

HFEA Executive Licence Panel Meeting

24 June 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 10

Centre 0021 (The Hull IVF Unit) –Variation of licence to include an Andrology laboratory (Treatment & Storage)

Members of the Panel: Mark Bennett, Director of Finance & Facilities (Chair) Nick Jones, Director of Compliance Juliet Tizzard, Head of Policy	Committee Secretary: Joanne McAlpine
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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

1. The Panel noted that the Person Responsible (PR) made an application on 29 March 2011 to vary the premises designated on the centre's treatment and storage licence.
2. The Panel noted that the PR wishes to include in the designated premises an Andrology laboratory situated adjacent to the centre, on the other side of the corridor which forms one side of the centre's perimeter.
3. The Panel noted that the application includes a variation of licence application, and a detailed floor plan of the centre denoting the location of the Andrology laboratory.
4. The Panel noted that the Andrology laboratory will be used for diagnostic purposes (pre-treatment semen evaluations) only and that validation records are available for the laboratory's air flow cabinet.
5. The Panel noted that the laboratory is CPA accredited and that it has locked filing cabinets, an alarm, and a series of 2 locked doors and key fob activated entry, to ensure that identifying information remains confidential.
6. The Panel noted that the premises designated as an Andrology laboratory within this application, is also designated as the premises occupied by a HFEA licensed research project (R0067: Biochemistry of Early Human Embryos).
7. The Panel noted that on 10 September 2010, the ELP approved the relocation of research project R0067 from the University of York to The Hull IVF Unit.
8. The Panel noted that information provided fulfils the requirements as defined in Direction 0008, paragraph 19 and the Inspectorate is satisfied.
9. The Panel noted that an inspection of the proposed new premises was not performed. A decision that an inspection was unnecessary was taken by Compliance Management on the basis that this is a limited change to the premises and the service. In addition, the Panel noted that an interim inspection is due on 11 August 2011.
10. The Panel noted that the Inspectorate is in support of this application.

Decision

11. The Panel agreed to the Inspectorate's recommendation to the variation of the centre's treatment and storage licence to include the Andrology laboratory, in accordance with section 18A of the HFE Act 1990 (as amended).

Signed: 
Mark Bennett (Chair)

Date:

6 July 2011