

HFEA Licence Committee Meeting

31 March 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 1

Centre 0044 (The Centre for Reproductive and Genetic Health) PGD for Haemoglobin E/ beta-thalassaemia

Members of the Committee:
David Archard (lay) – Chair
Debbie Barber (professional)
Anna Carragher (lay)
Sally Cheshire (lay)
Mair Crouch (lay)

Committee Secretary:
Terence Dourado

Legal Adviser:
Tom Rider, Field Fisher

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

The following papers were considered by the Committee:

- Executive Summary
- PGD Application Form
- Oliveri N F et al (2008) Studies in haemoglobin E beta-thalassaemia. *British Journal of Haematology* 141: 388-397
- Vichinsky E (2007) Haemoglobin E syndromes. *Haematology: The American Society of Haematology*. 2007: 79-83
- LC minutes – 24th February 2011
- LC minutes – 27th March 1997
- LC minutes – 21st August 1997
- Executive Summary for LC – 5th April 2004
- LC minutes - 5th April 2004

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 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); and
- 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 Directions 0000 – 0012
 - Guide to Licensing
 - Compliance and Enforcement Policy
 - Policy on Publication of Authority and Committee Papers
 - HFEA Pre-Implantation Diagnostic Testing (“PGD”) Explanatory Note for Licence Committee
1. The Committee, at the meeting on 24th February 2011, noted that it had been asked to consider whether PGD for Haemoglobin E/ beta-thalassaemia may be carried out under the title of beta-thalassaemia (OMIM +141900) and whether other variations on beta-thalassaemia, for example sickle cell/ beta-thalassaemia, may also be carried out under the title of beta-thalassaemia (OMIM +141900).
 2. The Committee, at the meeting on 24th February 2011, having sought legal advice, were minded to decide that once PGD was authorised for OMIM +141900 testing for any condition arising from an abnormality of that gene should be permitted for suitably licensed centres, subject to the provisions of paragraph 10.6 of the Code of Practice. However, before it was able to make a fully informed decision, the committee adjourned consideration of the item for receipt of the minutes of the meeting or meetings where the PGD conditions arising from OMIM +141900 was/were first considered by a committee.
 3. Having received and reviewed the minutes of those earlier licence committee meetings which it had requested, the Committee was satisfied that those minutes did not materially affect its approach to the issue under consideration.
 4. The Committee, having reminded itself of the advice received from the Legal Adviser on 24th February 2011, determined for the reasons stated in the minutes of 24th February 2011, that PGD for Haemoglobin E/ beta-thalassaemia be permitted under the title of beta-thalassaemia OMIM+ 141900 and that other variation on the condition be carried out subject to the minutes of 24th February 2011.
 5. The Committee noted paragraph 10.5 of the Code of Practice (8th edition)/ HFEA guidance for Centres: ‘The use of PGD should be considered only where there is a significant risk of a serious genetic condition being present in the embryo. When deciding if it is appropriate to provide PGD in particular cases, the seriousness of the condition in that case should be discussed between the people seeking treatment and the clinical team. The perception

of the level of risk for those seeking treatment will also be an important factor for the centre to consider.'

Signed...  ... Date... 14.4.2011..

David Archard (Chair)