New Premises Site Visit Report

Name of Applicant	Fisher Bioservices UK
Address of Proposed Premises	Unit 1, Woodside, Bishop's Stortford, Hertfordshire, CM23 5RG
Has the applicant been licensed before	NO
If yes: Centre Number and Address of previous premises	N/A
Inspector(s)	Wil Lenton Neelam Sood
Date of visit	4th April 2008
Date of any previous visits to these premises	18th December 2007

About the Site Visit

The purpose of the site visit report is to confirm to the PR the findings of the inspection highlighting areas of firm compliance and good practice, as well as areas where further improvement is required. The report may be shared with other regulators on a need to know basis, such as the HC and HTA.

Brief Description of the Centre

The Authority has received an application from Fisher Bioservices UK, based at Bishop's Stortford, Hertfordshire (centre 0300) for a licence to store gametes and embryos.

Prior to the initial visit the centre had supplied the following documentation :

- Completed application form
- Curriculum vitae's (CVs) from intended Person Responsible (PR) and Nominal Licensee (NL)
- Staff list
- Site plan
- An index of standard operating procedures
- An index of all current forms
- Copy of current Human Tissue Authority (HTA) licence (11074)
- Copy of ISO 9001:2000 Certificate of Registration (FS507309)

An initial site visit was undertaken on 18 December 2007 by Wil Lenton and Neelam Sood of the Executive, during which the premises and facilities were inspected and both the proposed PR and NL interviewed.

The unit is already licensed to store tissues by the HTA and has a quality management system (QMS) in place which is ISO accredited (ISO9001:2000)

The unit currently stores material for the National Blood Service, Health Protection Agency, government agencies and academic institutions.

The company has recently been licensed by the Medicines and Healthcare products Regulatory Agency (MHRA) (certificate # 32390)

The licence fee has been paid to the Authority.

The proposed PR is currently completing the PR entry programme (PREP).

Summary of findings for Licence Committee

The following issues were identified by the inspection team which require action by the centre:-

- Completion of PREP by proposed PR.
  S.4.1.5

- The receipt and dispatch area to be reviewed to ensure that samples are appropriately separated.
  S.6.3.2; S.6.3.7; S.6.3.8

- All documentation involved in the storage, handling and distribution of gametes and embryos to be made HFEA specific (some forms were HTA specific)
  S.4.1.7(d); S.4.1.8

- Updated technical agreement to include traceability and witnessing of patient material as required by the HFEA to be formalised.
  S.4.2.1(g); S.4.2.10; S.7.1.1

- Standard operating procedure (SOP) for the monitoring of cryostored material consent expiry to be developed.
  S.7.8.12(b)

- SOPs and work forms for activities including the receipt, handling, retrieval and transportation of gametes and embryo's, to include appropriate contemporaneous witnessing as required by the HFEA.
  S.7.7.11; S.7.7.12; S.7.7.13; S.7.7.14; S.7.7.15; S.7.7.16; S.7.8.5(b)(c); S.7.8.10; S.7.8.15

- Authorisation lists of personnel from each licensed centre involved in the manipulation of stored material on site to be supplied to the HFEA once the technical agreement is in place.
  S.4.2.10; S.7.8.5(b)(c); S.7.8.10;

- Details of any third party agreements in place with courier companies to be forwarded to the HFEA.
  S.4.2.10; S.7.7.14

- SOP for staff induction to be forwarded.
  S.6.2.12(d); S.6.2.7; G.13.6.1

Subject to the successful resolution of the outstanding issues highlighted above, the inspection team supports the centre's application for a storage licence and request the Licence Committee to grant an initial licence for one year.

Further Recommendations	Time scale
• CVs for both facilities manager and customer services/inventory manager to be forwarded to the HFEA.	3 months
• Transportation risk assessments undertaken for the transportation of material to be forwarded to the HFEA.	3 months
• Proposed fee structure for the storage of gametes and embryos to be forwarded to the HFEA.	As developed
• Details of any promotional literature to be sent to licensed centres to be forwarded to the HFEA as it is developed.	As developed

1. Organisation

Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

Summary of findings from inspection

Evidence of: *(Delete areas not reporting on)*

- Leadership and management
- Organisation of the centre
- Resource management
- Risk management
- Incident Management
- Contingency arrangements
- Business planning
- Clinical governance
- Knowledge of the legal requirements and COP

Summary of Findings
The centre appears to be well organised and is currently licensed by other regulatory bodies including the HTA (licence # 11074) and the MHRA (certificate # 32390) It also has an accredited QMS in place (ISO9001:2000 #FS 507309) which underpins its day-to-day activities. An organisational chart was supplied detailing the centre's lines of communication and reporting structure. A staff list was also supplied. There appeared to be an appropriate number of suitably qualified and trained staff to deliver the proposed licensed service. A quality manager (the proposed PR) is in post and oversees the QMS. Risk assessments of the facilities have been performed and found to be satisfactory. All staff are security screened prior to employment. An adverse incident policy is in place. A disaster recovery plan is in place.
Areas for improvement
Proposed PR to submit completed PREP.
Points to consider/action for next inspection
Completion of the proposed PR's PREP.

