inspection
The PR to develop a robust process which ensures that licensed material is not stored on site beyond the specified patient storage consent period.	Process implemented to ensure that licensed material is not stored on site beyond the specified patient storage consent period.	The PR was able to describe a process for ensuring that material is not stored beyond the consented storage period but the process is not documented in an SOP. See body of text. Further action required.
The PR to develop a robust process which ensures that confidential patient information is kept secure within the centre's information database.	Process implemented to ensure that confidential patient information is kept secure within the centre's database.	The PR has not established a SOP for this process as it was anticipated that confidential identifying information in the form of copies of storage consent forms and/or information maintained on a database would not be held (see body of text). However, gametes and embryos stored by the centre would be labelled with identifying information. Further action required.

3. Areas of concern

The analysis of the centre's self assessment questionnaire and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be reviewed during the inspection visit to this centre.

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
It was noted at the last licence committee meeting on 20 April 2009 that the PR planned to install a secure, expandable caged area with access control prior to the storage of HFEA licensed material.	The PR said that storage vessels in the facility are not locked. Although the centre does not yet store material under the auspices of an HFEA licence, the PR has not yet implemented measures to ensure that access to stored material is controlled. This means that if material were to be stored, there is a risk of disclosure of confidential identifying information in circumstances not permitted by law.	Further action required.
Statutory storage period for gametes and embryos.	The proposed technical agreement between the PR and the client does not outline the client's responsibilities to inform the PR of changes to patient or donor consent. This may lead to gametes and embryos being stored without consent or contrary to the terms of consent.	Further action required.

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 require are given as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical are of non compliance is an area of practice which poses a significant direct risk of causing harm to a patient, donor or to an embryo. A critical area of non compliance requires immediate action to be taken by the Person Responsible

Area of practice	Reference	Action required	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 or to an embryo through the procurement, use, storage or distribution of gametes and embryos, which do not comply with the centre's licence;
- 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
The PR does not anticipate holding copies of patient consents to storage or mediating contact with patients in relation to their consents to storage. The proposed technical agreement between the PR and the client does not outline the client's responsibilities to inform the PR of changes to patient or donor consent. This may lead to gametes and embryos being stored without consent or contrary to the terms of consent. Schedule 3, paragraphs 8 (1) and	The PR should ensure that there are robust systems in place to ensure that cryopreserved material is not stored without written consent. The PR should establish an SOP for the process to be followed and submit this to the HFEA prior to storing gametes or embryos. Before material is accepted for storage.	HFEA SOP to be completed first week in May that will detail the requirements for acceptance of material into the facility. Due to confidentiality issues the consent documentation will not be stored on site. Instead by the client signing the Declaration of Material (attached) for each shipment, they confirm that consent has been obtained for each sample within the shipment. In addition the QTA attached will enable the Supplier PR to audit the client consent documentation annually.	The centre has submitted a 'declaration of material' template which includes confirmation that consent has been obtained for all material prior to storage. The template work instruction submitted includes the requirement to audit consent forms held by the client against that recorded on the declaration of material on a biennial basis and details the centre's bring

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
(2) of the HF&E Act 1990 (as amended).			forward system. The template technical agreement submitted does not outline in detail the client's responsibility to inform the PR of changes to patient or donor consent. It is requested that a revised template technical agreement and the 'HFEA' SOP are submitted to the Executive on completion and prior to accepting material into storage.
There is no witnessing protocol in place for double checking the identification of samples and the patients or donors to whom they relate at all critical points of the laboratory process. T33(b).	The PR should establish a witnessing protocol for double checking the identification of samples and the patients or donors to whom they relate at all critical points of the laboratory process. The PR must submit the	Fisher Bioservices is a GMP facility and part of this requirement is that all documentation and inventory has a verification check this is captured with the SOP 45210 Inventory Control within FBS. Fisher Bioservices PR will develop the HFEA SOP that will confirm the witnessing requirements along with the critical information that will go into the	The centre has submitted an 'inventory control' SOP which states the requirement for double checking the identification of samples against the sample manifest, as defined in the 'work instruction'. It is recommended that

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	written procedures to the HFEA prior to storing gametes or embryos. Before material is accepted for storage.	Work instruction (soon to be called Client Specific Project Plan). Draft work instruction attached for perusal.	the 'HFEA' SOP and client specific project plan being developed by the PR are submitted to the Executive on completion and prior to accepting material into storage.
The PR has not yet implemented measures to ensure that access to stored material is controlled. This means that if material were to be stored there is a risk of disclosure of confidential identifying information in circumstances not permitted by law. Section 33(A) of the HF&E Act 1990 (as amended).	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 (T43). Prior to storing gametes and embryos, the PR should provide evidence to the Executive that recommendations have been implemented.	Fisher BioServices has lockable units and a segregated area will be put in place before any HFEA material is stored on site. These requirements will be identified in the HFEA SOP. Only permanent staff will be allowed to work on the samples and they have all signed confidentiality agreements in relation to discussing patient and client identification.	The Executive is satisfied with the PR's response. The PR is asked to inform the Executive when the segregated area is in place, prior to accepting material into storage.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	Before material is accepted for storage.		

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 good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Quality indicators have not yet been established. T35.	Establish quality indicators for witnessing. Before material is accepted for storage.	Deviations will be raised for all inventory discrepancies and a QA review of all documentation is performed. Right first time for all documentation is covered under an existing metric.	The Executive is satisfied with the PR's response. No further action is required.

Additional Information from the Person Responsible
Fisher Bioservices is a GMP facility that is licenced to do MHRA and HTA licenced activities. All activities are verified by a second checker and then goes through the QA review process. Each Licence will have a specific SOP that will related the licence requirements within it that will need to be captured in the client specific project plan and SOPs.

HFEA Executive Licence Panel Meeting
13 May 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 3

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

Members of the Panel: Peter Thompson, Director of Strategy & Information (Chair) Nick Jones, Director of Compliance Hannah Darby, Policy Manager	Committee Secretary: Joanne McAlpine Observing: Lauren Crawford, PA to Director of Finance & Facilities and Director of Strategy & Information

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 centre was first licensed by the HFEA as a storage only centre on 24 July 2008, and had its first renewal inspection on 20 January 2009 where a licence was granted for five years with no additional conditions.

2. The Panel noted that the centre is licensed to store human tissue by the Human Tissue Authority (HTA) and the Medicines and Healthcare products Regulatory Agency (MHRA). The centre also has a quality management system (QMS) in place, which is ISO certified.

3. The Panel noted that prior to the inspection, the Person Responsible (PR) confirmed that no gametes or embryos have been stored since being licensed in 2008. This meant that any non compliances identified posed a potential rather than an actual risk.

4. The Panel noted that at the time of the inspection three major and one other area of non-compliance were identified.

5. The Panel noted that since the inspection the (PR) has given a commitment that the following recommendations will be fully implemented:

    - The PR should establish quality indicators for witnessing;
    - The PR should ensure that there are robust systems in place to ensure that cryopreserved material is not stored without written consent.
    - The centre must establish procedures for ensuring that access to confidential identifying information would only be disclosed in circumstances permitted by law.

6. The Panel noted the Inspectorate's recommendation that the centre's licence should continue with no additional conditions, subject to the full implementation of the recommendations prior to any cryopreserved material being accepted for storage.

Decision

7. The Panel endorsed the Inspectorate's recommendations and relevant timescales within the report, and agreed to the continuation of the centres licence with no additional conditions.

Signed:  Date: 24/05/2011

Peter Thompson (Chair)