# HFEA Licence Committee Meeting

**12 November 2009**

21 Bloomsbury Street London WC1B 3HF

**Minutes – Item 1**

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

| Members of the Committee: | Committee Secretary: |
|---|---|
| David Archard (lay) – Chair<br>Anna Carragher (lay)<br>Jane Dibblin (lay) | Hannah Darby<br><br>Legal Advisers:<br>Ros Bedward |
| Apologies:<br>Sally Cheshire (lay)<br>Sue Price (clinician)<br>Rebekah Dundas (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
- Executive summary from 15 October Licence Committee
- Minutes of 15 October Licence Committee
- PGD application form (post-Oct 09 version of the form)
- Redacted peer review
- Correspondence from Genetics Interest Group (GIG) regarding PKU

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)
- 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.

1. The Committee noted that they had considered this application on 15 October and decided to adjourn the decision until further information was received about the extent to which the condition is detected at birth (in the UK), the quality of life of those treated and the impact on the families of those affected.

2. The Committee noted that it had now received a new application form (post October 09 version) and correspondence from the Genetic Interest Group, but they were not presented with a view from a patient support group. The Committee were satisfied that they now had enough information in order to satisfy themselves as to 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, including the matters referred to at point 1 above.

3. The Committee were satisfied that the information at 2.3 of the application form provided clarification on the likelihood of PKU being detected in a newborn: there is a neonatal screening programme to test all newborns at 6 to 14 days, but a recent review had shown there are regional variations in the timing of the test and commencement of treatment, and 8% of infants with severe PKU were still not on treatment by 20 days after birth.

4. The Committee noted that information on the quality of life of those treated and the effect on the families of those affected was outlined in the letter from the Genetic Interest Group and at 2.3 of the application form.

5. 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 (from 15 October Licence Committee meeting) which set out the purpose of the test as being to establish whether the embryo is at risk of having PKU.

6. The Committee considered the application in accordance with stage 16(b)(ii) of the PGD Decision Tree. The Committee felt that clear information about the risk of an embryo having the abnormality had been provided in the peer review and the Executive Summary (from 15 October Licence Committee meeting): PKU is an autosomal recessive condition, so where parents are both carriers there is a 1 in 4 chance of their children being affected and where one parent has PKU this is raised to 1 in 2.

7. The Committee considered stages 16(b)(iii) and (iv) of the PGD Decision Tree. In making a decision as to 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 they referred to the criteria set out in 2.3 of the application form. The Committee noted that the age of onset for the PKU is at birth, it is highly penetrant and that symptoms will vary. The Committee recognised that childhood symptoms of the disease include seizures, albinism, failure to obtain early developmental milestones, microcephaly and progressive impairment of cerebral function (as outlined in section 3 of the peer review). The Committee took into account that variation of the symptoms presented may be due to the point at which the condition is detected and treated. If not treated early the condition may become more complicated and harder to treat.

8. After considering the information outlined in the papers (regarding the symptoms of the disease, whether the condition is treatable, the type of treatment and the effect of the disease on quality of life) the Committee came to the following conclusions:
   - If the condition is detected at birth, and if treatment commences immediately, then it is treatable through a lifelong dietary regime and medication. Managing such a regime and monitoring the child can be seriously intrusive, psychologically and socially invasive and damaging. It can be physically unpleasant, emotionally difficult, disruptive of family life and can seriously adversely affect the quality of family and social relationships.
   - However, even when detected early, in some cases there is a real risk of the condition not being treated sufficiently early so that in these cases more serious effects can manifest.
   - Moreover, even in those cases where the condition is detected and treated immediately there is still a possibility that the affected individual will develop neurological problems or have seizures and mental retardation.
   - When the condition is not detected until adulthood affected individuals may develop severe behavioural or psychiatric problems (depression, anxiety, phobias) in the third or fourth decade.

<u>The Committee's Decision</u>

9. The Committee was satisfied that the purpose of testing is within paragraph 1ZA((b) of Schedule 2 to the 1990 Act, as amended, in that the proposed testing of embryos is for the purpose of establishing than

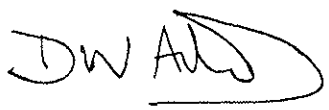
an embryo may have a gene, chromosome or mitochondrion abnormality.

10. 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 are both carriers there is a 1 in 4 chance of their children being affected and where one parent has PKU this is raised to 1 in 2.

11. With reference to the conclusions above the Committee decided that there is a significant risk that a person with the abnormality will have or develop a serious medical condition. They decided to vary the centre's treatment licence to authorise embryo testing for PKU. The Committee decided that this variation should be granted for the remaining duration of the current treatment licence at centre 0078 (until 31 December 2012) without any specific conditions.

12. In making this decision the Committee agreed that the condition should be added to the publicly available list of PGD conditions, allowing all licensed PGD centres to test for this condition as from the date of notification of this variation on the HFEA website.

Signed: Date:19/11/09



David Archard (Chair)