2. Quality of service

Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of findings from inspection: *(Delete areas not being reported on)*

- Live birth rates
- 'Welfare of the Child' arrangements
- Confidentiality (including safe storage of patients' records)
- Choice of treatments
- Privacy and dignity of patients
- Complaint handling
- Patient feedback and satisfaction
- Counselling facilities and services
- Donor selection
- Egg sharing and surrogacy
- Protection of children arrangements (for patients under 18yrs)

Summary of Findings
The centre is applying for a storage licence only. There are no clinical services provided on site. An accredited QMS is in place which underpins the centre's day-to-day activities.
Areas for improvement
None.
Points to consider/action for next inspection
None.

3. Premises and Equipment

Desired outcome: The premises and equipment are safe, secure and suitable for their purpose.

Summary of findings from inspection: *(Delete areas not being reported on)*

- Suitable premises
- Storage facilities for embryos and gametes
- Safe equipment, servicing and maintenance
- Prevention of incidents/ accidents

Summary of Findings
The premises have both external and internal closed circuit television (CCTV) in operation twenty-four hours a day which is recorded to a hard-disc drive. The premises are accessible via an electronic entry-phone at reception. There is good internal security with restricted swipe-card access and CCTV. All cryostorage equipment is continuously monitored via a dedicated state-of-the-art system, which records vessel temperature to a hard-drive which is then relayed to a central monitoring facility. An out-of-hours autodialler system is in place. Oxygen-depletion monitors are located at strategic positions within the facility and are connected to audio-visual alarms and the central monitoring area. An external 26,000 litre liquid nitrogen storage cylinder supplies the internal storage vessels. Servicing and maintenance of the cryovessels is delivered by an in-house team and all such actions are documented.
Areas for improvement
The receipt and dispatch area to be reviewed to ensure that samples are appropriately separated.
Points to consider/action for next inspection
Appropriate separation of samples within the receipt and dispatch area.
The standard of the premises and equipment
All areas seen during the inspection appeared to be clean and were well presented. Overall the inspection team considered the facilities to be suitable for the proposed activities with the exception of the one area for improvement.

4. Information

Desired outcome: Information is relevant, clear and up to date for patients and to the HFEA

Summary of findings from inspection: *(Delete areas not being reported on)*

- Information management
- Information to patients and donors
- Information to the HFEA
- Protocols
- Record keeping (including consents)

Summary of Findings
There is no patient-sensitive information presently stored on site. Client details are kept secure within a fire-proof office within the repository. All stored material is entered onto an electronic inventory which then tracks the movement of samples both in and out of the premises. A QMS is in place which includes details of all documentation which is document controlled.
Areas for improvement
A SOP for the monitoring of cryostored material consent expiry to be developed. SOPs and work forms for activities including the receipt, handling, retrieval and transportation of gametes and embryos, to include appropriate witnessing as required by the HFEA. Updated technical agreement to include traceability and witnessing of patient material as required by the HFEA to be formalised. All documentation involved in the storage, handling and distribution of gametes and embryos to be HFEA specific. (not HTA forms) Authorisation lists of personnel from each licensed centre involved in the manipulation of stored material on site to be supplied to the HFEA. Fee structure for the storage of gametes and embryo's to be developed. Details of promotional literature to be sent to licensed centres to be forwarded to the Authority as it is developed.
Points to consider/action for next inspection
The HFEA to have received: A SOP for the monitoring of cryostored material consent expiry. SOPs and work forms for activities including the receipt, handling, retrieval and transportation of gametes and embryos, to include appropriate witnessing.

Updated technical agreement to include traceability and witnessing of patient material.

All documentation involved in the storage, handling and distribution of gametes and embryos to be HFEA specific.

Authorisation lists of personnel from each licensed centre involved in the manipulation of stored material on site.

Fee structure for the storage of gametes and embryos.

Details of promotional literature to be sent to licensed centres

The standard of information provided

Overall both the information submitted with the application and that which was seen during the visit was considered to be compliant with requirements.

5. Laboratory and Clinical Practice

Desired outcome: Staff are competent and recruited in sufficient numbers to ensure safe clinical and laboratory practice.

Summary of findings from inspection: *(Delete areas not being reported on)*

- Assessment of patients and donors
- Safe handling systems
- Laboratory processes and practice
- Clinical practice
- PGD/ PGS
- Recruitment and retention of staff
- Staff competence, qualifications, training and CPD

Summary of Findings
The centre is applying for a storage licence only. There are no clinical services provided on site. There appear to be appropriate numbers of qualified/trained staff in order to deliver the proposed services. Staff have access to further training as deemed necessary to fulfil their duties.
Areas for improvement
Staff training logs to be appropriately completed by supervisor.
Points to consider/action for next inspection
Completion of staff training logs by supervisor.
The provision and quality of staff
The present staffing level appears to be adequate for the proposed service to be provided.

