HFEA Executive Licensing Panel Meeting

2 May 2014

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

Minutes – Item 1

Centre 0300 – (Fisher BioServices UK) Renewal Inspection Report

Members of the Panel:	**Committee Secretary:**
Juliet Tizzard – Interim Director of Strategy (Chair)	Dee Knoyle
David Moysen – Head of IT	**Also in attendance:**
Nick Jones – Director of Compliance & Information	Sam Hartley – Head of Governance & Licensing Sue Gallone – Director of Finance & Resources

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 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 considered the papers, which included a completed application form, inspection report and licensing minutes for the past three years.

2. The Panel noted that this centre has held a Storage Only licence with the HFEA since August 2008 and has a five-year licence due to expire on 31 July 2014. The centre offers storage services and a disaster recovery service to other HFEA licensed centres allowing centres to transfer cryopreserved gametes and embryos in an emergency for continued storage. At the time of the inspection, the Person Responsible (PR) confirmed that no gametes or embryos have ever been stored at the centre.

3. The Panel noted that the centre holds a Human Tissue Authority (HTA) licence to allow the storage of tissues and cells. The centre is also regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA) as a Good Manufacturing Practice (GMP) facility. The centre was inspected by the HTA prior to the HFEA inspection and the HTA inspection findings have been used to inform this report.

4. The Panel noted that the HTA had undertaken a 'themed' inspection on 11 February 2014, which included Quality Management, Contingency Planning and Risk Management. As the result of the centre's proactive approach to the inspection, its scope was extended to include equipment validation, maintenance and tracking. The HTA inspection report found that the centre had fully met all HTA Standards relevant to these areas.

5. The Panel noted that the HTA had undertaken a full inspection in February 2012, whereby four non-compliances were identified, two for governance and quality, and two for premises and facilities. The Panel noted that all of the four non-compliances were fully addressed.

6. The Panel noted that the centre's quality management system was accredited to ISO (International Organisation for Standardisation) standard 9001:2008 in February 2014.

7. The Panel noted that the HTA standards, with which the centre has demonstrated full compliance, are equivalent to HFEA standards. The Panel noted that the HTA considered the centre to be 'low risk' and as a result the HFEA performed only a themed inspection on 18 February 2014. The Panel noted that at the time of the HFEA inspection there were no areas of non-compliance identified in the themed areas.

8. The Panel noted that the Inspectorate recommended the renewal of the centre's Storage Only licence for a period of four years without additional conditions.

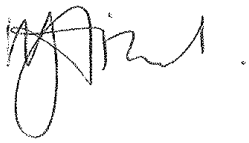
Decision

9. 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.

10. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licenced activities, and that he has discharged his duty under section 17 of the HF&E Act 1990 (as amended).

11. The Panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

12. The Panel agreed to renew the centre's Storage Only licence for four years, without additional condition.



Signed: Date: 19 May 2014

Juliet Tizzard (Chair)

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this storage centre complies with essential requirements in providing a safe and high quality storage service to patients and donors. 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: 18 February 2014

Purpose of inspection: Renewal of a licence for 'storage only'

Inspection details: The report covers the performance of the centre since the last inspection, findings from a recent HTA inspection report, findings from the inspection visit and communications received from the centre.

Inspectors: Lisa Beaumont (Lead) and Andy Leonard

Date of Executive Licensing Panel: 2 May 2014

Centre name	Fisher BioServices UK
Centre number	0300
Licence number	L/0300/2/c
Centre address	Unit 1, Woodside, Bishop's Stortford, Hertfordshire, CM23 5RG.
Person Responsible	Mr Colin Grant
Licence Holder	Mr Robert Jones
Date licence issued	1 August 2009
Licence expiry date	31July 2014
Additional conditions applied to this licence	None

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Section 1: Summary report

Brief description of the centre and its licensing history:

Fisher BioServices UK has held a HFEA storage licence since August 2008. The centre offers storage services and a disaster recovery service to other HFEA licensed centres, the latter allowing centres in an emergency to transfer cryopreserved gametes and embryos to Fisher BioServices UK for continued storage. At the time of the inspection, the Person Responsible (PR) confirmed that no gametes or embryos have ever been stored at the centre.

The centre holds a Human Tissue Authority (HTA) licence to allow the storage of tissues and cells. The centre is also regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA) as a Good Manufacturing Practice (GMP) facility. The centre was inspected by the HTA just prior to this inspection and the HTA inspection findings have been used to inform this report.

