HFEA Executive Licensing Panel Meeting

1 November 2013

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

Minutes – Item 1

Centre 0322 – (Brighton Fertility Associates) – Renewal Storage Inspection Report

Members of the Panel:	**Committee Secretary:**
Mark Bennett – Director of Finance and Facilities (Chair)	Dee Knoyle
Paula Robinson – Head of Business Planning	**Observing:**
Ian Peacock – Analyst Programmer	Sam Hartley – Head of Governance and Licensing

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

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

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

2. The Panel noted that this is a storage only centre. The Panel noted that at the time the centre received the initial licence the Person Responsible (PR) was intending to offer treatments, and therefore a treatment and storage licence was applied for and granted. However, since the initial licence was granted the centre has only been recruiting sperm donors and storing sperm, and has not provided any treatments; moreover, the PR does not intend to provide treatments in the immediate future. To reflect this, the PR applied to vary the licence to a storage only licence, and this variation was granted on 4 October 2013.

3. The Panel noted that the centre has been licensed by the HFEA since February 2012. The Panel noted that the centre is on an initial two-year licence, due to expire on 19 February 2014.

4. The Panel noted that at the time of the inspection on 20 August 2013 there was one major area of non-compliance that required improvement.

5. The Panel noted that following the inspection the Inspectorate recommended that the Person Responsible (PR) should provide the HFEA with a summary report of changes made to patient information, or evidence of how the information will be provided verbally to donors, that stress the importance of informing the centre of any changed medical information after donation and maintaining up to date contact information. The Panel noted that the PR has provided evidence since the inspection that this recommendation has been implemented, and that there were no outstanding recommendations.

Decision

6. The Panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

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

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

9. The Panel agreed with and endorsed the Inspectorate's recommendation to renew the centre's licence for storage only. The Panel noted that the activities the centre applied to conduct were only to procure, process and distribute sperm and urged the Authority's Inspectorate to ensure that these were the only activities the centre undertook.

10. After considering the guidance on periods for which new or renewed licences should be granted, the Panel agreed it had no concerns and agreed to renew the licence for a period of four years, with no additional conditions. The Panel took into account the absence of critical non-compliances and reported incidents, the overall performance of the centre and the current status and reported extent and severity of the non-compliance.

Signed:  Date: 7 November 2013

Mark Bennett (Chair)

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 20 August 2013
Purpose of inspection: Renewal of a licence to carry out 'Storage only'

Inspection details:

The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Inspectors: Vicki Lamb and Bhavna Mehta

Date of Executive Licensing Panel: 1 November 2013

Centre name	Brighton Fertility Associates
Centre number	0322
Licence number	L/0322/1/b
Centre address	Lower Ground Floor, Olivier House, 18, Marine Parade, East Sussex, Brighton, BN2 1TL, UK
Person Responsible	Ms Suzanne Duffy
Licence Holder	Carolyn Croucher
Date licence issued	20/02/2012
Licence expiry date	19/02/2014
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
Brighton Fertility Associates has held a licence with the HFEA since February 2012.

At the time the centre received the initial licence the PR was intending to offer treatments, ad therefore a treatment and storage licence was applied for and granted. However, since the initial licence was granted the centre has only been recruiting sperm donors and storing sperm, and has not provided any treatments, and the PR does not intend to provide treatments in the immediate future. To reflect this, the PR applied to vary the licence to a storage only licence, and this variation was granted on 4 October 2013.

Activities of the centre:

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

Outcomes
The centre has not provided any treatments since the initial licence was granted.

Summary for licensing decision
Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the PR is suitable and she has discharged her duty under section 17 of the HF&E Act 1990 (as amended)
- the premises are suitable
- the practices are suitable
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, in application for renewal of their licence
- the centre has submitted an application fee to the HFEA in accordance with requirements

The Executive Licensing Panel is asked to note that at the time of the inspection there was one major area of non-compliance which resulted in the following recommendation:

Major areas of non compliance:

- The PR should provide the HFEA with a summary report of changes made to patient information or evidence of how the information will be provided verbally to donors, and how previous donors will be made aware of any changes in relation to informing the recruiting centre of any medical information that may come to light after donation and of supplying up to date contact information.

The PR has provided evidence that this recommendation has been implemented.

Recommendation to the Executive Licensing Panel

Some improvement is required in order for the centre to reflect good practice and demonstrate the quality and safety of the service it provides. The inspection team is however satisfied that activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

The inspection team recommends the renewal of the centre's storage licence for a period of four years without additional conditions subject to compliance with the recommendations made in this report being implemented within the prescribed timescales

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

1. Protection of the patient, and children born following treatment

Witnessing and assuring patient and donor identification (Guidance note 18)

What the centre does well.

