

HFEA Executive Licence Panel Meeting

4 November 2011

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

Minutes – Item 3

Centre 0157 - (Assisted Reproduction and Gynaecology Centre) – Variation of Licence to include HLA tissue typing in a specified patient couple with a child with Diamond Blackfan Anaemia

Members of the Panel: Peter Thompson, Director of Strategy & Information (Chair) Nick Jones, Director of Compliance Danielle Hamm, Senior Policy Manager	Committee Secretary: 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 signed consent forms, a redacted letter from the clinician treating the affected child, an accreditation certificate from The College of American Pathologists, and patient information.
2. The Panel noted that this centre has considerable experience in carrying out PGD and has conducted other PGD cycles involving HLA tissue typing.
3. The Panel noted the certification from The College of American Pathologists. This states that the laboratory carrying out the HLA testing in the Reproductive Genetics Institute IVF, Chicago, USA, has met all applicable standards for accreditation and is fully accredited by the College of American Pathologists.
4. The Panel noted that Diamond Blackfan Anaemia (DBA) is on the list of conditions approved for PGD testing by the HFEA, and has been judged to be a serious medical condition under the terms of the HFE Act.
5. The Panel noted that the patient couple have a son with transfusion dependent Diamond Blackfan Anaemia, and that the child has no siblings from which to test for tissue match for haematopoietic stem cells/bone marrow transplant.
6. The Panel noted that the patient couple are planning to use PGD to test for DBA and the testing of embryo is to establish whether the tissue of any resulting child would be compatible with that of the sibling with DBA.
7. The Panel noted the letter from the clinician treating the affected child. This letter supported the application and provided appropriate detail about the severity of the condition and medical prognosis of the affected child.
8. The Panel noted that the Inspectorate recommended the variation of the centre's licence, to allow HLA for Diamond Blackfan Anaemia for the specified patient couple in the application.

Decision

9. 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.

10. 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 patient concerned.
11. The Panel were satisfied that those seeking treatment and their families will have proper access to counselling about the implications of the procedure.
12. 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 Diamond Blackfan Anaemia.

Signed:  Date: 11/11/11.
Peter Thompson (Chair)

