Initial Licence Inspection Report

Date of Inspection: **05 March 2013 & 23 April 2013**
Purpose of inspection: **New Treatment and Storage Licence**
Length of inspection: **12 hours**
Inspectors: **Douglas Gray, Gill Walsh, Sara Parlett**

Inspection details:
The report covers the pre-inspection analysis, the visit and information received with the new licence application. An initial inspection was carried out on 05 March 2013 and completed 23 April 2013 following the installation and validation of critical equipment.

Date of Licence Committee: 09 May 2013

Purpose of the Inspection Report
The purpose of the inspection is to assess whether centres are complying with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the Human Fertilisation and Embryology (HF&E) Act 2008 and the Code of Practice (CoP), to ensure that centres are providing a quality service for patients. The report summarises the findings of the initial licence 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 Licence Committee which makes the decision about the centre's licence application.

Centre details

Centre name	**Boston Place**
Centre number	**0327**
Licence number	**No active licence**
Centre address	**16-20 Boston Place, London, NW1 6ER**
Proposed Person Responsible	**Dr Anna Carby**
Proposed Licence Holder	**Mr Stuart Lavery**
Proposed date of Licence Issue	**10 May 2013**

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Report to Licence Committee

Brief description of the centre:
The HFEA received an initial licence enquiry from the proposed Person Responsible (PR) on 20 July 2012, and a new treatment and storage licence application on 20 September 2012. The licence application was for a full range of activities including embryo testing. However, the PR has confirmed that an application for embryo testing will now be made at a later date.

The centre will provide treatment to self funded patients. The centre is designed to provide a maximum of 900 cycles of in vitro fertilisation (IVF) or intracytoplasmic sperm injection (ICSI) per annum. There will be a phased increase in treatment activity and the PR estimates to provide 300 treatment cycles in the first year.

Projected Activities of the Centre:

Type of treatment	Projected annual activity
IVF	900
ICSI	
FET	
IUI/DI	200

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

Summary for licensing decision

In considering overall compliance, the inspection team considers that they have sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit to conclude that:

- The proposed PR satisfies the requirements of section 16 of the HF&E Act 1990 (as amended) necessary for a licence to be granted since:
    1. The proposed PR holds academic qualifications in the field of medicine and is registered with the General Medical Council (GMC). The proposed PR also has more than two years' practical experience which is directly relevant to the activities to be authorised by the licence.
    2. The proposed PR has satisfactorily completed the PR entry programme (certificate number: T/1220/8).
    3. Two referees have attested to the suitability of the character of the applicant for the post of PR.

- The licence application details the appointment of a Licence Holder (LH); the proposed LH's CV has been submitted.

- The premises and equipment are suitable. At inspection, the premises appeared appropriate for the proposed licensable activities and should provide a safe, clean and private environment for patients and donors, their gametes and embryos and centre staff. The premises have been handed over by the contractors to the centre and building regulation certification was made available on the day of the inspection. At the time of the second inspection visit, all critical clinical and laboratory equipment had been installed and had been validated.

- The proposed practices and processes are considered to be suitable. The centre has documented standard operating procedures (SOPs) for the proposed licensed activities and well established processes will be used.

  Staff provided evidence that they are suitably experienced to carry out their designated roles. The PR described plans to ensure that staff have appropriate induction and that competence to perform their designated roles will be effectively monitored and reviewed.

  The centre has documented quality indicators (QI) and audit schedules that will allow the PR to identify whether processes are being effectively implemented.

- The proposed PR has submitted documentation to satisfy the requirements of General Direction 0008 (Information to be submitted to the HFEA as part of the licensing process).

- The centre has submitted an application fee to the HFEA in accordance with requirements.

The Licence Committee is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including one major area of non-compliance and eight other areas of non-compliance. There were no critical non-compliances noted on this inspection.

Since the inspection visit the PR has provided evidence that the following recommendations have been fully implemented:

Major areas of non compliance:

- The centre should develop QIs to monitor donor selection and screening processes.

Other areas of practice that require improvement:

- The PR should amend documentation to adequately reflect the centre's description of the methodology used to validate critical processes.
- The PR should risk assess whether not labelling all containers at egg collection could lead to misidentification.
- The PR should amend relevant documentation governing legal parenthood to ensure compliance with Standard Licence Condition (SLC) T64.
- The PR should amend appropriate documentation to ensure that both gamete providers had consented prior to the use of their embryos for training.
- The PR should amend patient information to ensure that gamete providers consenting to the use of their embryos in training will be informed that they can vary or withdraw their consent until the point embryos are used.

