HFEA Executive Licensing Panel Meeting

22 August 2014

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

Minutes – Item 4

Centre 0086 – (BMI Chelsfield Park) – Change of Premises

Members of the Panel: Juliet Tizzard – Director of Strategy & Corporate Affairs (Chair) Hannah Verdin – Head of Regulatory Policy David Moysen – Head of IT	Committee Secretary: Dee Knoyle Observing: Sam Hartley – Head of Governance & Licensing

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

The Panel 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 an executive summary, a completed application form and licensing minutes for the past three years.

2. The Panel noted that BMI Chelsfield Park is a small centre located within the BMI Chelsfield Park Hospital in Orpington, Kent. The centre has been licensed by the HFEA since 1993 and provides a full range of fertility services.

3. The Panel noted that a building project was underway at Chelsfield Park Hospital to remove asbestos known to be present in walls and ceilings in the older, original part of the building. The assisted conception unit was affected by this work and therefore needed to be relocated. The embryology laboratory, cryostore, procedure room and offices were to be temporarily relocated within the newer part of the hospital (outside the footprint of the currently licensed premises) until this work is completed.

4. On 25 July 2014, the Executive Licensing Panel met and approved the centre's application for Special Directions to store gametes at an appropriate temporary location, outside the floor plan of the current licence. The Special Directions were to remain in force for three months with a start date of 8 August 2014 to facilitate a controlled move. The dewars were to be stored at the temporary location pending a future variation of licence application which has been received and was considered at this meeting.

5. The Panel noted that key documents were requested from the centre to support a desk-based assessment to provide assurance that the premises and equipment in the proposed temporary facility are suitable and satisfy the requirements of the Act in relation to the granting of a licence (HF&E Act 1990 (as amended) s16 (2) (d) and (e)). On the basis of the findings documented, it was concluded that the centre's proposed temporary premises and facilities were suitable for the conduct of licensed activities.

6. The Panel noted that the centre's critical processes and procedures will be unchanged and were considered appropriate at the time of the last renewal inspection in April 2013. The centre does not intend to change any activities or the type of licence.

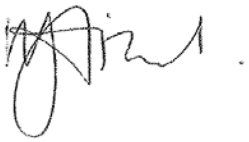
7. The Panel noted the Inspectorate's recommendation to vary the licence to reflect a change of existing premises subject to the Person Responsible providing confirmation and evidence prior to licensed activity starting, that:

    a. the laboratory and clinical procedure room areas have been subject to a final 'deep clean' and microbiological testing is satisfactory;
    b. repeat environmental air quality testing has been conducted and meets at least Grade C air quality, with a background environment of at least Grade D air quality;
    c. new and relocated critical equipment in the laboratory and clinical areas has been commissioned, calibrated and validated or revalidated as required.

Decision

8. The Panel noted that the centre has complied with the requirements of General Directions 0008 (section H 13) in submitting a relevant application form and a floor plan of the premises to be referenced on the licence.

9. The Panel endorsed the Inspectorate's recommendations and agreed to vary the centre's licence to reflect a change of premises.



Signed: Date: 5 September 2014

Juliet Tizzard (Chair)