HFEA Statutory Approvals Committee

27 February 2014

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

Minutes – Item 5

Centre 0199 (Guy's Hospital) – PGD application for Severe Combined Immunodeficiency (SCID) (Adenosine Deaminase (ADA) deficient) - OMIM #102700

Members of the Committee: David Archard (lay) Chair Rebekah Dundas (lay) Hossam Abdalla (professional) Jane Dibblin (lay) Debbie Barber (professional) Advisor: Dr Mary Porteous	Committee Secretary: Lauren Crawford Legal Adviser: Stephen Hocking, DAC Beachcroft Also in attendance: 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
- Redacted peer review

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 Severe Combined Immunodeficiency (SCID) (Adenosine Deaminase (ADA) deficient) (OMIM #102700) is inherited in an autosomal recessive pattern and there is a 1 in 4 chance of an embryo being affected with the condition where both parents are carriers.

4. The Committee noted that ADA deficient SCID is a metabolic condition which causes the loss of infection fighting cells. Affected individuals are prone to repeated infections with recurrent hospitalisation and isolation. Symptoms include chronic diarrhoea, skin rashes, pneumonia and failure of normal growth; without treatment individuals rarely survive past two years old.

5. The Committee noted that ADA deficient SCID is typically diagnosed within the first 6 months of life.

6. The Committee noted that ADA deficient SCID is treatable by bone marrow/stem cell transplantation from a HLA-identical healthy sibling/relative, however, this procedure comes with its own risks and a matching donor is often not available.

7. The Committee noted that the application is supported by the Peer Reviewer.

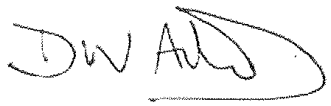
8. The Committee welcomed the advice of its Advisor, Mary Porteous, who confirmed that the condition was as described in the papers.

9. The Committee considered that the condition is serious because it is a severe life threatening disease which affects babies and is difficult to treat and in most cases death occurs within a year.

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 Severe Combined Immunodeficiency (SCID) (Adenosine Deaminase (ADA) deficient) (OMIM #102700).

Signed: Date: 11/03/2014



David Archard (Chair)