Initial licence Inspection Report

Date of Inspection: 13 February 2013
Purpose of inspection: New licence application
Length of inspection: 8 hours
Inspectors: Susan Jolliffe
Andrew Leonard
Victoria Mills
Claude Rennert

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the new centre.

Date of Licence Committee: 28 March 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, to ensure that centres are providing a quality service for patients. The report summarises the findings of the inspection. It is primarily written for the Authority's Licence Committee which makes the decision about the centre's licence application.

Centre details

Centre Name	Bourn Hall Clinic (Norwich)
Centre Number	0325
Centre Address	Unit 3, Gateway 11, Wymondham, Norwich NR18 OWF
Person Responsible	Dorian Ransome
Licence Holder	Thomas Mathews
Proposed date of licence issue	15 April 2013

Contents

Report to Licence Committee

Brief description of the centre:

An application form was received by the HFEA from Dorian Ransome (the proposed Person Responsible (PR)) on 22 November 2012 for a new treatment and storage licence.

The proposed centre at Norwich is in a dedicated building designed specifically for fertility patients.The centre is registered as Bourn Hall Clinic (Norwich) Limited and forms part of the Bourn Hall Group .

At inspection, the proposed PR stated that he had a Care Quality Commission (CQC) inspection in February 2013, and would forward a copy of the CQC report as soon as it is made available to him.

Projected activities of the centre:

Type of treatment	Number of treatment cycles the premises is designed to accommodate
Intra uterine insemination (IUI) and donor insemination (DI)	100
In vitro fertilisation (IVF) and intracytoplasmic sperm injection (ICSI)	600
Preimplantation Genetic Screening (PGS) and Preimplantation Genetic Diagnosis (PGD)	N/A

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

Summary for licensing decision

The proposed PR has submitted documentation to satisfy the requirements of General Direction 0008 - Information to be submitted to the Human Fertilisation and Embryology Authority - as part of the licensing process. These documents have been reviewed by the inspection team and are compliant with CoP requirements.

In considering overall compliance, the inspection team considers that there is sufficient information drawn from documentation submitted by the centre prior to and after the inspection, and from observations and interviews conducted during the inspection, 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 an academic qualification in the field of Biological Sciences, having a BSc (Hons) in Life Sciences. The proposed PR also has more than two year's practical experience 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/1216/8).
    3. Two referees, provided by the PR, have attested to the suitability of the character of the applicant for the post of PR.
    4. A letter has been received from the proposed PR stating that he is willing to assume responsibility for the role.

- The initial treatment and storage licence application details the appointment of a Licence Holder (LH). The proposed LH's CV has been submitted, together with a letter stating that he is willing to assume the responsibility of the role of LH.

- The premises and equipment are suitable, although a number of recommendations must be met before licensed activity is undertaken:

- The proposed practices and processes are anticipated to be suitable although a number of recommendations must be met before licensed activity is undertaken:

The Licence Committee is asked to note that there are a number of areas of practice that require improvement including, three major areas of non-compliance and three 'other' areas of non-compliance or poor practice.

The proposed PR has given a commitment to fully implement the three major recommendations before any treatment is offered at the centre, and to implement the three 'other' recommendations by 13 May 2013.

Major areas of non compliance:

- The PR should ensure all critical procurement and processing procedures are validated prior to treatment being offered.

- The PR should ensure the air quality in the processing areas is assessed and meets the requirements of Standard Licence Condition (SLC) T20 before treatment is offered.

- The PR should ensure that critical equipment, instruments, devices and other consumables to be used during the procurement and processing of gametes and/or embryos are validated prior to treatment being offered.

Other areas of practice that require improvement:

- The PR should ensure that the centre develops quality indicators for: counselling and the selection and recruitment of donors.

- The PR should ensure that all diagnostic testing services are provided by laboratories accredited to the appropriate standard.

- The PR should ensure that the following six SOPs form part of the centre's quality management system and are updated to reflect local practice at Bourn Hall Norwich: Counselling; The operation of critical equipment; Transporting of gametes and embryos; Traceability; Witnessing; Use of embryos in training.

Recommendation to the Licence Committee:

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

1. Granting a treatment and storage licence for a period of two years without additional conditions, subject to the proposed PR providing evidence for the implementation of the recommendations detailed in this report to the HFEA executive.