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

Other areas of practice that require improvement:

- The PR should inform the lead inspector when the lead embryologist receives confirmation that their Health and Care Professions Council (HCPC) registration application has been accepted.
- The PR should review all Third Party Agreements (TPAs) to establish if the requirements of SLC T114 (c) and (f) are met.
- The PR should review and amend as necessary documentation relating to import and export to ensure that all movements of gametes and embryos under general directions comply with Direction 0006.

Recommendation to the Licence Committee

The inspection team considers that there is sufficient information available to recommend:

1. Granting a treatment and storage licence for a period of two years without additional conditions.

2. Appointment of the proposed PR.

3. Appointment of the proposed LH.

Details of inspection findings

1. Protection of patients and children born following treatment

Focus

The purpose of the inspection was to assess whether the centre:

- conducts all licensed activities with skill and care and in an appropriate environment, in line with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring
- takes into account the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth
- ensures that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose
- reports all adverse incidents (including serious adverse events and reactions) to the HFEA, investigates all adverse incidents and shares lessons learned.

▶ **Witnessing and assuring patient and donor identification** (Guidance Note 18)
What the centre does well: The centre's proposed procedures for double checking the identification of gametes and embryos, and the patient or donor to whom they relate are compliant with HFEA requirements. The centre has an SOP for witnessing to ensure that no mismatches of gametes or embryos or identification errors occur (SLC T71). This SOP was audited during the inspection and was considered to be compliant with the requirements of Guidance Note 18.4. The template for recording witnessing is also considered to be fit for purpose. The centre intends to introduce an electronic witnessing system that will be validated once their manual system is embedded.
What the centre could do better. Nothing noted.

▶ **Patient selection criteria and laboratory tests** • Procuring, processing and transporting gametes and embryos (Guidance Note 15) • Counselling (Guidance Note 3)
What the centre does well. **Procuring, processing and transporting gametes and embryos** An SOP is in place for procuring, processing and transporting gametes and embryos (SLC T33b). Prior to the processing of gametes or embryos intended for use in treatment or storage, the centre will screen patients in accordance with SLC T50 under a TPA. The laboratory to be used for screening is accredited with Clinical Pathology Accreditation (UK)

Ltd (CPA) (SLC T51).

The centre does not intend to seek CPA accreditation for diagnostic semen analysis, but was able to demonstrate that they will be working to equivalent standards which include having a robust quality management system (QMS) and participation in the UK National External Quality Assessment Service (NEQAS) for reproductive science (SLC T21). Evidence of application to participate in NEQAS was seen on inspection. Centre staff stated that verbal confirmation has been received from NEQAS that the centre can participate in the scheme from May 2013.

If sperm is produced at home, the centre will record this in the gametes provider's records (SLC T68). The centre will not provide sperm for home insemination.

Counselling
Counselling will be offered to those providing consent as required by Schedule 3 and 3ZA of the HF&E Act 1990 (as amended).

The centre will offer counselling to all patients and donors prior to consent to treatment or donation being sought. An SOP is in place for counselling (SLC T33b).

When surrogacy is planned counselling will be offered to all parties in the arrangement. Where required there is provision in place for more specialist counselling to be made available.

QIs have been established and audits of the service are planned (SLC T35 and T36).

What the centre could do better.

Nothing noted.

Donor recruitment, assessment and screening

- Donor recruitment, assessment and screening (Guidance Note 11)
- Payments for Donors (Guidance Note 13)
- Donor assisted conception (Guidance Note 20)

Only applicable to centres licensed to carry out treatment using donor gametes and / or embryos

What the centre does well.

Donor recruitment, assessment and screening
The centre does not intend to recruit sperm or egg donors. Treatment will be provided using known sperm and egg donors for which an SOP is in place (SLC T33b). Proposed screening procedures are compliant with HFEA requirements (SLC T52). Screening tests will be performed by a third party laboratory that holds CPA accreditation (SLC T53).

Donor sperm will be provided by a third party and an appropriate TPA is in place (SLC T111).

Payments for donors
Centre staff are aware of the limitations for compensation for donors (General Directions 0001).

Donor assisted conception
Information will be provided to patients to ensure they understand the importance of informing any child at an early age that the child results from the gametes of a person who is not their parent and patients will be provided with information on how to tell the child (SLC T63).

What the centre could do better.

