HFEA Executive Licence Panel Meeting

2 December 2011

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

Minutes – Item 7

Centre 0044 (The Centre for Reproductive and Genetic Health) – Variation of Licence to include HLA tissue typing in a specified patient couple with a child at risk of Fanconi Anaemia and a child affected by the disease

Members of the Panel:	Committee Secretary:
Mark Bennett, Director of Finance & Facilities (Chair) Nick Jones, Director of Compliance Juliet Tizzard, Head of Policy & Communications	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, a redacted letter from the Clinician in support of the application (dated 30 July 2009), additional information – review article – 'HST for Fanconi Anaemia in children: factors that influence early and late results' and a redacted Clinician's email (dated 1 November 2011) .

2. The Panel noted that this centre has considerable experience of carrying out PGD and conducted 44 cycles in 2009, including five involving HLA typing.

3. The Panel noted that Fanconi's Anaemia has already been authorised by the HFEA for use in PGD.

4. The Panel noted that more general information about the testing methodology and PGD consent forms and information have been previously submitted by the centre to the HFEA and were considered compliant and appropriate by the HFEA Licence Committee.

5. The Panel noted that embryo testing for HLA tissue type to provide a stem cell match for a sibling suffering from a serious medical condition, even without additional PGD testing of the embryo for the serious medical condition, is a lawfully defined purpose for embryo testing, as specified at HFE Act (1990) as amended, Schedule 2, para 1ZA (1) (d), and qualified by HFE Act (1990) as amended, Schedule 2, para 1ZA (4).

6. The Panel confined its consideration to the evidence before it. The Panel noted that the patient couple have a child with Fanconi Anaemia A, and any child born to the couple without PGD screening has a 25% chance of inheriting the disease.

7. The Panel noted that the patient couple wish to undergo IVF treatment with PGD to conceive a child who will not be affected by Fanconi Anaemia and who will be an HLA match for the affected sibling. The child born will be a potential source of bone marrow and/or stem cells which may be used to treat the affected sibling in the future.

8. The Panel noted the letter from the clinician treating the affected child, and the suffering associated with the condition.

9. The Panel noted that the clinician states that haemopoietic stem cell replacement is the only viable treatment to avoid the likely future bone marrow failure and acute myeloid leukaemia. The Panel noted that a chance of a cure for these conditions is 80% if the graft is from a fully matched sibling, but is much less successful if alternative (i.e. less well matched) donors are used.

10. The Panel noted that the affected child has three siblings: the eldest was affected by Fanconi Anaemia and died following a bone marrow transplant. The two surviving siblings and the parents have all been tissue-typed and none are a HLA match.

11. The Panel noted that a previous Licence Committee had concluded that Fanconi Anaemia is a serious medical condition, and was therefore satisfied that this was an appropriate treatment. The Panel noted that the purpose of the application did not include research.

12. The Panel noted the Inspectorate's recommendation to grant the variation.

Decision

13. The Panel noted that the clinician treating the affected child was in support of this application and it considered the information provided.

14. The Panel referred to its PGD decision tree. The Panel concluded that stages 16d (i) – (iv), which sets out a number of factors when considering pre-implantation tissue typing, had been demonstrated and met.

15. The Panel was satisfied from the supporting clinician's letter, and so took into account, the high degree of suffering associated with the condition.

16. The Panel agreed that it had sufficient information and that it was satisfied that HLA tissue typing was appropriate for the patient concerned.

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

18. The Panel agreed to vary the centre's licence to include HLA tissue typing for the named patients with a child who has Fanconi Anaemia.

Signed: Date: 9 Dec 2011
Mark Bennett (Chair)