HFEA Licence Committee Meeting

15 January 2012

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

Minutes – Item 1

Centre 0102 (Guy's Hospital) PGD for X-Linked Thrombocytopenia (XLT) (OMIM # 313900)

Members of the Committee:	Committee Secretary:
David Archard (lay) Chair Sue Price (professional) Debbie Barber (professional) Jane Dibblin (lay) Rebekah Dundas (lay)	Lauren Crawford Legal Adviser: Juliet Oliver, Field Fisher Waterhouse

Declarations of Interest: members of the Committee declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the Committee

- Cover sheet
- Executive Summary
- PGD Application form
- Redacted Peer Review
- Previous LC Minutes 11/09/2008 – Wiskott Aldrich Syndrome (OMIM # 301000)

The Committee also had before it

1. HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
2. 8th edition of the HFEA Code of Practice
3. Human Fertilisation and Embryology Act 1990 (as amended)
4. Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree); and
5. Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
6. Guidance on periods for which new or renewed licences should be granted
7. Standing Orders and Instrument of Delegation
8. Indicative Sanctions Guidance
9. HFEA Directions 0000 – 0012
10. Guide to Licensing

11. Compliance and Enforcement Policy
12. Policy on Publication of Authority and Committee Papers
13. HFEA Pre-Implantation Diagnostic Testing ("PGD") Explanatory Note For Licence Committee

Background

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 considerable 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 case where there is a particular risk that any resulting child will have or develop a gender-related serious physical or mental disability, serious illness or serious medical condition' and also paragraph 1ZA(1)(b) of Schedule 2 ie '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 X-Linked Thrombocytopenia (XLT) (OMIM # 313900) is a disorder that is inherited in an X-linked manner. This means for male embryos there is a 1 in 2 chance of the embryo being affected and for female embryos there is a 1 in 2 chance of the embryo being a carrier.

4. The Committee noted that X-Linked Thrombocytopenia (XLT) is a rare genetic disorder caused by a mutation in the Wiskott Aldrich (WAS) gene. It causes a deficiency in the WAS syndrome protein, which in turn results in a low platelet count.

5. The Committee noted that symptoms of the disorder range from easy bruising and bleeding, to mild anaemia to severe haemorrhage or anaemia requiring long term blood transfusion therapy and some affected individuals also have abnormal white blood cells which can result in life threatening bacterial and fungal infections, malignancies and symptoms of disrupted immunity such as eczema.

6. The Committee noted that the severity of symptoms cannot be reliably predicted and symptoms can vary between affected families and even within

affected individuals in the same family. The onset of the condition is usually in infancy, but some babies in-utero may display signs of anaemia.

7. The Committee considered that XLT is serious because bleeding, infection and malignancies have all been reported to cause death in a number of patients with X-linked thrombocytopenia. The treatment of symptoms will involve medical and supportive care for blood/platelet transfusions, antibiotic therapy, stem cell transplantation, surgery for malignancies, immunosupressants for autoimmune disease and skin treatments including steroids for eczema. Some affected patients will require surgery for removal of the spleen which can in turn make them more prone to infection.

8. The Committee noted that the purpose for the proposed testing is to establish whether the embryo has an x-linked condition. It 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 male 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 for one or both of the purposes specified under paragraph 1ZA(1)(b) and (c) of Schedule 2 to the Act.

9. The Committee noted that the application is supported by the Peer Reviewer as well as by Genetic Alliance UK.

10. The Committee agreed to authorise the testing of embryos for X-Linked Thrombocytopenia (XLT) (OMIM # 313900). The Committee confirmed that this authorisation will be added to the published list of conditions for which PGD may be carried out.

Signed: Date: 15/02/2013

David Archard (Chair)