

Research Licence Committee Meeting

9 January 2008

21 Bloomsbury Street London WC1B 3HF

MINUTES Item 3

Evaluation of blastocoele collapse versus expanded blastocysts for successful cryopreservation using vitrification (R0176)
A novel approach for extracting cells during embryo biopsy without the use of acid Tyrode's (R0177)
Based at CARE Nottingham, Nottingham (0101)
Renewal Inspection

Members:

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

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

Providing Scientific Advice:

Neva Haites, Professor of Medical Genetics, University of Aberdeen

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 (22 pages)
- Three papers was tabled: Renewal Application Form (16 sides)
Methodology & SOP's (4 sides)
Patient Info & Consent Form (4 sides)

1. The papers for this item were presented by Andrew Leonard, HFEA Inspector. Dr Leonard informed the Committee that there are two projects at this centre, one related to blastocyst cryopreservation methods, the other to alternate methods of embryo biopsy that do not involve the use of chemicals seen in the Acid Tyrode technique. Dr Leonard went on to explain that project R0176 is now felt by the Person Responsible to be no longer required; the centre wish to withdraw the renewal application for this project. No embryos have been used

for R0176 since it was licensed on 1st March 2007 but data supporting validation has been published by other groups. As part of project R0177, the pre inspection report stated that the Centre had used 25 embryos (all fresh) in the last year, 23 were subject to the Acid Tyrode technique, 1 to laser biopsy and 1 to enucleation. On the inspection, updated figures were provided and they have now used 47 embryos, 4 of which were frozen, and 43 fresh.

2. Dr Leonard informed the Committee that research at centre 0101 was performed in a generally compliant manner, in particular relating to the organisation of the research, the premises, the storage of samples, witnessing, documentation, consents and laboratory activities. Dr Leonard went on to point out that at a previous committee it was noted that more detailed methodologies and experimental objectives should be supplied, and this has now been addressed by the centre. Dr Leonard informed the Committee that on the inspection two breaches of the Standards and Guidance in the Code of Practice, 7th edition related to patient information and consent were noted:

a) Patient information should describe the provision for patients to withdraw or vary their consent and provide contact details for a named individual through whom this can be achieved, (G.5.13.1 (g))

b) The consent form should note that the patient consenting understands they have the right to vary or withdraw consent at a later date, up to the time the embryos are under the control of the researchers, (G.5.13.1 (g))

Dr Leonard pointed out that the centre has agreed to comply with both these requirements.

3. It was noted by both the Licence Committee and the external reviewer that the progress on this project has been slow. Dr Leonard went on to explain that the PR had pointed out that the initial data was based upon a 3 month period (1.3.07 – 1.6.07; 25 embryos) and that at the time of the inspection further data had been supplied from a 9 month period (1.3.07-22.11.07; 47 embryos). The PR felt that this new data gave a better representation of work on the project.. Dr Leonard also explained that the Person Responsible believes that the progress of R0177 had been hampered by the clinical decision to move towards blastocyst culture which has resulted in fewer embryos donated to research.

4. Dr Leonard pointed out that the peer reviewer supported the application for project R0177, and stated that the use of human embryos was necessary, and agreed that the centre should be granted a one year licence.

5. The Committee applied the statutory tests in considering the application for project. To start, the Committee identified the activity under consideration as the use of donated embryos in research, and the storage of licensed material. The Committee agreed that these activities are not prohibited under the Human Fertilisation and Embryology Act 1990.

6. The Committee agreed that in the context of the project of research the activity appear to be necessary or desirable for the following specified purposes:

- Developing methods for detecting the presence or gene or chromosome abnormalities in embryos before implantation
Human Fertilisation and Embryology Act 1990 Sch 2 3(2)(e)

7. The Committee agreed that they continued to be satisfied that the proposed research could not be undertaken without the use of human embryos.

8. The Committee agreed that they were satisfied with the patient information and consent forms submitted by the centre, providing that the requirements set out above are implemented. Patient information must describe the provision for patients to withdraw or vary their consent and provide contact details for a named individual through whom this can be achieved. The consent form should note that the patient consenting understands they have the right to vary or withdraw consent at a later date, up to the time the embryos are under the control of the researchers.

9. The Chair noted that information supplied by the Centre implied that patients could be first approached about research donation on the day of egg collection or even embryo transfer. The Chair required the inspectorate to ensure that any discussion with patients about the possibility of donating embryos to research must take place before the treatment begins, so that the patients have sufficient time to understand what is involved & their right to withdraw or vary their consent at a later date, up to the time that the embryos are under control of the researchers. in accordance with paragraph S.8.4.2 (c) of the Code of Practice. The centre must ensure all patients are consented for research donation before or in the early stages of their treatment cycle

10 The Committee felt that the centre should be asked to confirm why nearly all embryos utilised have been treated with Acid Tyrode's buffer rather than enucleation.

11. The Committee decided to renew the licence for a period of one year, providing that Local Ethical Committee approval is in place and the licence application fee has been paid;

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