2. The appointment of the proposed Person Responsible.

3. The appointment of the proposed Licence Holder.

Details of inspection findings

1. Protection of patients and children born following treatment

Focus

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

- will conduct 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
- will take 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 has installed an electronic witnessing system in the laboratory and procedures room. (SLC T71). Training for staff in the use of this equipment has been arranged (SLC T12 and T15). Staff are competent to perform manual witnessing when necessary (SLC T15).

The centre has developed quality indicators relevant to witnessing (SLC T35).

All containers for gametes and embryos, including aspirate tubes at egg collection, will be appropriately labelled (SLC T101).

What the centre could do better.

The witnessing SOP has not yet been formally documented (SLC T33b). The Laboratory Manager advised that this task will be completed well before the commencement of licensed activity.

▶ 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

Prior to the processing of gametes or embryos intended for use in treatment or storage the centre will screen patients as required by SLC T50.

The centre was able to demonstrate accreditation to a standard equivalent to Clinical

Pathology Accreditation (UK) Limited (CPA) for diagnostic semen analysis (SLC T21 and T51a).

Counselling
Counselling will be offered to patients as required by Schedule 3 and Schedule 3ZA of the HF&E Act 1990 (as amended). Implications counselling is mandatory for egg and sperm donors and the recipients of donor gametes and embryos; the cost of this is included in the treatment costs.

Two of the three proposed counsellors are accredited by the British Infertility Counselling Association (BICA) and the third is working towards BICA accreditation (Code of Practice (CoP) Guidance 2.12b).

If required, the counsellor can refer patients to specialist genetic counsellors or oncology counsellors (CoP Guidance 3.10).

Counselling is included in the audit plan (SLC T36).

The counsellor has facilities to keep her notes secure and separate from the main medical notes (CoP Guidance 3.12).

What the centre could do better.

Some diagnostic tests will be performed in a laboratory at Bourn Hall Cambridge. This laboratory is waiting to be inspected by the UK Accreditation Service against an accreditation standard equivalent to that provided by CPA: the facility is not currently accredited to the required standard (SLC T51a).

The transport SOP discusses a recall procedure but it does not clearly define the responsibilities and actions required when a distribution is recalled, specifically that all recalls should be reported as adverse incidents to the HFEA (CoP interpretation of mandatory requirements 15C)

The centre does not have an SOP for the provision of counselling (SLC T33b).

The centre has not established quality indicators for counselling (SLC T35).

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

What the centre does well.

Donor recruitment, assessment and screening
There is a SOP for the recruitment of donors (SLC T33b). Centre staff are aware of the screening requirements for donors and donors will be screened as required by SLC T52.

Payments for donors
Centre staff are aware of the limitations on the compensation of donors (General Directions 0001) and will compensate donors according to these requirements.

Donor assisted conception
Patients will be informed of 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 quality indicators relevant to the selection and recruitment of donors (SLC T35).

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 (QMS)
There is a comprehensive QMS at the centre which has been developed from the Bourn Hall corporate quality management system (SLC T32). This consists of a quality manual, SOPs and work instructions (SLC T33).

There are SOPs for activities that the centre wishes to include on the licence and for non-licensable activities carried out in the course of providing those licensed treatment services, with the exception of those noted below (SLC T33b).

QIs have been established, with the exception of those noted below (SLC T35).

There is an audit programme in place (SLC T36).

An annual review of the QMS will be conducted (HF&E Act Schedule 3A (10)).

Traceability
An audit of traceability against the traceability SOP is planned (SLC T36).

Equipment and materials
Equipment is fitted with alarms where appropriate and equipment with a critical measuring function has been appropriately calibrated (SLC T24). Activities will be carried out using equipment designed for the purpose (SLC T23).

Service agreements are in place for all equipment (SLC T26) and the record sheets for recording equipment servicing and maintenance were provided during the inspection. Sterile equipment and devices will be used throughout the centre (SLC T28); no reusable instruments will be used (SLC T29).

Wherever possible, CE marked consumables will be used and evidence of this was provided during the inspection (SLC T30).

Premises
The inspection team considered the premises to be suitable (SLC T17). The main entrance has secure access arrangements. Rooms where records, gametes or embryos may be kept also have secure access.

Records of the cleaning of the premises are maintained (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
Third party agreements are in place with suppliers (SLC T111) and these comply with SLC T113, T114 and T116.

A list of all third party agreements is maintained (SLC T115).

