HFEA Executive Licensing Panel Meeting

1 March 2013

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

Minutes – Item 5

Centre 0044 – (Centre for Reproductive and Genetic Health) – Variation of Licence Application to include PGD HLA typing in a specified patient couple (Patient RE and Patient MW) with children suffering from Fanconi Anaemia OMIM #227645

Members of the Panel:	Committee Secretary:
Mark Bennett – Director of Finance and Facilities (Chair) Jasper Squire – Computer Programmer David Moysen – Head of IT	Rebecca Loveys

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 noted the papers which included an executive summary, a completed application form, an email confirming the OMIM number and a clinician's letter.

2. The Panel noted that this centre has considerable experience in providing pre-implantation genetic diagnosis (PGD) both with and without HLA tissue typing.

3. The Panel noted that Fanconi Anaemia is on the HFEA list of approved conditions for PGD testing and that, furthermore, PGD for Fanconi Anaemia with HLA typing has previously been authorised by the HFEA.

4. The Panel noted that embryo testing for HLA typing to provide a bone marrow/stem cell match for a sibling suffering from a serious medical condition is a lawful defined purpose for embryo testing, as specified in the HF&E Act (1990, as amended), Schedule 2, paragraph 1ZA (1) (d), and qualified by Schedule 2, paragraph 1ZA (4).

5. The Panel noted that the specified patient couple have two children who have recently been diagnosed with Fanconi Anaemia and are showing signs of bone marrow failure. They wish to undergo PGD with HLA typing to conceive a child who will be free from the condition and act as an HLA match for the affected siblings.

6. The Panel noted from the clinician's letter that, whilst an international bone marrow registry search is being conducted, it is unlikely to prove successful due to one parent's mixed race inheritance. Further, the Panel noted that the female patient involved is 39 years of age and that the centre wishes to begin procedures as soon as possible.

7. The Panel noted from the clinician's letter that the success rate of bone marrow transplantation from a matched sibling is currently around 90%, compared to 70% and 50%, respectively, when from a matched unrelated donor and a mismatched unrelated donor.

8. The Panel noted that the Inspectorate recommended the variation of the centre's licence to allow PGD HLA typing for Fanconi Anaemia for the specified patient couple in the application.

Decision

9. The Panel had regard to its decision tree. The Panel noted the purpose of the application did not include research. The Panel noted stages 16d (i-v), which set out the factors that needed to be addressed when considering pre-implantation tissue typing, had been demonstrated and were met.

10. The Panel agreed it had sufficient information about the patient couple's children's condition and was satisfied that PGD HLA typing was appropriate.

11. The Panel agreed to vary the centre's licence in accordance with the application to allow PGD HLA typing for the specified patient couple with two children suffering from Fanconi Anaemia.

Signed:  Date: 11 March 2013

Mark Bennett (Chair)