The centre has not established QIs to monitor the donor selection and screening process (SLC T35). See recommendation 1.

Good clinical practice

- Quality management system (Guidance Note 23)
- Traceability (Guidance Note 19)
- Validation (Guidance Note 15)
- Equipment and materials (Guidance Note 26)
- Premises – suitability of the premises and air quality (Guidance Note 25)
- Adverse incidents (Guidance Notes 27)
- Third party agreements (Guidance Note 24)
- Intracytoplasmic sperm injection (ICSI) (Guidance Note 21)

What the centre does well.

Quality management system
A comprehensive QMS is in place (SLC T32), including a quality manual, QIs, SOPs and associated documents (SLC T33 and T35). An appropriate audit schedule is in place (SLC T36), which includes an initial audit of critical SOPs within six months of the centre first providing treatment services.

SOPs are in place for activities included in the licence application, and those activities that do not require a licence (SLC T33b). Where relevant, SOPs detail the specifications for critical materials and reagents to be used (SLC T31).

There will be an annual review of the QMS (HF&E Act, Schedule 3A (10)).

Traceability
There is an SOP to ensure traceability of gametes and embryos and also materials and equipment coming into contact with them (SLC T22, T99 and T102). With the exception of tubes and dishes used during egg collection, all other containers for gametes and embryos will be appropriately labelled using the patient's full name, date of birth and hospital number (SLC T101). An SOP is in place to ensure data required for traceability is stored for the necessary period of time (SLC T103).

Validation
The centre's staff described how they will be using established protocols for critical procurement and processing procedures validated by their sister centre (0078 IVF Hammersmith). The validation approach used by centre 0078 includes a retrospective analysis of this centre's own data and benchmarking with other comparable centres and was considered to be compliant with SLC T72 at their renewal inspection in July 2012. On-going review of validations will be performed as the centre gathers their own data.

Equipment and materials
Activities will be carried out using equipment designed for the purpose (SLC T23). Service agreements are in place for equipment (SLC T26). Equipment will be regularly inspected and maintained and critical equipment has been validated (SLC T24). The records of commissioning and validation of equipment were reviewed during the inspection. There are documented procedures for the operation of all critical equipment and these outline what to do if the equipment malfunctions or fails (SLC T27). Equipment is monitored and fitted with alarms with auto dial-out facility where appropriate (SLC T24). Equipment with a critical measuring function is appropriately calibrated (SLC T24).

Sterile equipment and devices will be used for the procurement and processing of gametes and embryos (SLC T28). Wherever possible, CE marked consumables will be used (SLC T30).

Premises – suitability of the premises and air quality
The inspection team considered the premises to be suitable (SLC T17). The main entrance has secure access arrangements. All areas in which patient records and gametes/embryos may be kept are secure and are controlled by personnel secific swipe card access.

There is an uninterrupted power supply that will provide power to critical equipment in case of unexpected power failure.

Certificates were reviewed on inspection to show that processing of gametes and embryos will take place in an environment of at least Grade C air quality, with a background of at least Grade D (SLC T20). There are cleaning records held for these areas (SLC T26).

Adverse incidents
Centre staff are aware of the requirements for reporting and investigating adverse incidents and an SOP for this is in place (SLC T118 and T119).

Third party agreements
TPAs are in place with all suppliers that provide goods or services that influence the quality and safety of gametes and embryos (SLC T111) and a list is maintained of all TPAs (SLC T115). Five TPAs from this list were audited for compliance against regulatory requirements, and with some exceptions, these comply with SLC T113, T114 and T116.

The application form indicates that Boston Place will act as the primary licenced centre for satellite IVF services at 92 Harley Street. The PR has since confirmed that this will not be a satellite IVF arrangement (as defined by Direction 0010) as drug therapy and monitoring will take place at the primary centre.

ICSI
The centre has an SOP (SLC T33b) and quality indicators (SLC T35) relevant to ICSI. Laboratory staff who will perform ICSI are appropriately trained and have had their competence assessed (SLC T15).

What the centre could do better.

Traceability
Tubes used to collect follicular fluid which are transferred to the laboratory, and dishes into which the fluid is poured for egg collection, will not be labelled with the patient's/donor's full

name and a further identifier or a uniquely identifying donor code. See recommendation 4.

Validation
Although the inspection team considered the staff's description of critical process validation as compliant, sufficient documented evidence of this could not be provided to support this (SLC T72). See recommendation 3.