Intracytoplasmic sperm injection (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
There is a corporate Bourn Hall SOP to ensure traceability of gametes, embryos, consumables and equipment (SLC T22, T99 and T102) and the accurate identification of patients, gametes and embryos (SLC T100). The corporate SOP is currently being reviewed to ensure it accurately reflects the processes at Bourn Hall Norwich.

Validation

The centre staff will be using established protocols for all critical processes, which have been developed and used at the other Bourn Hall centres. Validation reports for these processes, as applied at the new centre, were not completed at the time of the inspection. The validation of processes was discussed with staff and was said to be in progress and to be scheduled for completion before the start of licensed activity (SLC T72).

Equipment and materials
The centre has not validated all critical equipment. The validation of equipment was discussed with staff and was said to be scheduled for completion before the start of licensed activity. A copy of the validation report will be submitted on completion in March 2013 (SLC T24).

There are no documented procedures for the operation of critical equipment at the centre and the actions to take in the event of equipment malfunction or failures are not documented (SLC T27).

Premises
The air quality in the critical processing areas and the background areas has not yet been assessed, though the PR stated that these assessments will be completed prior to activity commencing (SLC T20).

Intracytoplasmic sperm injection (ICSI)
The centre has not yet validated ICSI processes (SLC T72) though the Laboratory Manager advised that validation was soon to be completed.

Multiple Births (Guidance Note 7)

What the centre does well

The centre has a multiple births minimisation strategy in place which is compliant with General Directions 0003. Audits of the effectiveness of this strategy are planned.

Centre staff are aware of the requirements of General Directions 0003.

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 has academic qualifications in the field of biological sciences and has two years of practical experience 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).

The proposed PR has completed the PR Entry Programme (PREP) and achieved the pass mark.

Staff
The accredited consultant is registered with the General Medicine Council (GMC) and is on the Specialist Register for Obstetrics and Gynaecology; he was available at the time of the inspection. Information obtained during the day, along with the training and experience described in the accredited consultant's CV, demonstrated the accredited consultant's suitability for the role (SLC T16).

The lead embryologist is registered by the Health and Care Professions Council (SLC T14).

The lead counsellor is accredited with the British Infertility Counselling Association (BICA) (SLC T14). The counsellor was interviewed on inspection and information obtained along with the training and experience described in the counsellor's CV appeared to demonstrate her suitability for the role of counsellor.

The lead nurse is registered with the Nursing and Midwifery Council (NMC) (SLC T14). She was available for interview at the time of the inspection and information obtained during the interview, along with the training and experience described in her CV, demonstrated her suitability for the role of lead nurse at the centre.

There are documented induction and training procedures for 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.

Nothing noted.

Welfare of the Child (Guidance Note 8)

What the centre does well.

There is an SOP for conducting welfare of the child assessments. 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). If asked for an

opinion, the counsellor will write a report with the consent of the patient.
What the centre could do better. Nothing noted.

• **Embryo Testing** Preimplantation genetic screening (Guidance Note 9) • Embryo testing and sex selection (Guidance Note 10)
Not applicable to this centre.

2. Patient Experience

Focus

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

- treats prospective 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 patients and donors
- gives prospective 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)
- Confidentiality and privacy (Guidance Note 30)
- Complaints (Guidance Note 28)
- Provision of costed treatment plans (Guidance Note 4)
- Egg sharing arrangements (Guidance Note 12)

What the centre does well.

Treating patients fairly
The centre's policies and procedures appeared to enable patients to be treated fairly (Guidance Note 29).

Confidentiality and privacy
The centre will use a patient records system, which is well established in the Bourn Hall Group. Work instructions and SOP's were in place, and the PR was able to demonstrate the security of the system.

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

Provision of costed treatment plans
The process for issuing patients with individualised costed treatment plans was explained to the inspection team and appeared compliant with CoP Guidance Note 4.3.

Egg sharing arrangements
SOPs are in place to cover the treatment and management of egg share providers. Staff were aware of the requirements of Directions 0001.

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) –
- Information about legal parenthood (Guidance Note 6)

What the centre does well.

Patient information was reviewed by the inspection team and was considered to be comprehensive. The patient information was audited against SLCs T58 and T63 as well as the relevant guidance notes, and was found to be compliant. The centre's website was compliant with the requirements of Chair's Letter CH(11)02.

There is an SOP for providing information to patients (SLC T33b).

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.

