

Human Fertilisation and Embryology Authority

Minutes of the Statutory Approvals Committee

Meeting held at Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF on
26 February 2015

Minutes – Item 1

Centre 0035 (Oxford Fertility Unit) – PGD application for Nijmegen breakage syndrome-like disorder due to RAD50 OMIM # 613078

Members of the Committee:	David Archard (Chair, lay) Sue Price (professional) Tony Rutherford (professional)
Legal Adviser:	Philip Grey, Mills and Reeve
Specialist Attending:	Dr Anne Lampe
Members of the Executive:	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
- email trail confirming the condition applied for

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

Discussion

1. 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 applied for condition is not currently on the approved PGD condition list. The committee also noted that they were provided with a full set of paperwork.
3. The committee was alerted by its advisor, Dr Anne Lampe, that while the application was for Nijmegen breakage syndrome-like disorder (NBSLD) due to RAD50 (OMIM # 613078), the evidence and descriptions in the Executive Summary and Application form relate particularly to Nijmegen breakage syndrome (OMIM #251260). This had been acknowledged in the Executive Summary, and noted by the Peer Reviewer. The committee further noted that in the literature there is only one reported earlier case of NBSLD due to RAD50 which differs from Nijmegen breakage syndrome in that the patient at the age of 23 had no history of infections, normal investigations of immune function and no malignancy. No specific information was provided in the application to detail whether the patient/family the application relates to is actually more similar in its phenotype to Nijmegen breakage syndrome rather than NBSLD in the previously reported case.
4. The committee noted and accepted the advice of Dr Lampe. The committee considered whether it had the evidence and adequate information to proceed with the application for NBSLD due to RAD50 (OMIM #613078), when the condition described by the licence applicant, although very similar, as the separate condition Nijmegen Breakage Syndrome (OMIM #215260). The committee took advice from its legal adviser that, in these circumstances, it did not have sufficient information to grant the application. The committee accepted that advice and determined that it could not authorise the application. The committee noted that, in refusing the application, it was making no judgement as to the seriousness of the condition as described in the paperwork.

5. The committee further noted the Peer Reviewer's comments regarding the similarity of phenotype in both conditions. In the interests of the waiting patient, the committee asked for the minutes of its consideration to be expedited in order that the applicant centre might consider re-applying with the appropriate evidence. The committee would re-consider any new application at its earliest next meeting.

Signed:

Date: 6 March 2015

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

David Archard (Chair)