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

What the centre could do better.

Nothing noted on inspection.

Patient and donor selection criteria and laboratory tests

- Screening of patient and / or donors prior to procuring, processing and / or transporting gametes and embryos (Guidance notes 11 and 15)
- Payments for donors (Guidance note 13)
- Donor assisted conception (Guidance note 20)

What the centre does well.

Screening of donors

The centre's procedures for screening donors are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Payments for donors

Payments to donors are fully in line with the requirements of the HFEA. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

Donor assisted conception

People born as a result of donation are entitled to request and receive their donor's name and last known address, once they reach the age of 18. Therefore it is important that centres use donated gametes or embryos from identifiable donors. The centre is fully in

line with the requirements of the HFEA to ensure the donor conceived will be able to receive this information.

What the centre could do better.

Nothing noted on inspection.

Good clinical practice

What the centre does well.

Multiple births (Guidance note 7)
This centre does not provide treatment, and therefore this section is not relevant to this centre.

Process Validation(Guidance note 15)
The centre has fully validated all critical processing procedures to ensure that these procedures are effective and do not render the gametes clinically ineffective or harmful to the recipient.

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA requirements to ensure it has the ability -
(a) to identify and locate gametes during any step from procurement to use for human application or disposal,
(b) identify the donor of particular gametes,
(c) to identify any person who has carried out any activity in relation to particular gametes, and
(d) to identify and locate all relevant data relating to products and materials coming into contact with particular gametes and which can affect their quality or safety.

Quality management system (Guidance note 23)
The centre has a quality management system in place that is compliant with HFEA requirements. The centre uses its quality management system to ensure optimum outcomes and improve the quality and safety of the treatment and services it provides to patients.

Third party agreements (Guidance note 24)
The centre has agreements in place which covers the supply of any goods or services (including distribution services) to the licensed centre which may affect the quality or safety of gametes.

Equipment and materials (Guidance note 26)
All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to donors and/or staff.

Premises (Guidance note 25)

The centre conducts all of the licensed activities in an appropriate environment, in line with good clinical practice. All diagnostic testing is carried out in a suitable accredited laboratory.

Adverse incidents (Guidance note 27)
The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all of the adverse incidents that have occurred and shares the lessons learned in order to continuously improve the services it offers.

What the centre could do better.

Nothing noted on inspection.

Staff engaged in licensed activity

What the centre does well.

Person Responsible (Guidance note 1)
The PR has a key role to play in implementing the requirements of the HF&E Act 1990 (as amended) and is the person under whose supervision the licensed activities are authorised. The PR has the primary (legal) responsibility under Section 17 of the HF&E Act 1990 (as amended) to secure:

- that suitable practices are used in undertaking the licensed activities;
- that other persons working under the licence are suitable and;
- that the conditions of the licence are complied with.

The PR has academic qualifications in the field of biological sciences and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence.

The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1196/8).

Staff (Guidance Note 2)
The centre has suitably qualified and competent staff to carry out all of the licensed activities and associated services.

What the centre could do better.

Nothing noted on inspection.

Welfare of the child (Guidance note 8)

What the centre does well.

This centre does not provide treatment, and therefore this section is not relevant to this centre.

What the centre could do better. Nothing noted on inspection.

Embryo testing • Preimplantation genetic screening (Guidance note 9) • Embryo testing and sex selection (Guidance note 10)
What the centre does well. This centre does not provide treatment, and therefore this section is not relevant to this centre.
What the centre could do better. Nothing noted on inspection.

2. The experience of patients

Patient feedback

What the centre does well.

This centre does not provide treatment, but does recruit sperm donors.

On the basis of observations made in the course of the inspection it was possible to assess that the centre:

- has respect for the privacy and confidentiality of donors in the clinic;
- gives donors sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides donors with satisfactory facilities.

What the centre could do better.

Nothing noted on inspection.

Treating patients fairly

What the centre does well.

Gamete sharing arrangements (Guidance note 12)
This centre does not provide treatment, and therefore this section is not relevant to this centre.

Surrogacy (Guidance note 14)
This centre does not provide treatment, and therefore this section is not relevant to this centre.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek feedback and to be responsive to complaints. The centre uses feedback and any complaints as an opportunity to learn and improve their services.

Treating patients fairly (Guidance note 29)
The centre treats prospective and current donors fairly, and ensures that all licensed activities are conducted in a non-discriminatory way.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current donors.

What the centre could do better.

Nothing noted on inspection.

Information

What the centre does well.

The centre's procedures for providing information to donors are partially compliant with HFEA requirements. This ensures that the centre gives prospective and current donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

Provision of costed treatment plans (Guidance note 4)
This centre does not provide treatment, and therefore this section is not relevant to this centre.

