HFEA Executive Licence Panel Meeting

16 November 2012

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

Minutes – Item 4

Centre 0044 - (Centre For Reproductive and Genetic Health) – Variation of Licence to include HLA tissue typing in a specified patient couple with a child with Beta-thalassaemia OMIM #141900 (ref:2023)

Members of the Panel:	Committee Secretary:
Juliet Tizzard, Head of Policy & Communications (Chair) Matthew Watts, Regulatory Policy Manager Dave Moysen, Head of IT	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 noted the papers for this item consisted of 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 pre-implantation genetic diagnosis (PGD) both with and without HLA tissue typing.

3. The Panel noted that Beta-thalassaemia is on the HFEA list of approved conditions for PGD testing. In addition, PGD for Beta-thalassaemia with HLA typing had 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, para 1ZA (1) (d), and qualified by Schedule 2, para 1ZA (4).

5. The Panel noted that the specified patient couple have a child with Beta-thalassaemia, and any child born to the couple in the future without PGD screening would have a 25% chance of inheriting the condition.

6. The Panel noted that the specified patient couple wish to undergo PGD with HLA typing in order to have a new baby who is both free from Beta-thalassaemia and a HLA match for the affected sibling.

7. The Panel noted from the clinician's letter (24 September 2012) that the patient has no HLA matched siblings and, as the parents are not consanguineous, there is no scope for extended family testing.

8. The Panel noted that the clinician's letter states that unrelated transplantation is significantly inferior to related transplantation, which has disease free survival of 95% with transplant-related mortality of only 2-5%.

9. The Panel noted that the Inspectorate recommended the variation of the centre's licence to allow HLA for Beta-thalassaemia for the specified patient couple in the application.

Decision

10. The Panel referred 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 noted that the papers demonstrated the high degree of suffering associated with the condition and the lack of viable alternative treatment options. Accordingly, the Panel agreed it had sufficient information and was satisfied that HLA typing was appropriate.

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

13. The Panel agreed to vary the centre's licence in accordance with the application to allow HLA typing for the specified patient couple with a child suffering from Beta-thalassaemia.

Signed: Date: 22 November 2012
Juliet Tizzard (Chair)