

HFEA Licence Committee Meeting

29 July 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 2

Centre 0102 (Guys Hospital) – Variation application to perform PGD for Sanfilippo or Mucopolysaccharidosis Type III A- OMIM# 252900

Members of the Committee:

Anna Carragher (lay) – Chair
Mair Crouch (lay)
Sue Price (Professional)

Committee Secretary:
Terence Dourado

Legal Adviser:
Sarah Ellson, Field Fisher
Waterhouse LLP

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:

- Executive Summary
- PGD Application form
- Generic PGD patient information – three leaflets
- Redacted Peer Review
- Joint response from the MPS Society and GIG relating to the application

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

1. The Committee had regard to its Decision Tree and was satisfied that the Centre is already established and licensed for PGD.
2. The Committee noted that the Centre's 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 Sanfilippo or Mucopolysaccharidosis Type IIIA is inherited in an autosomal recessive pattern. If an embryo inherits a copy of the faulty gene from both parents it will develop the disease, i.e. there is a 25% chance of the embryo having the abnormality.
4. The Committee noted that there is a significant risk that a person with the abnormality will develop a serious medical condition because it is fully penetrant.
5. The Committee considered that the condition is serious because it usually presents between two and six years with severe neurological deterioration and death by early adulthood. Symptoms may start with diarrhea, multiple ear and chest infections with aggressive, hyperactive behaviour. This is followed by deterioration in intellect, loss of ability to speak, severe hyperactivity and behavioural problems and loss of basic functions. Many children will gradually become immobile and become fully dependant. Attempted treatments for the condition involve enzymatic therapy and bone marrow transplantation; however these have not been proven as effective long term treatments.
6. On the basis of the information presented, the Committee 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. Accordingly, it was appropriate to grant the application under 1ZA(1)(b) of Schedule 2 to the Act.
7. The Committee agreed that the licence should be varied to authorise the testing of embryos for Sanfilippo or Mucopolysaccharidosis Type IIIA-

OMIM# 252900, and that no conditions should be put on the licence in relation to the variation. The Committee confirmed that this condition will be added to the published list of conditions for which PGD may be carried out.

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Signed.....*Carragher*..... Date.....*8.8.2010*.....

Anna Carragher (Chair)