Executive Licensing Panel - minutes

Centre 0300 (Fisher Bioservices UK)

Renewal Inspection Report

Thursday, 10 May 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Anna Quinn Howard Ryan	Director of Strategy and Corporate Affairs Scientific Policy Manager Report Developer
Members of the Executive	Bernice Ash	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 application

1.1. The panel considered the papers, which included a completed application form, inspection report and licensing minutes for the last three years.

1.2. The panel noted that Fisher Bioservices UK is located in Bishops Stortford, Hertfordshire and has held a HFEA storage only licence since 2008. The centre offers tissue and cell storage services to a wide portfolio of clients and a disaster recovery service to HFEA licensed centres. The latter would allow 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.

1.3. The panel noted that the centre holds a Human Tissue Authority (HTA) licence to allow the storage of tissues and cells for human application. The centre was last inspected by the HTA in February 2016 and the inspection findings demonstrated that the centre had met all HTA standards, identifying three minor observations that have since been resolved. The centre is also regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA) as a Good Manufacturing Practice (GMP) facility and is accredited to ISO standard 9001:2015.

1.4. An inspection was carried out at the centre on the 20 March 2018.

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

1.6. The panel noted the inspectorate recommendation to renew the centre's storage only licence for a period of four years without additional conditions.

2. Decision

2.1. 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.

2.2. The panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

2.3. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR will discharge his duty under section 17 of the HFE Act 1990 (as amended).

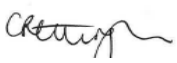
2.4. The panel congratulated the centre on having no areas of non-compliance.

2.5. The panel endorsed the inspectorate's recommendation to renew the centre's storage only licence for a period of four years, without additional conditions.

3. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

17 May 2018

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 gamete and embryo storage service for 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: 20 March 2018

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 the inspection visit and communications received from the centre.

Inspectors: Sara Parlett

Date of Executive Licensing Panel: 10 May 2018

Centre name	Fisher Bioservices UK
Centre number	0300
Licence number	L/0300/3/e
Centre address	Unit 1, Woodside, Bishop's Stortford, Hertfordshire, CM23 5RG
Person Responsible	Mr Wyn Forrest-Owen
Licence Holder	Mr Peter Day
Date licence issued	1 August 2014
Licence expiry date	31 July 2018
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

Fisher Bioservices UK is located in Bishops Stortford, Hertfordshire and has held a HFEA storage only licence since 2008. The centre offers tissue and cell storage services to a wide portfolio of clients and a disaster recovery service to HFEA licensed centres. The latter would allow 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 for human application. The centre was last inspected by the HTA in February 2016 and the inspection findings demonstrated that the centre had met all HTA standards with three minor observations identified that have since been resolved. The centre is also regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA) as a Good Manufacturing Practice (GMP) facility and is accredited to ISO standard 9001:2015.

The centre varied their licence in July 2017 and November 2017 to change the Licence Holder and in February 2015 and July 2017 to change the PR.

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, no recommendations for improvement were made.

Recommendation to the Executive Licensing Panel

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'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 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 note 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 Direction 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 recruit donors, therefore this area of practice is not relevant to this inspection.
What the centre could do better Nothing identified at this inspection.

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 licensed 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 so that 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 are not relevant to this inspection.

Laboratory accreditation (Guidance note 25)
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 (Guidance Note 25)
Medicines management (Guidance Note 25)
Pre-operative assessment and the surgical pathway (Guidance Note 25)
Multiple births (Guidance note 7; General Direction 0003)
Procurement of gametes and embryos (Guidance note 15)
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 Direction 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 will be:

- 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 gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if they are appropriately labelled and are accompanied by enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; General Direction 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. These requirements are important to ensure that the centre has the ability:

- to identify and locate gametes and embryos during storage;
- to identify the donor of particular gametes or embryos;
- to identify any person who has carried out any activity in relation to particular gametes or embryos; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS that is compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

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. Appropriate agreements will be developed with centres contracting for the emergency storage service when necessary. 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 Direction 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)
The centre uses equipment and materials that are compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

The centre is compliant with HFEA requirements to validate critical equipment. 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 they offer.

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.

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have 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.

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 (Guidance Note 25)
The centre does not treat patients, therefore this area of practice is not relevant to this inspection.

What the centre could do better
Nothing identified at this inspection.

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
Nothing identified at this inspection.

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
Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg 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 sharing arrangements (Guidance note 12; General Direction 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 HF&E Act 1990 (as amended).

What the centre could do better
Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre does not treat patients therefore this area of practice is not applicable to this inspection.

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;6)
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 (General Direction 0005)
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
Nothing identified at this inspection.

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
Nothing identified at this inspection.

Screening of patients and 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

What the centre does well

Use of embryos for training staff (Guidance note 22)
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 Nothing identified at this inspection.

4. Information management

Record keeping and 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 9001:2015 certification of the centre's QMS and HTA licensing provide good evidence that document control processes are compliant with HFEA requirements.

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
Nothing identified at this inspection.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2016, no recommendations for improvement were made.

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, General 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, 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.

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 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.

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 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.

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.			

Reponses from the Person Responsible to this inspection report
Thank you once again for the recent inspection and for recommending the renewal of our centre's storage license for a period of four years without additional conditions. Our compliant QMS and continuous improvement program helps us ensure the highest quality standards for storage, and distribution of gametes and embryos. FBS UK remains committed to consistently meeting the requirements of the HFEA and our customers.