HFEA Executive Licence Panel Meeting

10 February 2012

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

Minutes – Item 9

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

Members of the Panel:	Committee Secretary:
Mark Bennett – Director of Finance & Facilities - (Chair) Nick Jones – Director of Compliance Hannah Darby– Senior 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 noted the papers for this item consisted of an executive summary, a redacted application form, redacted letters from the treating clinician (dated 20 February 2011, 2 December 2011), and additional information submitted from the centre (dated 31 January 2012).

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 list of approved conditions for PGD testing by the HFEA. In addition, PGD for Beta Thalassaemia with HLA 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 at HF&E Act (1990) as amended, Schedule 2, para 1ZA (1) (d), and qualified by HF&E Act (1990) as amended, Schedule 2, para 1ZA (4).

5. The Panel noted that the patient couple (NA and MA) have a child with Beta-thalassaemia, and any child born to the couple in the future without PGD screening has a 25% chance of inheriting the disease.

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

7. The Panel noted from the Clinician's letter (2 February 2011) states that the patient has no HLA matched siblings and the detailed HLA testing profiles for the wider family as the patient couple are first cousins.

8. The Panel noted that the Clinician's letter states that one sibling is affected with Beta Thalassaemia, and the remaining siblings are not appropriate HLA matches. As well as the parents, aunts and cousins that have been tested and are not an HLA match.

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 that the purpose of the application did not include research. 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.

11. 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 patients concerned.

12. The Panel was satisfied that 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 to include HLA tissue typing for the named patients specified in the application, for a child suffering from Beta-thalassaemia.

Signed: Date: 10 Feb 2012
Mark Bennett (Chair)