

## Human Fertilisation and Embryology Authority

### Minutes of the Statutory Approvals Committee

Meeting held at Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF on  
**30 April 2015**

#### Minutes – item 1

Centre 0102 (Guys Hospital) – PGD application for Parkinson's disease 4 OMIM #605543, Parkinson's disease 1 #168601 and Lewy body dementia OMIM #127750

<b>Members of the Committee</b>	David Archard (Chair, lay) Sue Price (professional) Tony Rutherford (professional) Margaret Gilmore (lay)
<b>Legal Adviser</b>	Sarah Ellson, Fieldfisher
<b>Specialist Attending</b>	Dr Mary Porteous
<b>Members of the Executive</b>	Sam Hartley, Head of Governance and Licensing Trent Fisher, Secretary

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
- redacted peer review
- Genetic Alliance opinion
- additional information from the centre

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)
- HFEA decision trees

- 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

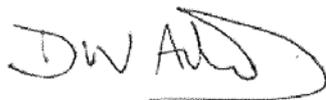
## **Discussion**

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 conditions being applied for are not on the approved PGD condition list.
3. 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'.
4. The committee noted that Parkinson's disease 4 OMIM #605543, Parkinson's disease 1 OMIM #168601 and Lewy body dementia OMIM #127750 are inherited in an autosomal dominant pattern and there is a 1 in 2 chance of an embryo being affected with the conditions where one parent is affected.
5. The committee noted that those affected by these conditions develop from early-onset Parkinson's disease, which is associated with psychiatric problems, cognitive decline and dementia. Symptoms of these conditions can lead to the loss of autonomy and death. Psychiatric symptoms can include hallucinations, delusions, anxiety and depression.
6. The committee noted that other symptoms that may develop are tremors, rigidity of limbs, slow movements, impaired balance and coordination.
7. The committee noted that the conditions demonstrate a high penetrance and symptoms usually develop before the age of 50 with a reported mean age of 36. There has been a documented case of onset of symptoms at 19 years of age.

8. The committee noted that there is no curative treatment for the condition and the only treatment options available are those to manage the symptoms that arise from the condition.
9. The committee noted that the application is consistent with the Peer Review.
10. The committee welcomed the advice of its advisor, Dr Mary Porteous, who confirmed that the conditions are as described in the papers adding that the conditions are similar to the non-genetic inherited versions and that the symptoms of these genetic forms have a more rapid onset of symptoms.
11. The committee considered that the conditions are serious due to early onset of symptoms, individual's loss of autonomy, premature death and the lack of any curative treatment.
12. The committee had regard to its decision tree and 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.
13. The committee agreed to authorise the testing of embryos for Parkinson's disease 4 OMIM #605543, Parkinson's disease 1 OMIM #168601 and Lewy body dementia OMIM #127750.

Signed:

Date: 12 May 2015

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

David Archard (Chair)