Third party agreements
From the five TPAs audited during the inspection, none identified how often the agreements will be reviewed and by whom (SLC T114(c)). One TPA for the laboratory that will perform patient/donor screening tests did not specify how any test results will be relayed to the centre, including sign off and confirmation that the result applies to the correct sample (SLC T114(f)). See recommendation 5.

Multiple Births (Guidance Note 7)

What the centre does well

The centre has a multiple births minimisation strategy that is compliant with Directions 0003. This comprises of a single embryo transfer policy setting out how the centre intends to meet the multiple birth target, and an SOP for the requirements to record information on the number of embryos transferred and to provide information to patients requesting multiple embryo transfer on the risks of multiple pregnancies.

What the centre could better

Nothing noted.

Staff engaged in licensed activity

- Person Responsible (Guidance Note 1)
- Staff (Guidance Note 2)

What the centre does well.

Person Responsible
The PR holds academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence (HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii).

The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1220/8).

Staff
Based on discussions at the time of inspection, the proposed staff numbers are likely to be sufficient for the projected initial activity levels of 300 cycles per year (SLC T12).

Staff appointed to work at the centre are appropriately registered with professional and/or statutory bodies (SLC T14 and T16). There are three consultants who are all registered with the General Medical Council. The lead nurse is registered with the Nursing and

Midwifery Council. The centre has access to a suitably qualified counsellor accredited with the British Infertility Counselling Association (Guidance Note 2.12).

The individual responsible for the clinical embryology laboratory has applied for HCPC registration (T14). Based on discussions at the time of inspection, and in consideration of the training and experience described in her CV, she is considered to have demonstrated suitability for the role. Until HCPC registration has been achieved, laboratory staff will work under the auspices of the HCPC registered individual responsible for the clinical embryology laboratory at IVF Hammersmith (centre 0078) and the centre's organisational chart reflects this.

There are documented induction and training procedures for all staff and these were provided to the inspection team (SLC T15). Arrangements for competence assessments are in place and processes have been established for all staff to participate in continuing professional development.

What the centre could do better.

The individual responsible for the clinical embryology laboratory is not yet HCPC registered (SLC T14 and CoP Guidance 2.19). See recommendation 2.

Welfare of the Child (Guidance Note 8)

What the centre does well.

Account will be taken of the welfare of any child who may be born as a result of treatment and of any other child who may be affected by the birth, before treatment is provided (SLC T56). The centre has an SOP for conducting welfare of the child assessments and appropriate QIs have been developed. Welfare of the child assessment forms part of the audit schedule (SLC T36).

What the centre could do better.

Nothing noted.

Embryo Testing – *only applicable to centres licensed to carry out preimplantation genetic diagnosis and screening)*

- Preimplantation genetic screening (Guidance Note 9)
- Embryo testing and sex selection (Guidance Note 10)

Embryo testing was included in the initial licence application. However, the PR has confirmed that they wish to amend the application to exclude embryo testing; an application will be made to vary the licence at a later date.

2. Patient Experience

Focus

The purpose of the inspection visit was to assess whether the centre:

- treats prospective and current patients and donors fairly, and ensures that all licensed activities are conducted in a non-discriminatory way
- has respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions
- ensures that patients and donors have provided all relevant consents before carrying out any licensed activity

Treating patients fairly

- Treating patients fairly (Guidance Note 29)
- Complaints (Guidance Note 28)
- Provision of costed treatment plans (Guidance Note 4)
- Egg sharing arrangements (Guidance Note 12)
- Surrogacy (Guidance Note 14)

What the centre does well.

Treating patients fairly
The centre's policies and procedures appeared to ensure that patients will be treated fairly.

Complaints
There is a complaints policy in place, and a log of complaints will be maintained (CoP Guidance Note 28).

Provision of costed treatment plans
Based on a description provided during inspection, the process for issuing individualised costed treatment plans is likely to be compliant with Guidance Note 4.3.

Egg sharing arrangements
The centre does not plan to facilitate egg sharing arrangements.

Surrogacy
The centre has an SOP that requires that gamete providers in surrogacy arrangements will be screened and registered as donors (SLC T52 and T53), and that sperm will be quarantined for a minimum of 180 days prior to repeat testing (SLC T53c). Patient information is available on parental rights and obligations in surrogacy arrangements. Centre staff are aware of potential changes to donor registration requirements and legal parenthood provisions relative to surrogacy effective from October 2013.

What the centre could do better.

Nothing noted.

