# HFEA Executive Licence Panel Meeting

**18 March 2011**

21 Bloomsbury Street London WC1B 3HF

## Minutes – Item 5

**Centre 0206 (Reproductive Genetics Institute) – Variation of Licence to include HLA tissue typing in a specified patient couple with a child with Diamond Blackfan Anaemia**

| Members of the Panel: | Committee Secretary: |
|---|---|
| Mark Bennett, Director of Finance & Facilities (Chair)<br>Nick Jones, Director of Compliance<br>Juliet Tizzard, Head of Policy | Joanne McAlpine |

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item. One member declared an involvement in quality assuring the papers for the recent renewal inspection of this centre. Together, the other members considered this against the relevant guidance on conduct of meetings and conflicts of interest. The Chair decided that this was not a conflict of interest as the item before the Panel is a patient and condition specific application and unrelated to clinic licence status or duration .

**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 consent forms, redacted letters from the treating child's clinician, the laboratory accreditation certificate and patient information.

2. The Panel noted that the Inspectorate states that the centre is licensed to provide Pre-implantation Genetic Diagnosis.

3. The Panel confined its consideration to the evidence before it.

4. The applicant has submitted a certificate for the laboratory carrying out the HLA testing. The Reproductive Genetics Institute IVF, Chicago, Illinois, USA has met all applicable standards and is fully accredited by the College of American Pathologists Reproductive Laboratory Accreditation Programme.

5. The Panel noted that the patient couple have a son with transfusion-dependant Diamond-Blackfan Anaemia (DBA), diagnosed via a bone marrow biopsy at 12 months old.

6. The Panel noted the clinician's supporting letter, which provides detail about the medical history of the couple's child and female sibling. The Panel noted that the clinician states that it is likely that the son is the index case (the first member of the family to be diagnosed with DBA).

7. The Panel noted that the female sibling is not affected by DBA and that cord blood was collected at her birth but was found not to be an HLA match.

8. The Panel noted that the couple are not planning to use PGD to test for DBA. The Panel noted that the purpose of testing the embryo is to establish whether the tissue of any resulting child would be compatible with that of the sibling with DBA.

9. 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).

10. The Panel noted from the clinician's supporting letter that a family-related stem cell transplant currently offers 90-95% disease-free survival, which therefore compares favourably with the standard medical treatment.

11. The Panel noted that a previous Licence Committee had concluded that DBA 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. The Panel agreed that it had sufficient information and that it was satisfied that HLA tissue typing was appropriate for the patient concerned.

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

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

Signed: Date: 3 March 2011
Mark Bennett (Chair)