

HFEA Licence Committee Meeting

11 July 2013

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

Minutes – Item 2

Centre 0332 (Oxford Heart Valve Bank) – Initial Inspection Report Storage Only

Members of the Committee:

Sally Cheshire (lay) Chair
Bishop Lee Rayfield (lay)
Gemma Hobcraft (lay)

Committee Secretary:
Lauren Crawford

Legal Adviser:
Stephen Hocking, DAC
Beachcroft

Declarations of Interest: Debbie Barber was conflicted on this item as she works with Oxford University Hospitals NHS Trust which this new centre is linked to. Gemma Hobcraft who had earlier given apologies for this meeting was able to hear the item in her place.

The following papers were considered by the Committee

- Initial inspection report
- Application form
- CV of the proposed PR
- Two references for the proposed PR

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 April 2013, regarding licensing requirements for a storage only centre.
2. The Committee noted that Oxford Heart Valve Bank is located at:

Cardiovascular & Thoracic Surgery Division,
Cardiac Unit, Level 0,
John Radcliffe Hospital,
Oxford University Hospitals NHS Trust,
Headington,
Oxford,
OX3 9DU
3. The Committee noted that Oxford Heart Valve Bank plans to treat patients who are at risk of premature ovarian failure: storage of cryopreserved ovarian tissue for future auto-transplantation will enable women to preserve their fertility after ovarian function has ceased.
4. The ovarian tissue will be procured in the main hospital operating theatre in the Oxford University Hospitals NHS Trust then transported in human tissue boxes by centre staff to the Oxford Heart Valve Unit where it will be processed and stored. The procurement will be carried out under the auspices of a third party agreement (TPA) between the Oxford University Hospitals NHS Trust and the Oxford Heart Valve Bank.
5. 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 two areas of ‘major’ non-compliance and one ‘other’ area of non-compliance or poor practice.
6. The Committee noted that the Person Responsible has given a verbal commitment to fully implement the recommendations which are:

‘Major’ areas of practice that require improvement:

 - The PR should consider guidance on CE marking requirements issued by the HFEA and review the use of non CE marked products.
 - The PR should review the proposed patient information in consideration of the CoP guidance.

‘Other’ areas of practice that require improvement:

- The PR should ensure that the counsellor can provide evidence of having accreditation equivalent to that conferred by the British Infertility Counselling Association (BICA).
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-compliances 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, Ms Jill Davies, 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 has academic qualifications in the field of biological sciences and 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)). Ms Davies is also the Designated Individual (DI) for the HTA licence. 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, Dr Chandi Ratnatunga.
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 does not include the use of embryos for training.
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 4.3 and noted paragraph 4.4 of the guidance which states [The Executive Licensing Panel] will normally only grant a renewal licence for treatments/ storage non-medical fertility services licence for a period of up to four years where the evidence before it reveals no concerns in the matters specified in paragraph 4.3.
17. The Committee noted the Inspectorate's recommendation for a two year licence, without additional conditions, subject to the proposed PR providing written evidence of compliance with the non-compliance detailed in the report.

Decision

18. The Panel agreed to appoint Ms Jill Davies as the Person Responsible for Oxford Heart Valve Bank (Centre 0332) with immediate effect, in accordance with section 18A of the HFE Act 1990 (as amended).
19. The Panel agreed to appoint Dr Chandi Ratnatungah as the Licence Holder for Oxford Heart Valve Bank (Centre 0332) with immediate effect.
20. The Committee agreed to grant the centre's licence for a period of two years with no additional conditions, However the PR should nevertheless provide the Inspectorate with evidence of compliance with the recommendations detailed in the report and referenced in paragraph 7 of these minutes, within the agreed timeframes.

Signed:

Date: 30/07/2013



Sally Cheshire (Chair)