Topic 1

(b) The following actions need to be taken by the date shown before the applicant meets the requirements for **organisation**

The PR to complete/submit the PREP

To be completed immediately

Topic 2

(a) The applicant meets the requirements for **quality**

Topic 3

(b) The following actions need to be taken by the date shown before the applicant meets the requirements for **premises**

The receipt and dispatch area to be reviewed in order that samples are appropriately separated.

To be completed within 6 months

Topic 4

(b) The following actions need to be taken by the date shown before the applicant meets the requirements for **information**

A SOP for the monitoring of cryostored material consent expiry to be developed.

SOPs and work forms for activities including the receipt, handling, retrieval and transportation of gametes and embryos, to include appropriate witnessing as required by the HFEA.

Updated technical agreement to include traceability and witnessing of patient material as required by the HFEA to be formalised.

All documentation involved in the storage, handling and distribution of gametes and embryos to be made HFEA specific. (not HTA specific)

To be completed prior to centre undertaking work with a licensed centre.

Topic 5

(b) The following actions need to be taken by the date shown before the applicant meets the requirements for **laboratory and clinical practices**

Staff training logs to be appropriately completed by supervisor.

To be completed within the next three months.

Next Action

The PR is to ensure that all outstanding issues highlighted in the report are addressed within the indicated timescales.

The Executive is to be kept informed on the progress of all work undertaken.

Report compiled by_ _____Wil Lenton _____

Designation_____ _____ Inspector _____

Date_____7th April 2008_____

RESPONSE OF PERSON RESPONSIBLE TO THE SITE VISIT

Centre Number……0300……..……

Name of PR……Mr Colin Grant……

Date of Inspection……4 April 2008……..…….....

Date of Response……14 June 2008……..…….....

Please state any actions you have taken or are planning to take following the inspection with time scales

1) The PR to complete/submit the PREP
- PR training attached to response: Please note training is from version 2 of the training manual and has been slightly modified to incorporate version 7 of the HFEA code of practice.

2) The receipt and dispatch area to be reviewed in order that samples are appropriately separated.
- The receipt and dispatch area has been labelled and procedure modified to state that only one shipment at a time is moved through the receipt/dispatch area. Plans have been forwarded to corporate to modify the sample receipt/dispatch area awaiting reply. Expected completion time for modification of area: Late September 08

3) A SOP for the monitoring of cryostored material consent expiry to be developed.
- All HFEA samples coming into Fisher Bioservices UK will have a work instruction completed per Client. The work instruction will detail all requirements including all details of contacts between the clinic and Fisher Bioservices and how the inventory will be controlled including consent expiry. The work instruction will be approved by both the Client's Person Responsible and Fisher Bioservice's Person Responsible. In addition all samples will be inventorised within Intrak. Intrak will detail expiry dates, appropriate consent has been obtained, testing and status of the samples as defined in the work instruction.
- Draft Work Instruction completed and attached.

4) SOPs and work forms for activities including the receipt, handling, retrieval and transportation of gametes and embryos, to include appropriate witnessing as required by the HFEA.
- Movement of Material or Equipment in Europe SOP has been modified and Forms updated to include HFEA requirements for witnessing. This coincides with the Work Instruction attached.

5) Updated technical agreement to include traceability and witnessing of patient material as required by the HFEA to be formalised.
- Technical Agreement and Declaration of Material Form attached to response.

6) Authorisation lists of personnel from each licensed centre involved in the manipulation of stored material on site to be supplied to the HFEA once the technical agreement is in place.

- Refer to attached HFEA Draft Work Instruction

7) Details of any third party agreements in place with courier companies to be forwarded to the HFEA.

- HFEA material will be transported by Fisher Bioservices within the UK unless requested by the client. The client to have 3rd party agreements with their dedicated Courier services.

8) SOP for staff induction to be forwarded.

- Checklist and Procedure attached to response. Additional training is currently been developed to explain the requirements for HFEA material. All work instructions will be trained and signed off by the people working on them once the Responsible Persons have approved the work instruction. All work instructions will be version controlled and each new version will be re-trained.

9) CVs for both facilities manager and customer services/inventory manager to be forwarded to the HFEA.

- Attached to Response

10) Transportation risk assessments undertaken for the transportation of material to be forwarded to the HFEA.

- Procedure currently been updated, all projects will have a risk assessment performed on them for transport.

11) Proposed fee structure for the storage of gametes and embryos to be forwarded to the HFEA.

- Prelimary Quote attached.

12) Details of any promotional literature to be sent to licensed centres to be forwarded to the HFEA as it is developed.

- Initial promotional literature attached, this will be forwarded as developed.

I have read the inspection report and agree to meet the requirements of the report.

Signed……

Name……Mr Colin Grant……..……..

Date…… 17 June 2008……....

2. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

We also welcome comments about the inspection on the inspection feedback form, a copy of which should have been handed out at the inspection. If you require a copy of the feedback form, please let us know.

Please return this section of the report to:

Head of Inspection, HFEA
21 Bloomsbury Street
London
WC1B 3HF