HFEA Licence Committee Meeting

7 March 2013

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

Minutes – Item 1

Centre 0078 (IVF Hammersmith) – PGD for Autism Spectrum Disorder

Members of the Committee:	Committee Secretary:
David Archard (lay) Chair Sue Price (professional) Rebekah Dundas (lay) Debbie Barber (professional) Jane Dibblin (lay)	Lauren Crawford Legal Adviser: Graham Miles, Morgan Cole

Declarations of Interest: members of the Committee declared that they had no conflicts in relation to this item.
A member declared that they have a child with Autism Spectrum Disorder

The following papers were considered by the Committee

- Cover sheet
- Executive Summary
- PGD Application form
- Additional Information – relating to purpose for testing (provided by centre)
- Redacted Peer Review
- Additional Information – response to peer review from centre
- Redacted letter from patients
- 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)
- 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 Centre's proposed purpose of testing the embryos was as set out in paragraph 1ZA(1)(c) of schedule 2 of the Act, ie. 'to establish the sex of the embryo in cases where there is a particular risk that any resulting child will have or develop gender-related illnesses, conditions or abnormalities'.

3. The Committee noted that Autism Spectrum Disorders (ASD) can cause lifelong difficulties that, at their core, affect a person's social and communication abilities. The autism spectrum is very broad. At one end people with autism can have no language, severe intellectual difficulties and no engagement with others. At the other end of the autism spectrum people (such as those with Asperger Syndrome) may have very good or even advanced language skills but find the rules governing social behaviour hard to fathom.

4. The Committee noted that the causes of ASD are unknown, however, research suggests that autism is likely to be caused by predominantly genetic effects, but there are also environmental factors that play a role. Recent research has found that there are some genes that increase the risk of a person developing autism but the genetic causes of the majority of people with autism remains unknown. Those genes that have so far been identified seem to have an important role to play in brain development, particularly in synaptic development. Synapses are areas across which cells in the brain communicate with each other. The environmental factors that play a role in autism are more challenging to reliably identify. It is also unclear how these environmental factors may interact with a person's genetic risk for developing autism (i.e. genetic/environment interactions).

5. The Committee noted that even though the exact genetic component is unknown, with no specific gene identified, the applicant has identified a link to the sex of the child in predicting recurrence risk in offspring, based on a suggested four-fold increase in the incidence of an autistic diagnosis in males. The application is therefore to select females to lower the risk.

6. The Committee noted that symptoms and signs include impairment in social interaction, repetitive and stereotypic behaviours, abnormal sleep patterns, tantrums and/or self injurious and aggressive behaviours, Impaired motor development, total disregard for danger, development of catatonia syndrome (15%), Intellectual disability (44.6%), Seizures (25%), Microcephaly (5%-15%), and Macrocephaly (30%). The disorder can be classed as Complex or Essential Autism. Essential autism is defined by the absence of generalized dysmorphology and microcephaly. Approximately 70%-80% of children with autism have essential autism. Children with essential autism are more likely to be male, to have a higher sibling recurrence risk, and to have a greater family history of autism and autism related disorders. Complex autism is associated with a poorer prognosis, a more even male-to-female ratio, and a lower sibling recurrence risk than essential autism.

7. The Committee noted that the centre proposes that, for families with two or more affected children, the recurrence risk of ASD approaches 35%. After the birth of one affected child, male siblings (brothers) of a proband (a person with the genetic condition) with essential autism have a 7% risk for autism and an additional 7% risk for milder ASD. Female siblings (sisters) of a proband with essential autism have a 1% risk for autism; the risk for a milder ASD is unknown. The recurrence risk to siblings of a proband with complex autism is 1% for autism and an additional 2% for a milder ASD.

8. The Committee noted that both the Peer Reviewer and the Genetic Alliance actively disagree with this application.

9. The Committee noted that the Peer Reviewer states that PGD could increase risk within individual families because there will undoubtedly be cases where the underlying cause of autism is autosomal recessive disorder, near dominant familial predisposition or other similarly high risk genetic situation with more equal sex distribution. The approach suggested in this application would be wholly unsuitable for a specific family.

10. The Committee considered that the statistics and evidence within the papers are based on affected population studies combined data, and that each individual family will have different risks based on the history within the family. Correlation between male embryos affected by this condition is not

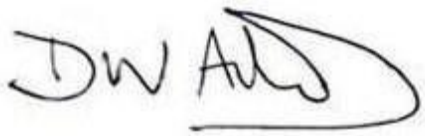
predictable within a family and therefore there is no predictability of outcome or risk reduction.

11. The Committee considered that whilst the condition is serious, the evidence supplied confirms population based risks, which do not translate into a 'particular' risk for any given embryo in specific family, even multiplex families – therefore the risks cannot reliably be predicted.

12. The Committee were not minded to grant the licence as they were not satisfied that the purpose of testing the 'embryo' was to establish the sex of the embryo in cases where there is a risk that any resulting child will have or develop a gender related illnesses, conditions or abnormalities'.

13. For these reasons the Committee agreed not to authorise the testing of embryos for Autism Spectrum Disorder.

Signed: Date: 26/03/2013



David Archard (Chair)