HFEA Executive Licensing Panel Meeting

25 January 2013

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

Minutes – Item 5

Centre 0035 – (Oxford Fertility Unit) – Variation of Licence to include HLA tissue typing in a specified patient couple with a child suffering from Diamond-Blackfan Anaemia OMIM#105650

Members of the Panel:	Committee Secretary:
Juliet Tizzard, Head of Policy & Communications (Chair) Ian Peacock, Analyst Programmer Matthew Watts, Regulatory Policy Manager	Joanne McAlpine

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 an executive summary, a redacted application form, and a redacted letter from the treating clinician.

2. The Panel noted that this centre has considerable experience in carrying out PGD and has conducted other PGD cycles involving HLA tissue typing.

3. The Panel noted that Diamond Blackfan Anaemia (DBA) is on the list of conditions approved for PGD testing by the HFEA, and has been judged to be a serious medical condition under the terms of the HFEA Act.

4. The Panel noted that the patient couple are planning to use PGD to test for DBA and the testing of the embryo to establish whether the tissue of any resulting child would be compatible with that of the sibling with DBA.

5. The Panel noted that the clinician was in support of the application and provided appropriate detail about the severity of the condition and medical prognosis.

6. The Panel noted the clinical spectrum can vary, from a condition responsive to steroids to severe anaemia requiring lifelong transfusions with associated risk of iron overload and other cytopenias.

7. The Panel noted that the Inspectorate recommends the variation of the centre's licence, to allow HLA for DBA for the specified patient couple in the application.

Decision

8. The Panel referred to its decision tree. The Panel noted that stages 16d (i-v), which sets out the factors that need to be addressed when considering pre-implantation tissue typing, had been demonstrated and met.

9. The Panel noted that the letter from the treating Clinician demonstrated the high degree of suffering associated with the condition and the lack of viable alternative treatment options. Accordingly, the Panel agreed that it had sufficient information and that it was satisfied that HLA tissue typing was appropriate for the patient concerned.

10. The Panel was satisfied that those seeking treatment and their families will have proper access to counselling about the implications of the procedure.

11. The Panel agreed to vary the centre's licence to include HLA tissue typing for the named patients specified in the application, for a child suffering from Diamond Blackfan Anaemia.

Signed: Date: 18 February 2013
Juliet Tizzard (Chair)