

## HFEA Statutory Approvals Committee

20 November 2014

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

### Minutes – Item 3

#### **Centre 0102 (Guys Hospital) – PGD application for Surfactant Metabolism Dysfunction, Pulmonary, Type 2 (SMDP2) OMIM #610913**

Members of the Committee:	Committee Secretary:
David Archard (lay) Chair	Trent Fisher
Rebekah Dundas (lay)	
Jane Dibblin (lay)	Legal Adviser:
Debbie Barber (professional)	Ros Foster, Browne Jacobson
Advisor:	Also in attendance:
Dr Anne Lampe	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
- 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) (“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 Surfactant Metabolism Dysfunction, Pulmonary, Type 2 (SMDP2) (OMIM#610913) is inherited in an autosomal dominant pattern and there is a 1 in 2 chance of an embryo being affected with the condition where one parent is affected.
4. The Committee noted that affected individuals suffer from respiratory insufficiency and respiratory arrest. Individuals have progressive failure to thrive and recurrent infections. Lung damage may be gradual but is irreversible. Individuals with this condition may die within the first few years of life. Individuals with this condition are dependent on portable oxygen.
5. The Committee noted that typically the condition develops at birth or soon after, however, it may present later in life for some individuals.
6. The Committee noted that currently there is no curative treatment for Surfactant Metabolism Dysfunction, Pulmonary, Type 2. Lung transplant may be advised but due to fragility the condition can cause to individuals the pre-transplant period is associated with a high risk of death.
7. The Committee noted that the application is consistent with the Peer Review.
8. The Committee welcomed the advice of its Advisor, Dr Anne Lampe, who confirmed that the condition was as described in the papers.

9. The Committee considered that the condition is serious because of the progressive nature of the irreversible lung damage, the risk of death and the dependence on portable oxygen.
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 Surfactant Metabolism Dysfunction, Pulmonary, Type 2 (SMPD2) (OMIM #610913).

Signed:

Date: 3 December 2014

A handwritten signature in black ink, appearing to read 'DWA' followed by a stylized flourish.

David Archard (Chair)