HFEA Statutory Approvals Committee

30 January 2014

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

Minutes – Item 6

Centre 0044 (The Centre for Reproductive and Genetic Health (CRGH)) – PGD application for Autism Spectrum Disorder OMIM #209850

Members of the Committee: David Archard (lay) Chair Rebekah Dundas (lay) Sue Price (professional) Hossam Abdalla (professional) Jane Dibblin (lay) Debbie Barber (professional) Advisor: Dr Peter Turnpenny	Committee Secretary: Lauren Crawford Legal Adviser: Graham Miles, Morgan Cole Observing: Sam Hartley, Head of Governance and Licensing, HFEA

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

The following papers were considered by the Committee:

- Executive summary
- Application form
- Clarification of condition and OMIM number
- Additional letter from centre
- Comment from public
- Redacted peer reviews

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)(c) of schedule 2 of the Act, i.e. 'where there is a particular risk that any resulting child will have or develop -

   (i) a gender-related illness serious physical or mental disability,
   (ii) a gender-related serious illness,
   (iii) any other gender-related serious medical condition.

3. The Committee noted that the centre would like to establish the sex of the embryo in families with at least two severely affected males, in order to avoid the inheritance of Autism Spectrum Disorder (Classic), as they consider the condition to be a gender-related serious medical condition.

4. The Committee noted that Autism Spectrum Disorders are a range of variable, gender-influenced neurological conditions that affect about 1 in 100 children. In the worst case scenario, patients with severe or 'classic' autism have no language skills, limited social interactions and mental health problems.

5. The Committee noted that Autism Spectrum Disorder (Classic) can be diagnosed in infancy, with symptoms apparent from 6 months. Babies will avoid direct eye contact, be unresponsive to familiar voices but respond to other sounds (e.g. a dog barking or a ringing bell) and will rarely make meaningful gestures, such as pointing or waving, though excessive hand-flapping is common. As the child develops, language limitations become more noticeable as they communicate using two-word sentences or fail to speak at all.

6. The Committee noted that the applicant has provided information about the risk that a person born with Autism Spectrum Disorder (Classic) will have a serious physical or mental disability, a serious illness or another serious medical condition. The applicant suggests that by selecting female embryos in families with two seriously affected males, the risk of the disorder being inherited would be reduced.

7. The Committee noted that Autism Spectrum Disorder (Classic) is diagnosed in approximately four times as many males compared to. Although some genetic imbalances, mainly very small chromosome deletions, increase a person's risk of developing autism, the genetic cause for the majority of affected patients is currently unknown.

8. The Committee noted that, in contrast, patients diagnosed with Asperger's Syndrome who are placed at the 'high functioning' end of the autism spectrum, have a higher level of intelligence and verbal ability and are able to fully integrate into society and usually lead independent lives. The applicant does not intend to use PGD in families where Asperger's Syndrome has been diagnosed.

9. The Committee noted that the inheritance pattern for Autism Spectrum Disorder is not known and may vary from one family to another; the applying centre suggests that 10% of autistic children have an identifiable genetic condition.

10. The Committee noted that Autism is not a life-threatening disorder and full life expectancy can be achieved. However the quality of life for those affected with the condition can be very difficult, due to their complete reliance on other people to perform day to day actions for them and their inability to communicate effectively with their family, peers and the wider society. Treatments are focused on increasing the quality of life and gaining independence. Multidisciplinary specialist teams provide behaviour therapy, speech and language therapy, social skills, occupational therapy.

11. The Committee noted that the application contained two independent Peer Reviews of the condition. Both specialists expressed concern about the use of PGD for Autism Spectrum Disorder (Classic) OMIM #209850 and the request to apply sex selection. The peer reviewers noted that even where a family has two affected male children this does not guarantee that female children will be free of the disorder, or indeed that in any particular family affected in this way that a female is at any less risk than a male.

12. The Committee noted that the application contained a Genetic Alliance Opinion that does not support the use of PGD for Autism Spectrum Disorders.

13. The Committee welcomed the advice of its Advisor, Dr Peter Turnpenny, who confirmed that the condition was as described in the papers. He also confirmed that autism and autistic spectrum disorder are umbrella terms for a range of conditions that affect a person's social and communication skills.

14. The Committee noted the comments of one of the peer reviewers: 'When taking a family history one often identifies possible females in the pedigree who have "autistic traits" and clearly females can have autism, however we don't know if this is x-linked disease expression in females, autosomal, or more complex inheritance (if indeed the disease is genetic at all in that individual).'

15. The Committee considered that the genetic recurrence risk statistics and evidence within the papers are based on affected population studies combined data, and that each individual family will have different risks according to the precise (but usually unknown) genetic factors 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.

16. The Committee noted the unpredictability and variability of the disorder within families and 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.

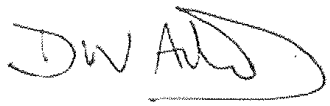
17. The Committee noted that the centre has asked that their application be considered on a case-by-case basis. The Committee further considered that this purpose of this application is to try to reduce the risk of having a child affected by autism in families where two or more male children are affected.

18. The Committee took into account the views of the peer reviewers and Genetic Alliance. The Committee was not satisfied that this application meets the criteria for 'embryo testing' as there is no specific conclusive test for autism and therefore no way to ensure that any resulting child, in particular a female child, would be born without the disorder. The Committee did not consider that any future applications could be approved unless and until there is more scientific certainty on the genetic cause(s) of Autism Spectrum Disorder.

19. The Committee decided that they could not see a way of authorising sex selection for the purpose of *possibly* reducing the risk of this family having another affected child.

20. For these reasons the Committee agreed not to authorise the testing of embryos for Autism Spectrum Disorder OMIM #209850.

Signed: Date: 13/02/2014



David Archard (Chair)