

HFEA Executive Licensing Panel Meeting

8 April 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 6

The Centre for Reproductive and Genetic Health (0044) - Application to vary present licence to include PGD for Beta Thalassaemia major (OMIM 141900) with HLA typing for named patients

Members of the Panel:

Peter Thompson, Director of Strategy & Information (Chair)	Committee Administrator: Joanne McAlpine
Juliet Tizzard, Acting Director of Strategy and Information	
Carmel Dodson-Brown, Head of Clinical Governance & Patient Safety	

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item

The following papers were considered by the Committee:

- papers for Licence Committee (13 pages)
- no papers were tabled for this item

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings of the Authority's Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Direction 0008 (where relevant), and any other relevant Directions issued by the Authority;
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Indicative applications guidance on the time period for which licences should be granted approved by the Authority on 21 October 2009
- Indicative sanctions guidance approved by the Authority on 18 March 2009
- Licence application and any relevant documentation

1. The Panel considered the papers for this item which included an executive summary, a redacted application to vary the licence to include Beta Thalassaemia with HLA typing, and a redacted letter from the treating clinician of the sick child in support of the application.
2. The Panel noted this centre has one of the largest PGD programmes of all UK licensed clinics and conducted 46 PGD cycles between 1 January 2008 and 31 December 2009.
3. The Panel noted that this condition is a serious, transfusion-dependant anaemia affecting people who have inherited the two abnormal beta Thalassaemia genes, one from each patient.
4. The Panel noted that Beta Thalassaemia has been previously licensed by the Licence Committee for this centre.
5. The Panel noted that the couple have one affected child and another sibling and both the parents and the sibling have been tissue-typed and found to be non-matching and therefore not suitable as bone-marrow donors.
6. The Panel noted that the centre has generic patient information and consents that have previously been considered appropriate and comply with the requirements of the Code of Practice.
7. The Panel noted that the couple have received counselling by both a consultant paediatric haematologist and a consultant gynaecologist/specialist in reproductive medicine.
8. The Panel noted from the clinician's letter that the couple have a four and half year old boy who has been on regular blood transfusions from the age of two and a half.
9. The Panel noted that the treating clinician indicates that the best option of treatment is for the child to have a bone marrow transplant as the parents and the sibling are not an HLA match.

The Panel's Decision

10. The Panel referred to section 16 d (i) of the PGD decision tree and applied the tests for the purposes of PGD with HLA for Beta Thalassaemia.
11. The Panel agreed that they were satisfied that they had enough information on which to make a decision and therefore decided to approve this application to vary the licence to include PGD for beta thalassaemia major, with HLA typing for named patients Mrs NAH & Mr SAAH.

Signed..........

Date.....4/4/10.....

Peter Thompson (Chair)