HFEA Licence Committee Meeting

26 August 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 5

Centre 0102 (Guys Hospital) – Application for Variation of licence to include embryo testing for Aicardi Goutieres Syndrome 1 (AGS1) OMIM #225750

Members of the Committee: Anna Carragher (lay) – (Chair) Jane Dibblin (lay) Sally Cheshire (lay) Sue Price (Professional) Debbie Barber (Professional) Mair Crouch (lay) Apologies: Rebekah Dundas (lay)	Committee Secretary: Joanne McAlpine Legal Advisers: Sarah Ellson – Field Fisher

Declarations of Interest: members of the Committee declared that they had no conflicts of interest in relation to this item, Debbie Barber noted that she works in a licensed centre.

The following papers were considered by the Committee:

- Executive summary
- Application for the variation of licence
- Lay summary of condition
- Redacted peer review
- Genetics Alliance UK opinion

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.
- 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 has been licensed to perform PGD for a number of years and has appropriately trained and experienced staff to deliver the service.

2. The Committee noted that the centre's proposed purpose of testing the embryos was as set out in paragraph 1ZA(1)(b) of schedule 2 of the Act, i.e. ' 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'.

~~3.~~ The Committee noted that Aicardi Goutieres syndrome 1 (AGS1) is an autosomal recessive disorder, and there is a 25% chance of the embryo being affected in a family both parents carry a mutation.

4. The Committee noted that there is a significant risk that a person with the abnormality will develop a serious medical condition because it is 100% penetrant.

5. The Committee considered that the condition is serious. Onset is usually at birth or within a short time after birth following what appears to be a period of normal development. Rapid neurological deterioration follows with death usually within the first year of life. There are different forms of AGS. AGS1 is severe with a very early onset frequently leading to death in infancy. Diagnosis usually follows the onset of an acute encephalopathy, sterile pyrexias, loss of skills, tonic-clonic seizures slowing of head growth and chilblain skin lesions on digits and ears which can lead to necrosis. Death is believed to be secondary to the neurological damage incurred at the start of the illness. Surviving children usually demonstrate cortical blindness, severe microcephaly, and profound developmental delay.

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

6. The Committee agreed that on the basis of the information presented, the Committee was satisfied that 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. Accordingly, it was appropriate to grant the application under 1ZA(1)(b) of Schedule 2 of the Act.

7. The Committee agreed that the licence should be varied to authorise the testing of embryos for Aicardi Goutieres Syndrome 1 (AGS1) – OMIM# 225750, and that no conditions should be put on the licence in relation to this variation. The Committee confirmed that this condition will be added to the published list of conditions for which PGD may be carried out.

Signed: Anna Carragher Date: 15.9.2010

Anna Carragher (Chair)