# Statutory Approvals Committee - minutes

## Centre 0035 (Oxford Fertility) – PGD application for Congenital Steroid Resistant Nephrotic Syndrome OMIM #600995

Friday, 24 June 2016

HFEA, Level 2, 10 Spring Gardens, London, SW1A 2BU

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| Committee members | David Archard (Chair)<br>Rebekah Dundas (Deputy Chair)<br>Margaret Gilmore<br>Anthony Rutherford<br>Anne Lampe<br>Ruth Wilde | |
| Members of the Executive | Ian Brown<br>Trent Fisher | Head of Corporate Governance<br>Secretary |
| External adviser | Jenny Carmichael | |
| Legal Adviser | Dawn Brathwaite | Mills & Reeve LLP |
| Observers | None | |

## Declarations of interest:

- members of the committee declared that they had no conflicts of interest in relation to this item.

## The committee had before it:

- 8th edition of the HFEA Code of Practice
- standard licensing and approvals pack for committee members

## The following papers were considered by the committee:

- executive summary
- PGD application form
- redacted peer review
- Genetic Alliance opinion

- minutes of the SAC meeting on 30 October 2014 which considered the PGD condition application for Finnish Nephrotic Syndrome Type 1 OMIM #256300

## 1. Consideration of application

**1.1.** The committee noted that the papers contained Statutory Approvals Committee minutes concerning a previous condition which had been authorised for PGD. The committee's legal adviser confirmed that the committee is not bound by previous decision made and that it needed to be satisfied that the particular risk and significant risks tests were met for each condition based on the paperwork and advice provided.

**1.2.** The committee welcomed the advice of its specialist advisor, Dr Jenny Carmichael, who confirmed that the condition is as described in the papers. Dr Carmichael gave an overview of the condition stating that it is primarily characterised by early onset kidney disease and 70 percent of cases result in end stage renal failure which would require a kidney transplant.

**1.3.** Dr Carmichael also informed the committee that even if a patient receives a kidney transplant, the disease can recur in the transplanted kidney.

**1.4.** The committee noted that the application is consistent with the Peer Review.

**1.1.** The committee noted the Genetic Alliance opinion which helped the committee gain an understanding of the condition from the patient perspective.

**1.2.** 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.

**1.3.** The committee noted that the condition being applied for is not on the approved PGD condition list.

**1.4.** 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'.

**1.5.** The committee noted that the condition is inherited in an autosomal recessive manner and there is a 1 in 4 chance of an embryo being affected with the condition where both parents are carriers of the gene mutation.

**1.6.** The committee noted that the condition is characterised by disease of the kidneys. The committee noted that in its worst case scenario, the condition could lead to end stage renal failure.

**1.7.** The committee noted that other symptoms can include blood clotting, risks of kidney infection, fluid build up and swelling most commonly starting around the eyes and lower legs.

**1.8.** The committee noted that the condition demonstrates complete penetrance and the condition can affect infants from birth.

**1.9.** The committee noted that there is no curative treatment for the condition. Treatment can include antibiotics to treat infection and diuretics to reduce fluid build-up. In severe cases dialysis and renal transplant will be needed which will carry associated surgical risks.

## 2. Decision

**2.1.** The committee considered that the condition is serious as in its worst case it can be fatal and the condition will need lifelong monitoring.

**2.2.** 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

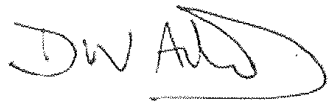
serious illness or any other serious medical condition. The committee was therefore satisfied that the condition meets the criteria for testing under paragraph 1ZA(1)(b) and (2) of Schedule 2 to the Act.

**2.3.** The committee agreed to authorise the testing of embryos for Congenital Steroid Resistant Nephrotic Syndrome OMIM #600995.

## 3. Chair's signature

**3.1.** I confirm this is a true and accurate record of the meeting.

**Signature**



**Name**

David Archard

**Date**

11 July 2016