HFEA Executive Licensing Panel Meeting

16 August 2013

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

Minutes – Item 8

Centre 0044 – (The Centre for Reproductive and Genetic Health) – Variation of Licence Application to include PGD HLA typing in a specified patient couple (Patient OB and Patient OB) with a child suffering from Sickle Cell Anaemia OMIM #603903

Members of the Panel:	Committee Secretary:
Juliet Tizzard – Head of Policy and Communications (Chair)	Rebecca Loveys
Jasper Squire – Computer Programmer	Observing:
Matthew Watts – Regulatory Policy Manager	Sam Hartley – Head of Governance and Licensing

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 and letters from the treating clinician.

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

3. The Panel noted that Sickle Cell Anaemia is on the HFEA list of approved conditions for PGD testing.

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 a child who has been diagnosed with Sickle Cell Anaemia and is showing signs of bone marrow failure, and that 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 sibling. Furthermore, the specified patient couple wish to avoid having another child affected by the condition.

6. The Panel noted that the affected child's brother has undergone HLA testing but was not a suitable match.

7. The Panel noted from one of the clinician's letters that the success rate of bone marrow transplantation from a matched sibling is currently around 95% with a transplant related mortality rate of 2-5%, compared to a disease free survival rate of 85% and a transplant related mortality rate of 5-10% when from a matched unrelated donor.

8. The Panel noted that the clinician stated PDG HLA typing in the specified patient couple would be the best course of action in this situation.

9. The Panel noted that the Inspectorate recommended that the ELP grant this licence variation.

Decision

10. 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.

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

12. 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 a child suffering from Sickle Cell Anaemia.

Signed: Date: 16 August 2013

Juliet Tizzard (Chair)