

HFEA Licence Committee Meeting

15 October 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 2

Centre 0078 (IVF Hammersmith) – Variation to include PGD for phenylketonuria (PKU).

Members of the Committee:	Committee Secretary:
David Archard (lay) – Chair	Rachel Fowler
Anna Carragher (lay)	Legal Advisers:
Jane Dibblin (lay)	Graham Miles, Morgan Cole
Sue Price (clinician)	
Rebekah Dundas (lay) – by videolink	
Apologies:	
Sally Cheshire (lay)	

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 (pre-Oct 09 version of the form, received 08/09/2009)
- Redacted peer review
- PGD application form (post-Oct 09 version of the form, received 16/09/2009)
- Associated correspondence

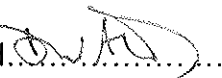
The Committee also had before it:

- 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)
- HFEA (Licence Committees and Appeals) Regulations 1991 (SI 1991/1889); and
- 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.
1. The Committee considered the papers and noted that the applicant had submitted a complete application on a pre-October 09 version of an application form and on instruction from the executive submitted a partially complete application on a post-October 09 version of an application form.
 2. GM gave legal advice that General Directions 0008 require that applications must be made by completing and submitting the application form set out in Schedule 1 to the Directions. However, Directions 0008 did not come into force until 1 October 2009, after this application had been submitted. Accordingly, there had not been a breach of the Directions in submitting the application in this form. However, the Committee had to consider the application in accordance with the requirements of the 1990 Act as amended by the 2008 Act. This particular situation was not addressed by the Human Fertilisation and Embryology (Consequential Amendments and Transitional and Saving Provisions) Order. However, Schedule 4 to the Order envisages that, where inspections have been carried out before 1 October 2009 but not considered prior to that date, the inspection reports should be provided in accordance with the provisions of the 1990 Act prior to amendment. The Committee might conclude, by analogy, that it is able to consider this application, notwithstanding the absence of a post- October 09 version of the application form. However, if the Committee concludes that the information provided, in whatever form, is insufficient to enable a determination of the application to be made, the Committee may adjourn consideration and request that the applicant provides any further information that may be required.
 3. The Committee considered the application in accordance with stage 16 (b) (i) of the PGD Decision Tree. The Committee noted section 3.1 of the Executive Summary which set out the purpose of the test as being to establish whether the embryo is at risk of having PKU.
 4. The Committee noted section 4.1 of the Executive Summary and the opinion of the Peer Reviewer which stated that PKU is an autosomal recessive condition and that where parents are proven carriers each of their future pregnancies would have a 1 in 4 chance of being affected and that where one parent has PKU this is raised in 1 in 2.

The Committee's Decision

5. The Committee was satisfied that the purpose of the testing is within paragraph 1ZA (1) (b) of Schedule 2 to the 1990 Act, as amended, in that the proposed testing of embryos is for the purpose of establishing that an embryo may have a gene, chromosome or mitochondrian abnormality.
6. The Committee was also satisfied that there is a particular risk that an embryo might have such an abnormality in the light of the evidence that, where parents have already had an affected pregnancy, each future pregnancy will have a 1 in 4 chance of being affected and that this risk rises to 1 in 2 where one parent has PKU.
7. The Committee then considered whether there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition, as required by paragraph 1ZA (2) of Schedule 2. The Committee noted the important differences in outcomes for those whose condition is detected at birth and for those whose condition is detected at some later stage and for whom the condition has more serious consequences. The Committee noted section 5.6 of the Executive Summary which stated that information sought by the Executive from the Genetic Information Group about the effect of PKU on quality of life had not yet been received. .
8. The Committee agreed that the application did not provide enough information to enable the Committee to make a determination. In particular, the Committee felt that there was insufficient information about, first, the extent to which in the UK the condition is detected at birth, and, second, the quality of life of those treated and the impact on the families of those affected.
9. Taking this into account, the Committee decided to adjourn the item until the Centre resubmits an application with further information. The reason for the adjournment was the insufficient information before the Committee rather than the form in which it had been provided. However, as the matter had to be adjourned, the Committee requested that the Centre submits a completed post- October 2009 version of the application form when providing the further information requested. The Committee noted that the item could be considered at the next Licence Committee meeting if the additional information was provided in a timely manner.

Signed  Date 20/04/09
David Archard (Chair)

