HFEA Statutory Approvals Committee

25 September 2014

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 7

Centre 0102 (Guy's Hospital) – PGD application for Episodic Ataxia Type 2 #108500

Members of the Committee:	Committee Secretary:
David Archard (lay) Chair	Sam Hartley, Head of Governance and Licensing
Debbie Barber (professional)	
Rebekah Dundas (lay)	
Jane Dibblin (lay)	Legal Adviser:
Hossam Abdalla (professional)	Dawn Brathwaite, Mills & Reeve
Advisor: Dr Edward Blair	

Declarations of Interest: The Members declared no conflicts in relation to this item.

The following papers were considered by the Committee:

- Executive summary
- PGD application form
- Redacted Peer Review form
- Genetic Alliance 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) ("the Act")
- 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

Discussion

1. The Committee had regard to its Decision Tree. The Committee noted that the Centre is licensed to carry out PGD. The Committee was also satisfied that the Centre has experience of carrying out PGD and that generic patient information about its PGD programme and associated consent forms had previously been received by the HFEA.

2. The Committee noted that the 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 Episodic Ataxia Type 2 (EA2) #108500 is inherited in an autosomal dominant pattern and there is a 1 in 2 chance of an embryo being affected with the condition where one parent is affected.

4. The Committee noted that EA2 is a genetic condition that results in sudden attacks of ataxia (inability to coordinate voluntary muscle movements resulting in lack of balance and coordination), vertigo and nausea. These attacks can also be associated with speech problems, double vision, tinnitus (a continual noise in the ear), headaches, dystonia (a brain disorder that causes involuntary muscle spasms and twisting of the limbs), and paralysis of one side of the body. Affected individuals may also develop permanent neurological deficit (weakness or paralysis of limbs or the entire body), in the long term. EA2 is a variable condition and the frequency of attacks can range from once or twice a year to three or four times a week. Attacks typically last for anything from a few minutes to several days.

5. The Committee noted that the onset of symptoms is typically in childhood or early adolescence (age range between two and 32 years). However, onset as late as the age of 61 has been reported.

6. The Committee noted that drugs are available to control or reduce the frequency and severity of the attacks. Acetazolamide is usually effective in controlling or reducing the frequency and severity of attacks. Although

generally well tolerated, the most common side effects are paresthesias of the extremities (tingling, pricking or burning sensations on the skin), rashes and renal calculi (kidney stones). Acetazolamide does not appear to prevent the progression of symptoms between attacks, and attacks can recur within 48 to 72 hours of stopping the medication. Patients may become medication-dependent and, in the most severe cases, may develop some tolerance to medication.

7. The Committee welcomed the advice of its advisor, Dr Edward Blair, who confirmed that the condition was as described in the papers.

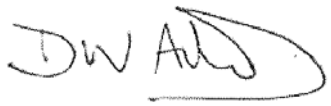
8. The Committee noted the responses from the Peer reviewer and also noted that this application is supported by the Genetic Alliance.

9. The Committee considered that the condition is serious due to the long-term degenerative nature of the disease, the fact that there is no curative treatment and the medication available does not appear to alter the underlying progression of the disease, and that significant amounts of care would be needed for severely affected patients.

10. The Committee had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it 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. The Committee was therefore satisfied that the condition meets the criteria for testing under paragraph 1ZA(1)(b) and (2) of Schedule 2 to the Act.

11. The Committee agreed to authorise the testing of embryos for Episodic Ataxia Type 2 (EA2) #108500.

Signed: Date: 07/10/2014



David Archard (Chair)