Written consent will be obtained before gametes or embryos are used in treatment or placed in storage (SLC T57); completed consent forms will be held in the patient records (SLC T46f). There is a SOP for obtaining consent for treatments from patients (SLC T33b).

Consent to legal parenthood will be obtained and centre staff understand the requirements in relation to legal parenthood. There are mechanisms in place 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.

Nothing noted.

3. Protection of gametes and embryos

Focus

The purpose of the inspection was to assess whether the proposed 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 conduct the proposed licensed activities only on the proposed licensed premises(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 for the use of gametes and embryos based on the patient's medical history and therapeutic indications (SLC T49). Embryos will only be stored for licensed purposes.

Staff are aware of the requirements of General Directions 0001 in respect of compensation for 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)

What the centre does well.

Patients will be screened in accordance with SLC T50 before their gametes or embryos are stored

The centre staff explained how the bring forward system will work to ensure that gametes and embryos are not stored beyond their consented storage period (SLC T79, T80 and T81).

There is the facility to provide information about counselling and mediation services in cases where disputes arise when one gamete provider withdraws consent to the storage or use in treatment of embryos.

What the centre could do better.

Nothing noted.

Distribution and / or receipt of gametes and embryos

- Distribution of gametes and embryos (Guidance Note 15)
- Export of gametes and embryos (Guidance Note 16)
- Receipt of gametes and embryos (Guidance Note 15)
- Import of gametes and embryos (Guidance Note 16)

What the centre does well.

Centre staff demonstrated their understanding of the requirements for distribution, receipt, import and export of gametes and embryos (SLC T105, T106, T107, T108, T109 and T110).

What the centre could do better.

Nothing noted

Use of embryos for training staff (Guidance Note 22)

What the centre does well.

An information sheet was available for patients, stating that there is an option for them (the gamete providers) to consent to the use of their gametes or embryos in training (SLC T94).

What the centre could do better.

A SOP is required to describe the processes to be used by embryologists engaged in using embryos in training. This SOP should specifically cover: that it is clearly communicated to embryologists that embryos used in training should not be later used in treatment (SLC T92); which training activities can be attempted using donated embryos (SLC T93); that the consents of gamete providers must be verified before embryos are used in training (SLC T94); the processes used to prevent a conflict of interest between the use of the embryos in training and in treatment (SLC T95).

4. Good governance and record keeping

Focus

The purpose of the inspection was to assess whether the proposed 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 are document 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 included.

Procedures are in place to ensure that records are protected from unauthorised access and amendment (SLC T47). These measures include secure notes storage and password protection on the computers.

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). The PR confirmed that he was familiar with the mechanism by which data is submitted to the HFEA (Directions 0005 and SLC T15a).

The centre responded to all requests for information prior to inspection (SLC T4).

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 confidentiality and privacy for the patients. Patients will be identified by their photographic identity documentation, a copy of which will be retained in the patient's records and stored on the computer system.

Computers are password protected and the centre aims to have a paperless record system.

Access to critical areas is restricted by key fob locks. Access to the centre is restricted during the day by the reception staff and at night effective locking systems, CCTV and alarms are in place.

Staff are aware of the option for patients to consent to disclose their information for use in research.

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 potential non compliance. Each area is referenced to the relevant sections of the Act, 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 his/her legal duties
- a combination of several "other" areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. The centre has not validated all critical procurement and processing procedures (SLC T72).	The PR should ensure all critical procurement and processing procedures are validated. A sample including: The storage procedures and the ICSI processes should be forwarded to the inspector before the first treatment occurs.	A plan is in place to ensure that all critical procurement and processing procedures are validated. The validation protocols for the storage procedures and the ICSI Processes will be provided to the inspector before the first treatment occurs	The validation plan is being implemented as requested; a copy of the validation progress matrix provided on 20.03.2013 shows significant progress, with assurance from the PR that evidence of final approval will be forwarded to the lead inspector before the first treatment occurs. A sample of validation documents will be reviewed by the lead inspector on completion of validation. Further action required.
2. The air quality in the processing areas has not been assessed (SLC T20).	The PR should ensure the air quality in the processing areas is assessed and meets the	The validation of the facility is ongoing and the quality of the air in the processing areas is	The validation progress matrix provided on 20.03.2013 included evidence that the

