

HFEA Licence Committee Meeting

24 June 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 4

Centre 0044 (Centre for Reproductive and Genetic Health) – Variation application to perform PGD for Non-Classical Congenital Adrenal Hyperplasia (CAH), OMIM# 201910

Members of the Committee:	Committee Secretary:
David Archard (lay) – Chair	Terence Dourado
Debbie Barber (lay)	
Anna Carragher (lay)	Legal Adviser:
Sally Cheshire (lay)	Rosalind Bedward
Jane Dibblin (lay)	
Sue Price (Professional)	

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:

- Amended Executive summary
- Signed application form (including appendix)
- Redacted peer review
- Additional redacted response from peer reviewer to further information from centre
- Further information from the centre clarifying the purpose for which the embryo will be tested
- Further information from the centre regarding OMIM number and CAH
- Licence Committee minutes (application to vary) 25 March 2010

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
1. The Committee had regard to its Decision Tree. The Committee was satisfied that the Centre already has considerable experience of carrying out PGD and had conducted 46 PGD cycles between 1 January 2008 and 31 December 2009.
 2. The Committee noted that the purpose of testing the embryos was set out in paragraph 1ZA(1)(b) 'where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality'. The Committee noted that the PR had initially applied for an additional purpose of testing in error. The PR had since confirmed that it had intended to apply for the purpose of testing embryos set out in paragraph 1ZA(1)(b) only.
 3. The Committee noted that although the Executive confirmed Non-Classical Congenital Adrenal Hyperplasia (NCAH) and Classical Congenital Adrenal Hyperplasia (CAH) shared the same OMIM number, NCAH would not progress into CAH in affected individuals, and furthermore NCAH presents with much milder symptoms than CAH.
 4. The Committee noted that the condition is not life threatening. The condition may result in rapid growth (or stunted growth in some cases), excessive hair growth and acne. The peer reviewer had commented that the symptoms were eminently treatable and had not been satisfied that the condition to which the application related, as opposed to classical CAH, met the statutory test as to seriousness. The Committee also noted that treatment for the condition may be optional and need not be life long.
 5. Having considered the additional information put before it regarding NCAH and the comments of the peer reviewer, the Committee was not satisfied that this particular condition met the statutory requirements in that there was not a significant risk that persons with the condition would have or

develop a serious physical or mental disability, a serious illness or any other serious medical condition. The Committee therefore proposed to refuse the licence to authorise testing for Non-Classical Congenital Adrenal Hyperplasia (NCAH) OMIM# 201910.

Signed  ... Date... 9/7/2010

David Archard (Chair)