

HFEA Research Licence Committee Meeting

19 May 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 2

Centre 0017 (Newcastle Fertility Centre at LIFE) - Application to vary research licence R0152

Members of the Committee: Emily Jackson (lay) – Chair Andy Greenfield (Professional) Clare Lewis-Jones (lay) Neva Haites (Professional)	Committee Secretary: Terence Dourado Legal Adviser: Mary Timms
Apologies: Lesley Regan (Professional)	

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
- Application to vary research licence R0152 (2010)
- Minutes of the Research Licence Committee 18 November 2009
- Letter re variation of R0152 (2009)
- Peer review
- Patient information and consent forms
- Ethics Committee approval
- Additional Licence committee minutes from last 3 years

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)
- 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

Background:

1. The Research Centre, Newcastle Fertility Centre at Life, previously had three research licences for its research projects: Understanding and harnessing pluripotency in human embryos (R0145); Derivation of human embryonic stem cell lines using therapeutic cloning and parthenogenetically activated oocytes (R0152); Mitochondrial DNA disorders: Is there a way to prevent transmission? (R0153). In November 2009, Licence R0152 was varied to encompass the activities covered by the other two licences, creating a single research project under the title Pluripotency, reprogramming and mitochondrial biology during early human development (R0152).

Consideration of Application

2. The Committee noted that the Centre, which had previously used embryos created by somatic cell nuclear transfer for its research, wished to vary its licence, for research project R0152, to include the use of donated sperm to inject or mix with donated eggs to create embryos.
3. The Committee noted that the Centre's licence for this research project already authorised the creation of embryos in vitro and the keeping or using of embryos under paragraph 3(1) of Schedule 2 of the HFE Act 1990 as amended. It noted that that paragraph 3(1) of Schedule 2 of the Act did not differentiate between different methods of creating embryos; therefore the Centre's existing licence covered the creation of embryos using donated sperm and eggs. It also noted that its licence already covers the storage of embryos; the use of donated embryos in research and the derivation of human embryo stem cell lines. The Committee also noted that the Peer Reviewer continues to support the granting of the Licence.

4. While the creation of embryos was already licensed, new patient information and consent forms were needed in order to accommodate this new method of creating embryos for research, and the Committee was grateful for the opportunity to review the Centre's draft amended forms. The Committee recommended the following changes to the forms, wherever the following words appear in the various forms, and requested that the PR forward the amended forms to the Executive upon completion:


- The Centre should remove ‘..These embryos (tiny clusters of cells not visible to the eye) would otherwise be discarded’ from the second bullet point under the heading ‘points that you should know about research’ (pg 22 of bundle and repeated throughout) as the Committee considered it was not correct that the embryos ‘would otherwise be discarded’ in this research project, since the point of the project was specifically to create these embryos. This wording is appropriate to the donation of embryos created during IVF which will not be used, but not where embryos are specifically created for research. The Centre should replace these words with a reference to the legal requirement that embryos may not be cultured for more than 14 days.
- The Centre should include a fuller description of Ovarian Hyperstimulation Syndrome (OHSS) under ‘what are the possible disadvantages and risks of taking part?’ (page 26 and repeated elsewhere). The description must include more detail about the seriousness of the condition, the likelihood of it occurring and the risks it poses to the woman's health.
- The Centre should also add information about OHSS to the Egg Sharers' documentation as they also need proper information about the condition.
- The Centre should replace “We are asking if you would donate your eggs for research” with “We are asking if you would donate some of your eggs for research” (page 31 under the heading “What am I asked to do/” and elsewhere where it appears)
- The Centre should replace “During your caesarean section operation we will make an incision in your abdomen” with “During your caesarean section operation an incision will be made in your abdomen” because an incision is not an additional procedure carried out by the Centre. (page 69 under the heading “what will happen to me if I take part”)
- The Committee thought it would be preferable to refer to “placenta (afterbirth)” rather than just “afterbirth” wherever it appears in the documentation (for example the sentence under ‘What will happen to my cells/tissue if I take part? (page 69) -‘We will grow cells from your skin and placenta (afterbirth) to make cell lines...’

Decision

5. The Committee agreed that project R0152's ongoing licence, supported by peer review, was inclusive of the creation of embryos and the use of embryos in research and was content for the creation now to include the use of donated sperm and eggs.

Signed:

Date:



1.6.10.

Emily Jackson (Chair)