	requirements of SLC T20. The results of the assessment should be forwarded to the inspector before the first treatment occurs.	included in this validation. The results of the air quality assessment will be provided to the inspector before the first treatment occurs	initial air quality test was completed, and that air quality met the required standard. Results of the final testing must show that they meet the requirements of SLC T 20, before the first treatment occurs. Further action required.
3. The validation of all critical equipment, including instruments, devices and other consumables has not yet been performed (SLC T24 and T28).	The PR should ensure that critical equipment, instruments, devices and other consumables to be used during the procurement and processing of gametes and/or embryos are validated. The inspector should be informed when the external service supplier has completed the validation, and a copy of the validation report should be sent to the lead inspector before the first treatment occurs.	Validair are currently undertaking the validation of the facility and equipment. The validation activities are currently on schedule and the validation report(s) will be provided to the lead inspector before the first treatment occurs	The centre are making significant progress to meet the requirement in March or early April. The PR has agreed to provide evidence of validation before the first treatment occurs. A sample of validation documents will be reviewed by the lead inspector on completion of validation. 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
4. The centre has not established quality indicators for the provision of counselling, and the selection and recruitment of donors (SLC T35).	The PR should ensure that the centre develops quality indicators for: counselling and the selection and recruitment of donors. A copy of the quality indicators should be submitted to the lead inspector by 13 May 2013.	Quality indicators for counselling and the selection and recruitment of donors will be developed and a copy of these will be provided to the lead inspector by 13 May 2013. The counselling QIs will be based on BICA information and measurement against them will be prepared by the counsellors, who are independent of Bourn Hall Clinic. The output against the QI will be reviewed as part of the QA audit of the counselling services. The QI for the selection and recruitment of donors will be based on the requirements detailed in SOP MN003 and its associated documents. The measurement against the QI	The PR has shown a commitment to establish the two quality indicators by 13 May 2013. This will be monitored by the lead inspector to ensure that the target date is met. Further action required.

		will be undertaken by Clinic staff and this output will be reviewed during the QA audit of the medical and nursing functions	
5. All diagnostic testing will be performed in the laboratories at Bourn Hall Cambridge, with the exception of Andrology. Currently Bourn Hall Cambridge are waiting to be inspected by UK Accreditation Services so the laboratory is not currently appropriately accredited (SLC T51a).	The PR should ensure that all diagnostic tests are provided by laboratories accredited to the appropriate standard. The PR should update the lead inspector when all diagnostic testing laboratories are appropriately accredited, or submit a progress update by 13 May 2013.	Some of the diagnostic testing will be conducted within the CPA accredited laboratories at the Norwich and Norfolk Hospital. The Clinical Science Laboratories at Bourn Hall Clinic Cambridge are scheduled to be inspected by UKAS during April 2013. The outcome of this inspection and / or a progress update will be provided to the lead inspector by 13 May 2013.	The lead inspector will ensure that a progress update is made by the PR on or before 13 May 2013, if not sooner, regarding the Clinical Science Laboratories at Bourn Hall Clinic Cambridge. Further action required.
6. The centre does not have a documented SOP to follow for counselling, the operation of critical equipment, transporting of gametes and embryos, traceability, witnessing and embryos in training (SLC T33b).	The PR should ensure that the following six additional SOPs form part of the quality management system, and are updated to reflect local practice at Norwich: Counselling; The operation of critical equipment; Transporting of gametes and embryos; Traceability; Witnessing; Use of embryos in training.	The following documents are appended / will be provided to the lead inspector by 13 May 2013. Counselling (how the counselling sessions are conducted) - will be provided The operation of critical equipment - will be provided	Three of the six SOP documents have been received and are comprehensive. The following three are outstanding; The operation of critical equipment. Witnessing.

	A copy of the amended SOPs should be submitted to the lead inspector by 13 May 2013.	Transporting of gametes and embryos - Please see appended documents EM003-WI01, EM003-FM12 and EM003-FM13 Traceability - Please see appended document EM005-WI04. Witnessing - will be provided Use of embryos in training - Please see appended document EM003-WI03	Counselling (how the counselling sessions are conducted) The PR has given a commitment to forward these by 13 May 2013. Further action required.

Additional information from the Person Responsible
Could I once again thank the visiting inspection team on your professionalism and timeliness.