Information

- Information to be provided prior to consent (Guidance Note 4)
- Information about storage of embryos (including cooling off periods)
- Information about Intracytoplasmic sperm injection (Guidance Note 21)
- Information about preimplantation genetic testing (Guidance Notes 9 & 10) – *only applicable to centres licensed to carry out preimplantation genetic diagnosis and screening*
- Information about legal parenthood (Guidance Note 6)

What the centre does well.

There is an SOP for providing information to patients (SLC T33b). A suite of patient information has been reviewed by the inspection team and considered to be comprehensive. The patient information was audited against SLC T58, T63 and the relevant guidance notes and was considered to be compliant.

The centre did not have a dedicated website at the time of inspection for assessment of compliance with Chair's Letter CH (11)02.

What the centre could do better.

Nothing noted.

Consent

- Consent to treatment, storage, donation, training and disclosure of information (Guidance Note 5)
- Consent to legal parenthood (Guidance Note 6)

What the centre does well.

The centre will take consent before gametes or embryos are used in treatment or storage (SLC T57). Consents will be held in the patient's electronic records (SLC T46f). There is an SOP for taking consent (SLC T33b), and an audit is planned (SLC T36). The identity of the person providing consent will be appropriately verified (CoP Guidance Note 5.10). There is an SOP in place to manage withdrawal of consent that adequately manages the 'cooling-off' period in the even that gamete providers are in dispute regarding the continued storage of embryos created with their gametes (Guidance Note 5H).

Consent to legal parenthood will be obtained where required and centre staff understand the requirements in relation to legal parenthood. Centre staff were able to describe mechanisms to ensure that where a patient or second parent withdraws consent, the second parent or patient will be informed and in the case of the patient this will be before treatment takes place (SLC T64 and T65).

What the centre could do better.

Staff described the process for informing women in the situation that the second parent has withdrawn their consent to be treated as the parent of any child born both verbally and by writing prior to being treated (SLC T64). However, this process has not been documented (SLC T33b). See recommendation 6.

3. Protection of gametes and embryos

Focus

The purpose of the inspection was to assess whether the centre has respect for the special status of the embryo when conducting licensed activities

Legal Requirements [Human Fertilisation and Embryology Act 1990 (as amended)]

- Licensed activities only take place on licensed premises
- Only permitted embryos are used in the provision of treatment services
- Embryos are not selected for use in treatment for social reasons
- Embryos are not created by embryo splitting
- Embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman
- Embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies
- Embryos which are or have been stored are not given to a person, other than in the course of providing treatment services, unless that person is a person to whom a licence applies
- No money or other benefit is given or received in respect of the supply of gametes or embryos unless authorised by the Authority

What the centre does well.

The centre will be conducting the activities essential to the provision of licensed activities at the licensed premises only (SLC T1).

Only permitted embryos will be used in the provision of treatment services. Embryos will not be selected for use in treatment for social reasons and will not be created by embryo splitting. Centre staff are aware that embryos must only be created where there is a specific reason to do so and the clinician responsible for the patient will document the justification of the use of gametes and embryos based on the patient's medical history and therapeutic indications (SLC T49).

Staff are aware of the requirements of General Directions 0001 for compensation of gamete and embryo donors.

What the centre could do better.

Nothing noted.

Storage of gametes and embryos

- Storage of gametes and embryos (Guidance Note 17) – *only applicable for centres licensed to store gametes and / or embryos*

What the centre does well.

SOPs (SLC T33b) and QIs (SLC T35) are in place for storage related activities and the process and related equipment have been validated (SLC T24 and T72).

Patients and donors will be appropriately screened before their gametes or embryos are stored (SLC T50 or T52 as appropriate).

Based on a description provided during inspection, the process to ensure that gametes and embryos are not stored beyond their consented storage period is likely to be compliant with Guidance Note 17.18.

There is a process in place to manage the 'cooling off' period where required and staff demonstrated their understanding of this (CoP Guidance Note 5.35).

What the centre could do better.

Nothing noted.

Distribution and / or receipt of gametes and embryos

- Distribution of gametes and embryos (Guidance Note 15) – *only applicable for centres that has distributed or exported gametes and / or embryos*
- Export of gametes and embryos (Guidance Note 16) – *only applicable for centres that has exported gametes and / or embryos*
- Receipt of gametes and embryos (Guidance Note 15) – *only applicable for centres that has received gametes and / or embryos*
- Import of gametes and embryos (Guidance Note 16) – *only applicable for centres that has imported gametes and / or embryos*

What the centre does well.

