

Research Licence Committee Meeting

9 January 2008

21 Bloomsbury Street London WC1B 3HF

MINUTES Item 4

Indicators of oocyte and embryo development (R0155) Based at the Centre for Reproductive Medicine, Coventry (0013) Interim Inspection

Members:

Emily Jackson, Lay Member – Chair
Clare Brown, Lay Member
Maybeth Jameson, Consultant
Embryologist, Glasgow Royal
Infirmary
William Ledger, Professor of
Obstetrics and Gynaecology,
University of Sheffield

Providing Scientific Advice:

Neva Haites, Professor of Medical
Genetics, University of Aberdeen

In Attendance:

Graham Miles, Legal Adviser
Chris O'Toole, Head of Research
Regulation
Trish Davis, Deputy Chief
Executive/Director of Regulation
Joanne McAlpine, Minute Taker
Barbara Lewis, Minute Taker

Observing:

Elaine Suthers, Inspector

Conflicts 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:

- papers for Licence Committee (67 pages)

1. The papers for this item were presented by Sarah Hopper, HFEA Inspector. Ms Hopper informed the Committee that this project was inspected in November 2007 and that its licence expires at the end of October 2008.

2. Ms Hopper stated that the PR has taken action in response to a number of the recommendations which were made at the previous inspection; the protocol for patient consent has been updated and the protocol for disposal of embryos has been amended to include the length of time embryos can be kept in culture.

3. Ms Hopper explained that during the inspection the PR had drawn an incident to the attention of the inspection team. During the PR's own audit of the research

records she had noted that one set of embryos had been used in research without the consent of the sperm donor whose sperm had been used to create the embryos. Ms Hopper confirmed that this incident has been reported formally to the HFEA. The Committee noted that this was a breach of the statutory licence condition imposed by section 12 (c) of the 1990 Act. The Committee decided that no action would be taken in relation to this breach but that it should be recorded as part of the centre's licensing history. The centre should be advised that the breach may be taken into account in the future when assessing the cumulative effect of any future breaches.

4. Ms Hopper also highlighted the fact that a low oxygen monitor is still not in place within the embryology laboratory where the research tank, and 6 other storage tanks, are stored. This was also an issue at the previous inspection. However, Ms Hopper also referred the Committee to the PR's response in the inspection report, which states 'We were notified yesterday that the CRM's requested oxygen deficiency monitor has now been formally signed off by the Trust and finance, and we are waiting notification of an installation date.'

5. Ms Hopper informed the Committee that the PR is planning to use time-lapse microscopy as part of the project but that the inspectorate had concerns about the security of the embryos during this analysis, and noted this as a breach of Code of Practice Standard 6.3.8. The Committee acknowledged that the PR was meeting with her team to discuss this issue on the 10th January 2008, and asked that the PR must submit a report to the HFEA about how they plan to safeguard the security of embryos. This report is to be sent to the Executive for assessment.

6. Ms Hopper informed the Committee that 226 frozen embryos have been donated to this project and 178 survived the thaw process and were used in the research. Ms Hopper stated that the PR had explained that the numbers of embryos used varied from the numbers in the original proposal due to the lack of staff available to work on this research project. The PR anticipates using 100 frozen embryos during the next 12 month period.

7. The Committee noted the PR's comments in response to the report regarding the time at which patients are approached regarding donation to research, and her view that it is appropriate to do this at the time of egg collection or at the time of embryo transfer. The Committee agreed that it was not appropriate for this to happen at either of the points above and that the patient should be given the patient information and allowed sufficient time to digest this and ask any relevant questions at the point of the first consultation meeting. In reaching this conclusion, the Committee took into account the paragraph S.8.4.2 (c) of the Code of Practice, which requires a centre to ensure that a person donating gametes or embryos to research is given sufficient time to consider the implications of their donation.

8. The Committee agreed that the centre's licence should continue with no additional conditions.

Signed..... Date.....
Emily Jackson (Chair)