What the centre could do better.

The centre does not provide the following information to donors in written documentation or verbally:

- the importance of informing the recruiting centre of any medical information that may come to light after donation that may have health implications for any woman who receives treatment with those gametes or for any child born as a result of such treatment;
- the importance of supplying up to date contact information so that the donor can be informed if and when disclosure of identifiable information will be made.

This puts the centre at risk of failing to provide proper information to donors giving consent, as required by the HF&E Act 1990 (as amended) paragraph 3 (1)(b) of schedule 3.

Consent

What the centre does well.

The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that donors have provided all relevant consents before carrying out any licensed activity.

Disclosure of information, held on the HFEA Register, for use in research
The Register started operating in August 1991 and is a rich source of information about assisted reproductive technologies (ART), its outcomes and the factors that contribute to the birth of a baby following treatment. This information can be used by researchers and, in certain circumstances, linked to other health registers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment. Whereas the HFEA is permitted to disclose non-identifying information to researchers it can only provide identifying information with the consent of patients and donors. Therefore, it is important that patients and donors are asked to give their consent and that their wishes are accurately recorded and passed on to the HFEA. The centre's procedures for doing this ensure that the HFEA holds an accurate record of the donor's consent, so that it only releases the donor's identifying information, to researchers, with their consent.

What the centre could do better. Nothing noted at inspection.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well.

No embryos are present at this centre, and therefore respect for the special status of the embryo is not relevant to this centre.

What the centre could do better.

Nothing noted on inspection.

Storage of gametes and embryos

What the centre does well.

The storage of donor gametes is an important service offered by fertility clinics.

The centre's procedures for storing gametes are compliant with HFEA requirements. These measures ensure that the gametes are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes in accordance with the consent of the gamete providers.

What the centre could do better.

Nothing noted on inspection.

Distribution and / or receipt of gametes and embryos

What the centre does well.

The centre's procedures for distributing and / or receiving gametes are compliant with HFEA requirements. This ensures that all gametes sent to other licensed centres within or outside the UK are appropriately labelled and relevant information is sent to the other centre to ensure the continued quality and safety of the gametes. The centre only accepts gametes from other centres if the gametes are appropriately labelled and has enough information to permit the gametes to be stored or used in a way that does not comprise their quality and safety.

What the centre could do better.

Nothing noted on inspection.

Use of embryos for training staff (Guidance note 22)
What the centre does well. No embryos are present at this centre, and therefore use of embryos for training staff is not relevant to this centre.
What the centre could do better. Nothing noted on inspection.

4. Information management

Record keeping and submitting information to the HFEA

What the centre does well.

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained.

Obligations and reporting requirements (Guidance note 32)
The HFEA has a legal responsibility to maintain a register containing information about all licensed activities including information on donors and on any children conceived as a result of their donation. In order to maintain this Register, clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

The centre's procedures for submitting information about donors to the Authority are compliant with HFEA requirements and ensure the HFEA can supply accurate information to a donor-conceived person and their parents.

What the centre could do better.

Nothing noted on inspection.

Section 3: Monitoring of the centre's performance

Following the initial inspection in 2011, recommendations for improvement were made in relation to three 'other' areas of non-compliance.

The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales.

Section 4: Areas of practice requiring action

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

Critical area of non compliance

A critical area of non-compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

Major area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several "other" areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. The centre does not provide the following information to donors in written documentation or verbally: • the importance of informing the recruiting centre of any medical information that may come to light after donation that may have health implications for any woman who receives treatment with those gametes or for any child born as a result of such treatment; • the importance of supplying up to date contact information so that the donor can be	The PR should provide the HFEA with a summary report of changes made to patient information or evidence of how the information will be provided verbally to donors, and how previous donors will be made aware of any changes in relation to informing the recruiting centre of any medical information that may come to light after donation and of supplying up to date contact information. By 20 November 2013	The donors are provided with this in the current BFA consent form. However this has been updated throughout the year and only the newest donors have this form. However, after HFEA recommendation we have contacted all completed donors to update their consent to this newest version which includes a statement to cover this issue. Furthermore all donors sign a statement at each donation if there have been any changes in health or relationship status. This sheet has been in use for all donors. To strengthen this issue I have already amended our	The amended patient information has been provided to the inspector. The amended patient information was considered satisfactory. No further action required.

informed if and when disclosure of identifiable information will be made. HF&E Act 1990 (as amended) paragraph 3 (1)(b) of schedule 3.		screening information and donor information leaflet for donors to include this information given to all new donors.	

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

Reponse from the Person Responsible to this inspection report