A framework of SOPs is in place for the distribution, receipt, and recall of gametes and embryos (SLC T105, T106, T107, T108, T109 and T110).

A courier will be used for transport of gametes or embryos and there is a TPA in place that ensures required transport conditions are maintained during distribution (CoP Guidance Note 15B; T11).

Donor sperm will be imported and appropriate TPAs are in place (SLC T111).

What the centre could do better.

Although staff were aware of the requirements of Direction 0006 relating to the import and export of gametes and embryos, the centre could not provide documented evidence of procedures that will be used to ensure these requirements are met (SLC T33b).
See recommendation 7.

Use of embryos for training staff (Guidance Note 22)
What the centre does well. The centre does not intended to use embryos in training initially but patients will be given the option to consent to this once the centre is established (SLC T94). Embryos will only be used for the purposes of training staff in embryo biopsy, embryo storage or other embryological techniques and activities that are expressly authorised by the Authority (SLC T93). Prior to giving consent, each gamete providers will be provided with information on the nature of the training, and informed that their decision will not affect their treatment (SLC T97).
What the centre could do better. The centre could not provide documented evidence of procedures to ensure that both gamete providers have consented prior to the use of their embryos for training (SLC T94). See recommendation 8. Documentation reviewed during the inspection did not adequately ensure that each gamete provider will be informed that they can vary the terms or withdraw consent until the point the embryos are used in training (SLC T97(c)). See recommendation 9.

4. Good governance and record keeping

Focus

The purpose of the inspection was to assess whether the centre:

- maintains accurate records and information about all licensed activities
- conducts all licensed activities with regard for the regulatory framework governing treatment involving gametes and embryos within the UK, including
    - maintaining up-to-date awareness and understanding of legal obligations
    - responding promptly to requests for information and documents from the HFEA
    - co-operates fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare

Record keeping

- Record keeping and document control (Guidance Note 31)

What the centre does well.

Documents reviewed on inspection were controlled, with version numbers and review dates (SLC T34).

The content of patient records as required by SLC T46 was discussed with the PR who confirmed that the required elements will be retained in their electronic records management system.

Electronic records are protected from unauthorised access and amendment (SLC T47). These measures include password protection on the computers and the electronic records management system. The intention is that no paper based records will be retained; all records will be retained electronically including signed HFEA consent forms.

Records will be held for a minimum of 30 years, and there is the facility to hold records for longer where circumstances require (SLC T48, T103 and T104).

What the centre could do better.

Nothing noted.

Legal requirements [Human Fertilisation and Embryology Authority 1990 (as amended)]

- Obligations and reporting requirements of centres (Guidance Note 32)

What the centre does well.

There is an SOP for submitting data to the HFEA (SLC T33b). Staff confirmed that they are familiar with submitting data to the HFEA and the PR is satisfied with the competence of staff (SLC T15a).

Staff were aware of the requirements of General Directions 0005.

What the centre could do better.

Nothing noted.

Disclosure of information

- Confidentiality and privacy (Guidance Note 30)
- Disclosure of information, held on the HFEA Register, for use in research

What the centre does well.

The inspection team considered that there is good provision for maintaining the confidentiality and privacy of patients. The centre has a range of SOPs in place to ensure that all information is kept confidential and only disclosed in circumstances permitted by law (SLC T43). The centre will operate a password protected paperless records management system that will guarantee traceability whilst preventing unauthorised disclose of information (SLC T44).

Access to areas where confidential identifying information can be seen or obtained will be restricted by swipe card and authorised by the PR (Section 33A(1) HF&E Act, 1990 as amended).

Patients will be identified by reference to their photographic identification and a copy of which will be retained in the patient's electronic notes (CoP Guidance Note 5.10).

What the centre could do better.

Nothing noted.

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

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. 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 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
1. There are no QIs relating to the required standards of quality and safety for donor selection and screening. SLC T35	The centre should develop QIs to monitor donor selection and screening processes and forward these to the centre's inspector by 23 October 2013.	Quality Indicators for selection and recruitment of donors have been amended to reflect the process of screening rather than selection given that only known egg donors will be recruited (DATQM03v3 NU04)	Documentation has been reviewed and is considered compliant. No further action required.

