HFEA Licence Committee Meeting

27 September 2012

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

Minutes – Item 1

Centre 0044 (Centre for Reproductive and Genetic Health (CRGH)) – PGD for Hypochondroplasia (OMIM #146000)

Members of the Committee:	Committee Secretary:
David Archard (lay) Chair Sue Price (professional) Jane Dibblin (lay) Anna Carragher (lay) Mair Crouch (lay) Rebekah Dundas(lay) – Videoconference	Lauren Crawford Legal Adviser: Graham Miles, Morgan Cole

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
- Resubmitted Application Form
- Additional Information – Redacted Patient Account
- Additional Information – Redacted Clinician support letter
- Licence Committee minutes – 26th April 2012

Previous Papers:

- Executive Summary
- PGD Application Form
- Redacted Peer Review
- Genetic Alliance Opinion

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)
- 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

Background

1. The Committee noted that this application was previously considered by the Licence Committee on the 26th April 2012. The Committee adjourned the application pending further information relating to a:

   - Clear statement on the impact on quality of life and the activities of day to day living of shortness of stature from relevant and informed interest groups

   - statement on the probability of each of the possible effects of this syndrome manifesting themselves in an affected individual and how the syndrome meets the statutory test of a significant risk of a serious physical or mental disability, serious illness or other serious

Discussion

2. The Committee noted that additional information had been submitted in the form of:

   - redacted patient account

   - redacted letter from a specialist clinician

3. 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

4. The Committee noted that the Centre's proposed purpose of testing the embryos was as set out in paragraph 1ZA(1)(b) of schedule 2 of the Act, ie. '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'.

5. The Committee noted Hypochondroplasia (OMIM #146000) is a disorder that is inherited in an autosomal dominant manner. There is a 1 in 2 chance of an embryo being affected if one parent is affected.

6. The Committee noted Hypochondroplasia is a form of short-limbed dwarfism. This condition affects the conversion of cartilage into bone (ossification), particularly in the long bones of the arms and legs. People with hypochondroplasia are of short stature, with short arms and legs and broad, short hands and feet. Other characteristic features include a large head, limited range of motion at the elbows, a curvature of the lower back (lordosis) and bowed legs. These features can result in arthritis, back problems, joint pain and reduced mobility. Spinal stenosis can also occur, resulting in neurological complications including paraplegia.

7. The Committee noted major and repeated orthopedic surgery can be used to elongate the long bones. However this may require long stays in hospital.

8. The Committee noted that additional information submitted for this item provided a clearer statement on the unpredictability of the condition.

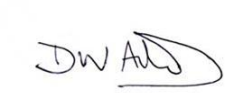
9. The Committee had regard to its explanatory note, in particular paragraph 5.5 '*Where a condition has variable symptoms, the Licence Committee will base its determination of how serious the disability, illness or condition is, on the worst possible symptoms'*, and noted that on the basis of the information presented, given the condition's worst symptoms, it was also 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. Accordingly, it was appropriate to grant the application under paragraph 1ZA(1)(b) of Schedule 2 to the Act.

10. The Committee noted that the condition is serious because people with the more severe form of hypochondroplasia are at risk of spinal stenosis and secondary neurological complications, with irreversible damage to the lower spinal cord and resultant paraplegia, if it is not detected and treated surgically. Treatment options are those to manage specific complications. Growth hormone therapy is generally not effective in improving final height and may exacerbate the physical and functional problems. If limb lengthening procedures are pursued they involve several major surgeries with frames fitted for a number of months.

11. The Committee noted that the application is supported by the Peer Reviewer and the Genetic Alliance.

12. The Committee agreed to authorise the testing of embryos for Hypochondroplasia (OMIM #146000). The decision was by majority vote. The Committee confirmed that this condition will be added to the published list of conditions for which PGD may be carried out.

Signed: Date: 09/10/2012



David Archard (Chair)