# HFEA Statutory Approvals Committee

## 25 September 2014

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

### Minutes – Item 1

**Centre 0102 (Guy's Hospital) – PGD application for Retinitis Pigmentosa Type 11 (RP11) (OMIM# 600138)**

| Members of the Committee: | Committee Secretary: |
|---|---|
| David Archard (lay) Chair | Sam Hartley, Head of Governance and Licensing |
| Debbie Barber (professional) | |
| Rebekah Dundas (lay) | |
| Jane Dibblin (lay) | Legal Adviser: |
| | Dawn Brathwaite, Mills & Reeve |
| Advisor: | |
| Dr Edward Blair | |

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

The following papers were considered by the Committee:

- Executive summary
- PGD application form
- Redacted Peer Review form

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 Retinitis Pigmentosa Type 11 (RP11) (OMIM# 600138) 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 typically symptoms of Retinitis Pigmentosa 11 present during childhood. Penetrance of the condition is incomplete in affected families. Known carriers can remain asymptomatic but pass the mutation on to offspring who develop the disease and all of the symptoms.

5. The Committee noted that currently there is no curative treatment for Retinitis Pigmentosa 11. Individuals with the condition may develop complications such as cataracts which can be treated by surgery but this would have no effect on the underlying condition.

6. The Committee welcomed the advice of its specialist advisor, Dr Edward Blair, who confirmed that the condition was as described in the papers

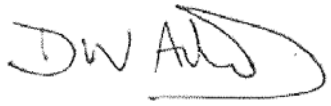
7. The Committee considered that the condition is serious because of the impact on the quality of life of the patient, and the fact that there is no curative treatment. The committee noted that in the most severe cases, night blindness in childhood can lead to complete blindness before the age of 30.

8. 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.

9. The Committee agreed to authorise the testing of embryos for Retinitis Pigmentosa Type 11 (RP11) (OMIM# 600138).

Signed: Date: 07/10/2014



David Archard (Chair)