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
2. The lead embryologist is not yet HCPC registered. SLC T14 and CoP Guidance 2.19	The PR should inform the lead inspector when the lead embryologist receives confirmation that her HCPC registration application has been accepted.	(PR will inform lead inspector once registration has been obtained.	The PR's commitment is noted.

3. Validation documentation available on inspection did not adequately describe the rationale and methodology for validation of critical processes, SCL T72	The PR should amend documentation to adequately reflect the centre's description of the methodology used to validate critical processes. Amended documentation should be forwarded to the centre's inspector by 23 July 2013.	Documentation has been amended to refelct methodology (DATEM10 appended)	Documentation has been reviewed and is considered compliant. No further action required.
4. Tubes used to collect follicular fluid which are transferred to the laboratory, and dishes into which the fluid is poured for egg collection will not be labelled with the patient's/donor's full name and a further identifier or a uniquely identifying donor code. SLC T101	The PR should risk assess whether not labelling all containers at egg collection could lead to misidentification and take corrective action where appropriate. The risk assessment and details of any action taken should be submitted to the centre's inspector by 23 July 2013.	A risk assessment has been performed (as appended risk assessment for egg collection)	Documentation has been reviewed and is considered compliant. No further action required.
5. An audit of five TPAs showed that none of the agreements identified how often the agreements will be reviewed and by whom. One agreement did not specify how test results will be relayed to the centre. SLC T114(c) and (f)	The PR should review all TPAs to establish if the requirements of SLC T114 (c) and (f) are met, and make any amendments necessary. A summary report including details of any action taken should be provided to the centre's inspector by 23 July	Template TPA form has been amended to address how often TPA's will be reviewed and by whom and to include information regarding responsiblities of 3rd party and agreed procedures with respect to each parties responsibilities	The PR's response is noted. The PR has further committed (by email) to forward the requested report by 23 July 2013.

	2013.		
6. The centre cannot provide evidence that women will not be treated prior to being informed of changes to consent to legal parenthood by the second parent. SLC T64	The PR should amend relevant SOPs governing legal parenthood to ensure compliance with SLC T64 and forward a copy of this to the centre's inspector by 23 July 2013.	SOPGE03 amended to clarify that treatment will not be provided to a woman until she has been informed of changes to consent to legal parenthood by a second parent	Documentation has been reviewed and is considered compliant. No further action required.
7. The centre cannot provide evidence that they will comply with all the requirements of Directions 0006. General Direction 0006	The PR should review and amend as necessary documentation relating to import and export to ensure that all movements of gametes and embryos under general directions comply with Direction 0006. The PR should consider whether staff training is required relating to the requirements of Direction 0006. Amended documentation should be forwarded to the centre's inspector by 23 July 2013.	Documentation amended and attached as per SOPEM10.7	The PR's response is noted and we request that the document mentioned is forwarded to the centre's inspector by 23 July 2013.
8. The centre cannot provide evidence that only embryos will be used for the purpose of training staff if both gamete providers have given consent for such use. SLC T94	The PR should amend appropriate documentation to ensure that both gamete providers had consented prior to the use of their embryos for training. Amended documentation should be	Documentation amended and attached as per SOPEM01 5.6.13, FRMEM01, DATEM05, SOPEM01 9.7.1 and 9.7.5	Documentation has been reviewed and is considered compliant. No further action required.

	forwarded to the centre's inspector by 23 July 2013.		
9. The centre cannot provide evidence that gamete providers consenting to the use of their embryos in training staff will be informed that they can vary or withdraw the terms of their consent until the point the embryos are used in training. SLC T97(c)	The PR should amend patient information to ensure that gamete providers consenting to the use of their embryos in training will be informed that they can vary or withdraw their consent until the point embryos are used. Copies of amended documents should be forwarded to the centre's inspector by 23 July 2013.	Information amended as per INFCL06 v3	Documentation has been reviewed and is considered compliant. No further action required.

Additional information from the Person Responsible

HFEA Licence Committee Meeting

9 May 2013

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

Minutes – Item 4

Centre 0327 (Boston Place) – Initial Inspection Report

Members of the Committee:	Committee Secretary:
Sally Cheshire (lay) Chair Andy Greenfield (lay) Bishop Lee Rayfield (lay) Gemma Hobcraft (lay) Debbie Barber (professional)	Lauren Crawford Legal Adviser: Stephen Hocking, DAC Beachcroft

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

The following papers were considered by the Committee

- Initial inspection report
- Application form
- CV of the proposed PR
- Two references for the proposed PR
- CV of proposed LH
- Confirmation letter from the proposed PR
- Confirmation letter from the proposed LH

The Committee also had before it

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 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); and
- 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 Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Background

1. The Committee noted that an initial enquiry was received by the HFEA from the proposed PR of Boston Place in July 2012, regarding licensing requirements for a treatment and storage centre.