HFEA Licence Committee Meeting

28 March 2012

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

Minutes – Item 1

Centre 0325 (Bourn Hall Clinic (Norwich) – Initial Inspection Report

Members of the Committee: Sue Price (professional) Chair Debbie Barber (professional) Jane Dibblin (lay) Andy Greenfield (lay)	Committee Secretary: Lauren Crawford Legal Adviser: Stephen Hocking, Beachcroft LLP

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

- Cover sheet
- Initial inspection report
- Application form
- CV of proposed PR
- References (x2) for proposed PR
- CV of proposed LH
- Confirmation from 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 inspection of Bourn Hall Clinic (Norwich) took place in February 2013.

2. The Committee noted that Bourn Hall Clinic (Norwich) is in a dedicated building designed specifically for fertility patients. The centre is registered as Bourn Hall Clinic (Norwich) Limited and forms part of the Bourn Hall Group. The premises address is:

   Unit 3
   Gateway 11
   Wymondham
   Norwich
   NR18 OWF

3. The Committee noted that the application is for a licence for treatment and storage at the new centre.

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 three major areas of non-compliance and three 'other' area of non-compliance or poor practice.

5. The Committee noted that since the inspection the proposed PR has given a commitment to fully implement the three major recommendations before any treatment is offered at the centre, and to implement the three 'other' recommendations by 13 May 2013.

   Major areas of non-compliance:

   - The PR should ensure all critical procurement and processing procedures are validated prior to treatment being offered.
   - The PR should ensure the air quality in the processing areas is assessed and meets the requirements of Standard Licence Condition (SLC) T20 before treatment is offered.
   - The PR should ensure that critical equipment, instruments, devices and other consumables to be used during the procurement and processing of gametes and/or embryos are validated prior to treatment being offered.

   'Other' areas of practice that require improvement:

   - The PR should ensure that the centre develops quality indicators for counselling and the selection and recruitment of donors.

- The PR should ensure that all diagnostic testing services are provided by laboratories accredited to the appropriate standard.
- The PR should ensure that the following six SOPs form part of the centre's quality management system and are updated to reflect local practice at Bourn Hall Norwich: Counselling; The operation of critical equipment; Transporting of gametes and embryos; Traceability; Witnessing; Use of embryos in training.

6. 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

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

8. The Committee was satisfied that the character of the proposed PR, Dorian Ransome, 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).

9. The Committee noted that the proposed PR holds an academic qualification in the field of Biological Sciences, having a BSc (Hons) in Life Sciences. The proposed PR also has more than two year's practical experience directly relevant to the activities to be authorised by the licence. He has successfully completed the HFEA PR Entry Programme and has two satisfactory references.

10. The Committee considered that the proposed PR is suitable.

11. The Committee was also satisfied regarding the suitability of the proposed Licence Holder, Thomas Mathews, having seen his CV.

12. The Committee noted that the licence application concerns treatment and storage services which relate to gametes or embryos intended for human application.

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

14. The Committee noted that the application includes the use of embryos for training, the Committee was satisfied that this activity was necessary and desirable and that the use of embryos was necessary for that purpose.

15. 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 and noted which states that "[The Licence Committee] will normally grant an initial treatment/storage 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.

16. 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 non-compliance detailed in the report.

Decision

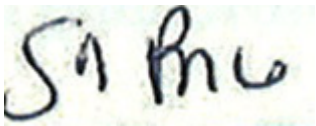
17. The Panel agreed to appoint Dorian Ransome as the Person Responsible for Bourn Hall Clinic (Norwich) (Centre 0325) with immediate effect, in accordance with section 18A of the HFE Act 1990 (as amended).

18. The Panel agreed to appoint Thomas Mathews as the Licence Holder for Bourn Hall Clinic (Norwich) (Centre 0325) with immediate effect.

19. The Committee agreed to grant the centre’s licence for a period of two years with the additional condition, ‘**That no licensed activity should take place at the centre until PR provides satisfactory evidence of compliance with the outstanding recommendations relating to the major areas of non-compliance detailed in the report and referenced in paragraph 5 of these minutes’**. The condition was considered necessary and proportionate given the ongoing issues to be addressed by the centre, the current resources available for enforcement and the need to safeguard patients.

20. The Committee agreed that the condition should remain on the licence until such time as the centre has provided evidence which shows that all non-compliances have been addressed. It is then open to the PR to apply to have the licence varied to remove the additional condition, if he so wishes. If such an application is made the Committee directed that the matter should come back to the Licence Committee.

Signed: Date: 15/04/2013



Sue Price (Chair)