Executive Licensing Panel - minutes

Centre 0067 (St Mary's Hospital)

Interim Inspection Report

Research Project R0171

Friday, 6 October 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Ian Peacock Anna Quinn	Director of Strategy and Corporate Affairs Systems Manager Scientific Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers		

Declarations of interest

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

The panel had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

1.1. The panel noted that St Mary's Hospital is a treatment and research centre.

1.2. The current research project R0171, entitled 'In-vitro development and implantation of normal human pre-implantation embryos and comparison with uni- or poly-pronucleate pre-embryos', was first licensed in June 1996.

1.3. The panel noted that the current research licence is due to expire on 31 December 2018.

1.4. The panel noted that at the time of the inspection on 11 July 2017, there were no areas of non-compliance or poor practice.

1.5. The panel noted that the Person Responsible (PR) had informed the inspector, that due to building and layout changes at the hospital, the postal address for the centre had changed. The centre has not changed its physical location and the change of address is solely an administrative change. There is no application form available for this type of change and no fee is due. The new address for the centre is:

The Department of Reproductive Medicine
Old Saint Mary's Hospital
Oxford Road
Manchester
M13 9WL

1.6. The panel noted the inspectorate's recommendation for the continuation of the centre's research licence with no additional conditions. The inspectorate also recommends the licence is varied to reflect the change of address.

2. Decision

2.1. The panel congratulated the centre on their lack of non-compliances and endorsed the inspectorate's recommendation to continue the centre's research licence, with no additional conditions, varying the address.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

18 October 2017

Research Interim Inspection Report

Date of Inspection: 11 July 2017
Purpose of inspection: Interim inspection of research licence
Length of inspection: 6 hours
Inspectors: Dr Vicki Lamb

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre.

Date of Executive Licensing Panel: 6 October 2017

Centre details

Project title	Derivation of human embryonic stem cell lines from embryos created from clinically unused oocytes or abnormally fertilised embryos.
Centre name	St Mary's Hospital
Centre number	0067
Research project number	R0171
Previous centre address	The Department of Reproductive Medicine, St Mary's Hospital Whitworth Park Manchester M13 0JH
New centre address	The Department of Reproductive Medicine Old Saint Mary's Hospital Oxford Road Manchester M13 9WL
Person Responsible	Professor Daniel Brison
Licence Holder	Dr Cheryl Fitzgerald
Treatment centres donating to this research project	0007 Hewitt Fertility Centre 0008 IVI Midland 0033 Manchester Fertility 0078 Wolfson Family Clinic 0144 Nuffield Health Woking Hospital 0196 Jessop Fertility 0295 Bristol Centre for Reproductive Medicine
Date licence issued	01/01/2016
Licence expiry date	31/12/2018

Additional conditions applied to this licence	None

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Purpose of the Inspection report

The purpose of the inspection is to assess whether research using human embryos is carried out in compliance with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended) and the Code of Practice and that progress is made towards achieving the stated aims of the project. The report summarises the findings of the inspection highlighting areas of firm compliance and good practice, as well as areas where improvement may be required to meet regulatory standards. It is primarily written for the Authority's Executive Licensing Panel which makes the decision about the centre's licence.

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:
Centre 0067 is a treatment and research centre. The current research project, entitled "Derivation of human embryonic stem cell lines from embryos created from clinically unused oocytes or abnormally fertilised embryos" (R0171), was first licensed in August 2006.

The current licence is due to expire on 31 December 2018, having been renewed for three years by a Licence Committee on 5 November 2015. There are no additional conditions on the licence.

Summary for licensing decision:
In considering overall compliance, the inspection team considers that it has sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit to draw a conclusion on the continuation of the centre's licence.

The Executive Licensing Panel is asked to note that at the time of the inspection there were no areas of practice that required improvement.

Additionally, the PR has informed the inspector that due to building and layout changes at the hospital, the postal address for the centre has changed. The centre has not changed its physical location and the change of address is a solely administrative change. There is no HFEA application form available for a change of this kind. No fee is due for a change of this kind.

The new address of the centre is:
The Department of Reproductive Medicine
Old Saint Mary's Hospital
Oxford Road
Manchester
M13 9WL

Recommendation to the Executive Licensing Panel:
The inspection team considers that overall there is sufficient information available to recommend the continuation of this centre's licence without additional conditions. In making this recommendation it is noted that no recommendations were made.

The inspection team also recommends that the licence is varied to reflect the change of address.