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

The HTA undertook a 'themed' inspection on 11 February 2014, which included Quality Management, Contingency Planning and Risk Management. As the result of the centre's proactive approach to the inspection, its scope was extended to include equipment validation, maintenance and tracking. The HTA inspection report found that the centre had fully met all HTA Standards relevant to these areas. The centre was last fully inspected by the HTA in February 2012 whereby four non compliances were identified: two for Governance and Quality, and two for Premises and Facilities. All four non compliances were fully addressed. The HTA considered the centre to be 'low risk' hence only a themed inspection was performed in February 2014. The centre's quality management system was also accredited to ISO (International Organisation for Standardisation) standard 9001:2008 in February 2014.

In this HFEA inspection report, the inspection team consider that the HTA inspection reports, together with the recent ISO accreditation, provide suitable and appropriate evidence for compliance with HFEA requirements in many areas because:

- The HTA standards, with which the centre has demonstrated full compliance, are equivalent to HFEA standards.

- The most recent HTA inspection was performed a week before this HFEA inspection, so findings are current and practices and procedures at the centre were unchanged at the time of the HFEA inspection.

Centre's activity levels:

Other licensable activities	✓ or Not applicable (N/A)
Storage of gametes	✓
Storage of embryos	✓
Embryo testing	N/A

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 his 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 the centre's 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 were no areas of practice that required improvement.

Recommendation to the Executive Licensing Panel

The centre has no critical, major or 'other' areas of non-compliance. The inspection team is satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed storage services.

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 has never stored any HFEA material, therefore following the last inspection in January 2013 the ELP recommended the next inspection should include a 'walk through', to allow the inspection team to examine the critical witnessing steps from receipt to placing cryopreserved material in storage, and subsequent removal. A 'walk through' of the receipt and dispatch processes which would be used if a primary centre sent cryopreserved material to Fisher BioServices UK, was performed by centre staff on this inspection, and was observed by the inspection team. It demonstrated the critical witnessing practices and documentation of witnessing from the arrival of gametes and embryos at the centre to their placement in storage and from their retrieval from storage to dispatch.

The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate, are compliant with HFEA requirements. This ultimately ensures that patients receive treatment using the correct gametes or embryos.

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.

What the centre could do better

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 suitable. This is important to ensure that all licenced 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 staff are in safe surroundings that prevent harm.

The centre only stores and distributes gametes and embryos. It does not process them so HFEA requirements related to air quality were not reviewed on this inspection.

Laboratory accreditation(Guidance note 20)
The primary centre (i.e. the HFEA licensed centre sending cryopreserved material to Fisher BioServices UK) is responsible for undertaking the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them. This centre will only store gametes and embryos which have already been placed in storage at a primary centre, therefore this area of practice is not relevant to this

inspection.

Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births (Guidance note 7; General Directions 0003)
Procurement of gametes and embryos (Guidance note15)
The centre does not provide treatment or procure gametes or embryos, therefore these areas of practice are not relevant to this inspection.

Transport and distribution of gametes and embryos (Guidance note 15;General Directions 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes / embryos 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's procedures for the receipt of cryopreserved gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from primary centres if the gametes and embryos are appropriately labelled and have enough information to permit the gametes and embryos to be stored in a way that does not comprise their quality and safety.

Imports and exports (Guidance note 16; General Directions 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. The HTA inspection included a traceability audit during which no discrepancies or anomalies were identified.

These requirements are important to ensure that the centre has the ability to

- identify and locate gametes and embryos during storage,
- identify the donor of particular gametes or embryos,
- identify any person who has carried out any activity in relation to particular gametes or embryos, and
- identify and locate all relevant data relating to products and materials coming into contact with the gametes or embryos and which may 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. The QMS is well designed to meet the requirements of not only the HFEA, but also the HTA, MHRA and ISO 9001:2008 accreditation. There was evidence of good systems in place which included a workplace organisation programme to measure performance and drive continuous improvement.

Third party agreements (Guidance note 24)
The centre has third party agreements in place for service provision, but not with HFEA centres, as no HFEA centre has yet to make a contract with the centre to store gametes and embryos. The draft of the 'HFEA Guidelines for Fisher BioServices' states that appropriate agreements will be developed with centres contracting for the emergency storage service which will consist of: Master Service Agreement, Individual Project Agreement and a Quality Technical Agreement. The systems and processes in place are HTA compliant and were assessed by the inspection team as compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General 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)
Observations on inspection and the recent HTA inspection report indicate that the centre uses equipment and materials that are compliant with HFEA requirements. All of the equipment and materials which will be used in licensed activity if gametes and embryos are to be stored at the centre are validated, designated for the purpose and are 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)
The centre's storage and handling procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the cryopreserved gametes or embryos clinically ineffective or harmful to the recipient. The centre has validated its processes using stored HTA regulated material and associated critical parameter monitoring, as the centre has never stored any HFEA regulated material.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre has not reported any adverse incidents (including serious adverse events and reactions) to the HFEA, since it has never stored any HFEA regulated material.

Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Nothing identified at this inspection.

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 has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme, PREP number R/1144/7.

Staff (Guidance note 2)
The centre is compliant with HFEA requirements. 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 does not require access to a nominated registered medical practitioner, within the UK, to advise on or oversee medical activities.

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 treat patients, therefore this area of practice is not relevant to this inspection.

Safeguarding
The centre does not treat patients, therefore this area of practice is not relevant to this inspection.

What the centre could do better

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.

What the centre could do better

2. The experience of patients

Patient feedback

What the centre does well

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

What the centre could do better

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 treat patients therefore this area of practice is not relevant to this inspection.

Counselling (Guidance note 3)
The centre does not treat patients and, if gamete and embryo storage is to occur in future, the primary centres who store the material before it is transferred to Fisher BioServices UK will have responsibility to make counselling available to the gamete providers. Therefore this area of practice is not relevant to this inspection.

Egg [and sperm] sharing arrangements (Guidance note 12; General Directions 0001)
The centre does not offer egg and sperm sharing services therefore this area of practice is not applicable to this inspection.

Surrogacy (Guidance note 14)
The centre does not offer a surrogacy service therefore this area of practice is not applicable to this inspection.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek client (HFEA primary centre) 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 confidentiality is maintained and understood by staff, in relation to The Human Fertilisation and

Embryology Act 1990 (as amended). Paper and electronic documents are secure, and staff with access to HFEA data or material are either named on the licence or work under the direction of the PR.

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 does not treat patients therefore this area of practice is not applicable to this inspection.
The centre does provide sufficient, accessible and up-to-date information to prospective primary centres to enable them to make informed decisions about the options for storage offered by the centre.

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)
The centre does not take consent therefore this area of practice is not applicable to this inspection.

Disclosure of information, held on the HFEA Register, for use in research(Guidance note 6)
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

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.

What the centre could do better

Screening of patients
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)
It is important that centres appropriately screen gamete providers to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

The centre is not responsible for the screening of patients; this is the responsibility of the primary centre. The centre does however have procedures for ensuring that the providers of gametes from which cryopreserved material has been derived, have been screened before the material is placed into storage. Such procedures ensure compliance with HFEA screening requirements is maintained.

Storage of gametes and embryos (Guidance note 17)
The storage of gametes and embryos is an important service offered by off-site storage facilities to primary centres and can provide a safe and secure storage option in an emergency or as part of a longer term planned off-site storage strategy.

The centre's procedures for storing gametes and embryos are HTA compliant and compliant with HFEA requirements. These measures will ensure that gametes and embryos will be stored appropriately to maintain their quality and safety. The centre will only store gametes and embryos in accordance with the consent of the gamete providers, however the taking of storage consent is and will be the responsibility of the primary centre. The centre aims to operate to a business model in which the monitoring of storage consent expiry dates and any manipulation of the cryopreserved samples will remain the responsibility of the primary centre.

What the centre could do better

Nothing identified at this inspection.

Use of embryos for training staff (Guidance note 22)
What the centre does well No embryos will be processed at the centre or made available for training so this area of practice is not applicable to this inspection.
What the centre could do better

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre does not currently keep any HFEA patient records, however, ISO 9001:2008 accreditation of the centre's QMS provides good evidence that document control processes are compliant with HFEA requirements. All documents viewed on inspection were version controlled and regularly reviewed.

Obligations and reporting requirements (Guidance note 32 ; General Direction 0005)
The centre does not undertake patient treatment therefore this area of practice is not applicable to this inspection.

What the centre could do better

Section 3: Monitoring of the centre's performance

Following the interim inspection in January 2013, recommendations for improvement were made in relation to one 'other' area of non-compliance.

The PR provided information and evidence that the recommendation has 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, and 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
None			

Reponses from the Person Responsible to this inspection report
The inspectors provided the opportunity of discussing what is done in Fisher BioServices in relation to the HFEA licence and this allowed a very practical audit against the areas we needed to cover in relation to storage and distribution of HFEA material in the future. One point in particular on how we will deal with HFEA clinics that have had a disaster and need to store offsite in an emergency situation was very useful and allowed the inspectors to see the time issues including completion of master service agreements and Quality Technical agreements. The inspectors have taken this issue back to the HFEA to discuss, meanwhile a generic QTA and MSA have been developed at Fisher BioServices to speed up the set up process. In future it would be useful to have both the HTA and HFEA do a joint inspection of Fisher BioServices. Both Inspectors were fair and allowed open communication which was appreciated by the FBS inspection team.