Licence Committee - minutes

Centre 0017 (Newcastle Fertility at LIFE)
Executive Update - Variation of Aims & Objectives
- Research Project R0152

Thursday, 2 May 2019

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Kate Brian (Chair) Anita Bharucha (Deputy Chair) Ruth Wilde Gudrun Moore Jonathan Herring	
Members of the Executive	Dee Knoyle Jennifer Rogerson Amanda Evans	Committee Secretary Research Manager (Staff Induction) Research Manager (Staff Induction)
Legal Adviser	Sarah Ellson	Fieldfisher LLP
Specialist Adviser		
Observers		

Declarations of interest:

- Members of the committee declared that they had no conflicts of interest in relation to this item.

The committee had before it:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members

The following papers were considered by the committee:

Papers enclosed:

- Executive Summary

Part 1 – Interim Inspection paper set

- Interim Inspection Report.
- Previous licensing minutes:
    - Licence Committee Minutes: 4 May 2017 – Renewal report
    - Licence Committee Minutes: 12 January 2017 – Variation of research objectives
    - Licence Committee Minutes: 10 November 2016 – Variation of research objectives
    - Licence Committee Minutes: 8 September 2016 – Variation of research objectives

Part 2 – Variation Inspection paper set

- Variation Inspection report
- Application
- Supplement to application
- Patient information
    - PIS ART patients ARTI
    - PIS ARTI EDR
    - PIS sperm donor ARTI
- Consent forms
    - ARTI EDR ICF
    - ARTI sperm donor ICF
- Peer review
- Previous licensing minutes for the last three years:
    - Licence Committee Minutes: 4 May 2017 – Renewal Report
    - Licence Committee Minutes: 12 January 2017 – Variation of research objectives
    - Licence Committee Minutes: 10 November 2016 – Variation of research objectives
    - Licence Committee Minutes: 8 September 2016 – Variation of research objectives

Part 3 – New Material

- Minutes of the original discussion
    - Licence Committee Minutes: 7 March 2019 – Interim & Variation of aims and objectives
- Email from PR

1. Background

1.1. Newcastle Fertility Centre, centre 0017, is based within the International Centre for Life. The research laboratory is located within the same unit as the treatment and storage centre. Research project R0152, entitled 'Towards improving assisted reproductive technologies for the treatment of infertility and prevention of disease', has been licensed by the HFEA since August 2004.

1.2. Since the project was first licensed, amendments have been made to reflect updates in the research objectives and the number of embryos expected to be created and/or used.

Licence Variation Application to change the aims and objectives

Application

1.3. The Person Responsible (PR) applied to vary the licence to reflect the revised aims and objectives of the research project.

1.4. A desk-based assessment for the variation application took place on 29 January 2019 and the centre's interim inspection visit took place on 5 February 2019. The premises were suitable for the proposed research activities and the proposed practices were also suitable.

1.5. The interim inspection report and licence variation report were submitted to the Licence Committee for consideration, with a recommendation for the continuation of the centre's licence and approval of the licence variation. The Executive also recommended that none of the additional research objectives commence until approval for them has been obtained from an appropriately constituted research ethics committee and evidence of this has been provided to and acknowledged by the HFEA Executive.

Licence Committee Decision on Variation of Licence - 7 March 2019

Considerations:

Use of 'fresh' human embryos in research

1.6. The committee noted that in order to accommodate the variation applied for, the PR had increased the forecasted number of 'fresh' human embryos required for use in research project R0152 since the initial forecast in the renewal application.

Materials donated to the research project

1.7. Altruistic gamete donors are recruited directly into the research programme, with all information sessions and consultations provided by dedicated research staff. Surplus gametes and embryos are also donated by patients who have completed treatment cycles at Newcastle Fertility Centre, centre 0017.

Peer Review

1.8. The committee noted that the Peer Reviewer had stated that since the work described for the project is largely directed towards development of tools to investigate/correct defects in mitochondrial or chromosome function it will require optimisation and extensive testing. The Peer Reviewer stated that the number of embryos predicted for use is therefore quite reasonable.

Ethics Approval

1.9. The committee noted that the PR was in the process of seeking ethics approval for the variation of the aims and objectives of this project.

Decision:

1.10. The committee endorsed the inspectorate's recommendation for the continuation of the centre's research licence and approved the variation application to reflect the revised aims and objectives of research project R0152.

1.11. The committee agreed that the PR should ensure that none of the additional research objectives commence until approval for them has been obtained from an appropriately constituted research ethics committee and evidence of this has been provided to and acknowledged by the HFEA Executive.

1.12. The committee agreed that, for the sake of transparency, the PR should provide information on the circumstances in which 'fresh' embryos are considered to be surplus to the requirements of treatment. The committee asked for this information to be considered at the Licence Committee meeting scheduled in May 2019.

2. Consideration of application

Use of 'fresh' human embryos in research

2.1. The committee noted that the PR had provided information on the circumstances in which 'fresh' embryos are considered to be surplus to the requirements of treatment.

2.2. The PR confirmed that fresh embryos obtained from patients are considered to be surplus to the treatment if they are not suitable for either fresh embryo transfer, or freezing, or the couples have opted not to freeze their spare suitable embryos for treatment.

3. Decision

3.1. The committee noted the Executive update and the PR's response.

4. Chair's Signature

4.1. I confirm this is a true and accurate record of the meeting.

Signature

Name

Kate Brian

Date

30 May 2019

Executive update for Licence Committee
2 May 2019

Centre number	0017
Centre name	Newcastle Fertility at LIFE
Person Responsible	Meenakshi Choudhary

Response to request for information by the Licence Committee

Background

1. A report of both a research interim inspection and a variation of research aims and objectives of project R0152 at centre 0017, was considered by Licence Committee (LC), on 7 March 2019.

2. The committee was satisfied with the interim inspection report and endorsed the inspectorate's recommendation for the continuation of research licence R0152, without additional conditions, subject to the PR responding to the recommendations in the inspection report.

3. The committee considered that it had sufficient information, drawn from documentation submitted by the Executive to consider the application to vary research licence R0152 to reflect the revised aims and objectives of the research project. The committee endorsed the inspectorate's recommendation for the approval of the licence variation application.

4. The committee noted that the PR had increased the forecasted the number of fresh embryos required for use in research project R0152 since the renewal application.

5. The committee were unaware of the circumstances in which embryos are classified as surplus to requirement for treatment and requested that the PR should inform them of the circumstances in which fresh embryos are considered surplus to requirement for treatment, for the licence committee to consider at it's next scheduled meeting in May 2019.

6. The PR responded by email on 5 April 2019, stating; "Fresh embryos obtained from patients are considered to be surplus to the treatment if they are not suitable for either fresh embryo transfer or for freezing or the couples have opted not to freeze their spare suitable embryos for treatment".