HFEA Statutory Approvals Committee

24 April 2014

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

Minutes – Item 5

Centre 0102 (Guy's Hospital) – PGD application for Renal Cysts and Diabetes Syndrome (RCAD) OMIM #137920

Members of the Committee: David Archard (lay) Chair Rebekah Dundas (lay) Sue Price (professional) Jane Dibblin (lay) Debbie Barber (professional) Advisor: Dr Peter Turnpenny	Committee Secretary: Lauren Crawford Legal Adviser: Graham Miles, Morgan Cole Also in attendance: 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
- Two additional articles

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 Renal Cysts and Diabetes (RCAD) Syndrome (OMIM #137920) 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 RCAD results in early onset diabetes called Maturity-Onset Diabetes of the Young (MODY) and non-diabetic renal (kidney) problems resulting from abnormal development of the kidney. Gene changes (mutations) in one of a number of different genes may result in MODY but mutations in the HNF1B gene result in the combination of diabetes and non-diabetic renal disease. Not all patients with RCAD develop renal disease but impaired renal function may occur in 55% of cases and end stage renal failure may occur in 13-15% of cases (leading to dialysis and the need for renal transplant). It is a multisystem disorder with additional problems including: abnormal liver function, uterine and male genital tract abnormalities, pancreatic malformations and hyperuricaemia (overproduction of uric acid which impairs the kidneys).

5. The Committee noted that RCAD may develop at any age. A recent review of the condition provided a mean age of onset of 21 years old with standard deviation of +/- 19 years.

6. The Committee noted that treatment of (RCAD) is symptomatic and supportive with management of diabetes and renal disease. Depending on the extent of the renal structure abnormality renal dialysis and transplantation may be required.

7. The Committee noted that the application is consistent with the Peer Review.

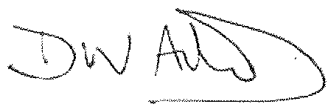
8. The Committee welcomed the advice of its Advisor, Peter Turnpenny, who confirmed that the condition was as described in the papers and further explained that renal function can be severely impaired early on as a result of cysts. A small number of females may also suffer further abnormalities such as absence of a uterus. If transplant is necessary there may be limited options for potential donors given that siblings may be gene carriers.

9. The Committee considered that the condition is serious because it is a highly penetrant multisystem disease which severely affects the renal function and in the worst can lead to kidney and liver problems also.

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 Renal Cysts and Diabetes (RCAD) Syndrome (OMIM #137920).

Signed: Date: 07/05/2014



David Archard (Chair)