# Statutory Approvals Committee - minutes

## Centre 0044 (The Centre for Reproductive and Genetic Health) – PGD application for Galactosaemia OMIM #230400

Thursday, 29 October 2015

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

| | | |
|---|---|---|
| Committee members | David Archard (Chair)<br>Rebekah Dundas (Deputy Chair)<br>Sue Price<br>Margaret Gilmore<br>Anthony Rutherford | |
| Members of the Executive | Trent Fisher<br>Sam Hartley | Secretary<br>Head of Governance and Licensing |
| External adviser | Dr Alan Fryer | |
| Legal Adviser | Graham Miles | Blake Morgan |
| Observers | Anna Quinn | Scientific Policy Officer |

## Declarations of interest:

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

## The panel 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
- OMIM website entry for Galactosaemia
- Genetic Alliance opinion

## 1. Consideration of application

**1.1.** 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.

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

**1.3.** 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'.

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

**1.5.** The committee noted that the condition is a rare metabolic disorder. If undetected the mortality rate in infants is 75 percent. Symptoms can include renal failure, brain damage, acute liver failure, sepsis, cataracts and seizures.

**1.6.** The committee noted that other symptoms include decreased muscle tone, enlarged spleen and liver, scarring of the liver, vomiting, diarrhoea, low blood glucose, lethargy and food intolerance

**1.7.** The committee noted that the condition demonstrates a complete penetrance and onset of symptoms is from birth.

**1.8.** The committee noted that there is no curative treatment for the condition, but that treatment for symptoms

**1.9.** The committee welcomed the advice of its specialist advisor, Dr Alan Fryer, who confirmed that the condition is as described in the papers and gave a verbal summary of the condition in lieu of a peer review.

**1.10.** The committee noted that the application had not been peer reviewed however with the verbal summary of the condition given by the specialist advisor the committee felt it had enough information to make a decision.

## 2. Decision

**2.1.** The committee considered that the condition is serious due to range of severe symptoms that present and high chance of mortality if not detected.

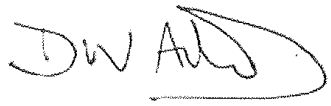
**2.2.** The committee had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it was satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, 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 Galactosaemia, OMIM #230400.

## 3. Chair's signature

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

**Signature**



**Name**

David Archard

**Date**

11 November 2015