Summary of project

Lay summary of the research project:

We plan to continue our current project to derive embryonic stem cells from eggs and embryos donated by IVF patients at our participating centres. If eggs are used they can be cultured or chemically activated to form embryos, with or without cryopreservation. We remove cells from embryos at different stages of development from day 3 to day 8 after fertilisation. This prevents any further development of the embryo well before the limit of 14 days post-fertilisation. We take the cells from the embryos and encourage them to grown in special culture conditions usually on a layer of supportive feeder cells. If the cells do develop, they can form embryo stem cells, and eventually, an embryonic stem cell (hESC) line (defined as 3 million cells or more, some of which have been placed in frozen storage). These hESC lines are tested for their ability to form all cell types in the body, to make sure that they are genetically normal and remain so after being cultured in the laboratory, and to make sure that they are not contaminated in any way which would make them unsuitable to be used in the treatment of disease. We also study the gene expression profile of the cell lines and also some of the embryos, or cells taken from the embryos, in order to increase our basic understanding of cell fate in embryos and hESC cells. This work will ultimately benefit IVF treatments by increasing our understanding of human embryo development.

Objectives of the research:

In the continuation of this licence we will aim to:
1) derive new embryonic stem cell lines in order to develop more efficient methods to generate hESCs from embryos.
2) analyse expression of pluripotency-related genes in embryos. Although we also use induced pluripotent stem cells in our research, the derivation and use of human embryonic stem cells is essential as these continue to be the gold standard pluripotent stem cell for therapeutic use, and because these are the best model for study of early human embryo development.

Donation and use of embryos:

In the period from 1 January 2016 to 31 December 2016, the project has used 100 frozen embryos. This is in line with the number of frozen embryos the PR expected to use each year.

Details of inspection findings

Inspection findings

Ensure that all licensed research by the centre meets ethical standards, and is done only where there is both a clear scientific justification and no viable alternative to the use of embryos
(Guidance note 29, 30, 31)

What the centre does well.

The centre was granted a renewal of its research licence by a licence committee in November 2015 for the following activities:

- Creation of embryos in vitro
- Keeping embryos
- Using embryos
- Storage of embryos

None of these activities are prohibited by the HF&E Act 1990 (as amended). The renewal of the licence was approved to allow research for the following designated purposes:

- Increasing knowledge about serious disease or other serious medical conditions
- Developing treatments for serious disease or other serious medical conditions
- Promoting advances in the treatment of infertility
- Increasing knowledge about the development of embryos

At the last renewal, a peer reviewer agreed that the use of human embryos was necessary and justified for the proposed research project.

The research project has been approved by the NRES Committee North West- Greater Manchester East Ethics Committee, and this approval remains in place.

What they could do better.

Nothing noted.

Have respect for the special status of the embryo when conducting licensed activities
(Guidance note 15, 18, 22, 25, 26)

What the centre does well.

On inspection, a review of centre documentation and discussions with centre staff demonstrated that:

- Proper records of the storage of embryos in the research project are maintained.
- Robust procedures are in place to ensure proper records of the use of embryos are maintained from donation to the project, use in research through to disposal at the end of the research process (RLC R13).

- The researchers have a documented procedure for ensuring that embryos do not develop beyond 14 days post-fertilisation or the appearance of the primitive streak, whichever is earlier (RLC R28).
- Discussions with the PR provided assurance that all embryos donated to the project will only be used for the objectives authorised by the licence to meet the defined statutory purposes (RLC R5 and R23). This is facilitated by restricted access to embryos during storage and use, and supervision of research staff by the PR.
- A storage log is maintained which records the storage consent expiry dates for any embryos in storage for research purposes. All frozen embryos in storage were within their consented storage period (RLC R39).

An audit of donor records showed that:

- Effective consent for the use of the embryos in the research project had been documented by the gamete providers (RLC R18).
- Embryos are not allowed to develop after 14 days or the primitive streak has appeared (if earlier) (RLC R28).

The PR has ensured that appropriate records of embryo use are maintained and that annual use is reported to the HFEA (General Direction 0002 and RLC R13, R14 and R15).

What they could do better.

Nothing noted.

Changes and improvements since the last inspection

Following the renewal inspection in 2015, recommendations for improvement were made in relation to three major areas of non-compliance.

The PR provided information and evidence that recommendations to address all the areas of non-compliance were fully implemented within the agreed timescales.

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non-compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Act, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non-compliance

A critical area of non-compliance is an area of practice which poses a significant direct risk of causing harm to a patient, donor or to an embryo. A critical area of non-compliance requires immediate action to be taken by the Person Responsible

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

Major area of non-compliance

A major area of non-compliance is a non-critical area of non-compliance:

- which poses an indirect risk to the safety of a patient, donor or to an embryo through the procurement, use, storage or distribution of gametes and embryos, which do not comply with the centre's licence;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several "other" area of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non-compliance, but which indicates a departure from good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

Additional information from the Person Responsible
Thank you for the inspection visit and report, we are very pleased with the positive nature of both.