2. The Committee noted that Boston Place is located at:

   16-20 Boston Place
   London
   NW1 6ER

3. The Committee noted that the application is for a licence for Treatment and Storage Licence, although the original application form was for the full range of activities including embryo testing. The PR has now confirmed they may re-apply for this activity at a later date but are not seeking to be licensed for it in this application.

4. The Committee noted that at the time of the inspection, the Inspectorate reported that there were a number of areas of practice that required improvement, including one area of major non-compliance and eight 'other' areas of non-compliance or poor practice.

5. The Committee noted that since the inspection the Person Responsible (PR) has provided evidence to the Inspectorate that the one 'major' area of non-compliance and five of the 'other' areas of non-compliance have been fully implemented.

6. The Committee noted that the Person Responsible has given a commitment to fully implement the following recommendations by the 23 July 2013:

   'Other' areas of practice that require improvement:

   - The PR should inform the lead inspector when the lead embryologist receives confirmation that their Health and Care Professions Council (HCPC) registration application has been accepted.
   - The PR should review all Third Party Agreements (TPAs) to establish if the requirements of SLC T114 (c) and (f) are met.
   - The PR should review and amend as necessary documentation relating to import and export to ensure that all movements of gametes and embryos under general directions comply with Direction 0006.

7. The Committee noted the Inspectorate's recommendation to grant the centre's licence for a two year period without additional conditions, subject to the proposed PR providing evidence of compliance with the non-compliance detailed in the report and to also appoint the proposed PR and Licence Holder (LH).

Discussion

8. The Committee referred to its decision tree. It was satisfied that the appropriate application and fee had been submitted, and noted that the executive had received the supporting information required by General Direction 0008.

9. The Committee was satisfied that the character of the proposed PR, Dr Anna Carby, is such as required for the supervision of the licensed activities and that the PR will discharge the duties under section 17 of the HF&E Act 1990 (as amended).

10. The Committee noted that the proposed PR holds academic qualifications in the field of medicine and is registered with the General Medical Council (GMC). The proposed PR also has more than two years' practical experience which is directly relevant to the activity to be authorised by the licence as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii). She has successfully completed the HFEA PR Entry Programme and has two satisfactory references.

11. The Committee noted the PR is suitable and will discharge her duty under section 17 of the HF&E Act 1990 (as amended).

12. The Committee was satisfied regarding the suitability of the proposed LH, Mr Stuart Lavery.

13. The Committee was satisfied that the licence application concerns treatment, storage or non-medical fertility services which relate to gametes or embryos intended for human application.

14. The Committee was satisfied that premises to be licensed are suitable for the conduct of licensed activities based on evidence provided within the report.

15. The Committee noted that the application includes the use of embryos for training. The Committee referred to their decision tree for the use for embryos in training and were satisfied with the justification given for such use.

16. The Committee referred to 'Guidance on periods for which new or renewed licences can be granted'. The Panel took into account matters set out in paragraph 4.2 which states "The Licence and Research Licence Committees or Executive Licensing Panel will normally grant an

initial treatment/storage/non-medical fertility services licence for up to two years. This is because in granting an initial licence, there will be no history of compliance to support a longer licence."

17. The Committee noted the Inspectorate's recommendation for a two year licence, without additional conditions, subject to the proposed PR providing evidence of compliance with the areas of non-compliance detailed in the report.

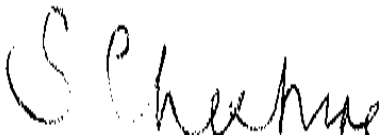
Decision

18. The Panel agreed to appoint Dr Anna Carby as the Person Responsible for Boston Place (0327) with immediate effect, in accordance with section 18A of the HFE Act 1990 (as amended).

19. The Panel agreed to appoint Stuart Lavery as the Licence Holder for Boston Place (Centre 0327) with immediate effect.

20. The Committee agreed to grant the centre's application for Treatment and Storage licences for a period of two years with no additional conditions, The PR must provide evidence of compliance with the non-compliance recommendations detailed in the report and referenced in paragraph 6 of these minutes, within the agreed timeframes.

Signed: Date: 24/05/2013



Sally Cheshire (Chair)