Executive Licensing Panel - minutes

Centre 0102 (Guys Hospital)

Interim Inspection Report - Research Project R0075

Tuesday, 7 April 2020

HFEA Teleconference Meeting

Panel members	Clare Ettinghausen (Chair) Kathleen Sarsfield-Watson Helen Crutcher	Director of Strategy and Corporate Affairs Communications Manager Risk and Business Planning Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing Manager

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:

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

1. Consideration of application

1.1. The panel considered the papers, which included a report and licensing minutes for the last three years.

1.2. The panel noted that Guys Hospital is a treatment and research centre. There are currently two research projects licensed at this centre. Research project R0075, entitled ‘Improving methods for preimplantation genetic diagnosis of inherited genetic disease and predicting embryo quality’, was first licensed in 1994.

1.3. The panel noted that an inspection was carried out on 10 February 2020.

1.4. The panel noted that, at the time of the inspection, no areas of non-compliance or poor practice were identified.

1.5. The panel noted the inspectorate's recommendation for the continuation of the centre’s research licence with no additional conditions.

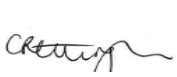
2. Decision

2.1. The panel agreed to the continuation of the centre’s research licence, with no additional conditions.

3. Chair’s signature

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

Signature



Name

Clare Ettinghausen

Date

16 April 2020

Research Interim Inspection Report

Date of inspection: 10 February 2020
Purpose of inspection: Interim inspection of research licence
Length of inspection: 4 hours
Inspectors: Mhairi West, Vicky Brown (observing)

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

Date of Executive Licensing Panel: 7 April 2020

Centre details

Project title	Improving methods for preimplantation genetic diagnosis of inherited genetic disease and predicting embryo quality
Centre name	Guys Hospital
Centre number	0102
Research licence number	R0075
Centre address	Stem Cell and Embryology Research Laboratories, Assisted Conception Unit, 11th Floor Tower Wing, Guy's Hospital, London, SE1 9RT, United Kingdom
Person Responsible	Dusko Ilic
Licence Holder	Yacoub Khalaf
Treatment centres donating to this research project	Guy's Hospital (centre 0102)
Date licence issued	1 September 2018
Licence expiry date	31 August 2021
Additional conditions applied to this licence	None

Contents

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 0102 is a treatment and research centre. There are currently two research projects licensed at this centre. Research project R0075, entitled “Improving methods for preimplantation genetic diagnosis of inherited genetic disease and predicting embryo quality” (R0075) was first licensed in 1994.

The current licence is due to expire on 31 August 2021, having been renewed for three years by a Licence Committee in August 2018. There are no additional conditions on the licence. The centre was last inspected on 29 March 2018.

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 there are no areas of practice that require improvement.

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. The PR has reviewed this report and stated that, as there were no recommendations, he does not wish to make any comment.

Summary of project

Lay summary of the research project:

Our work is aimed at both developing new approaches to diagnostic testing of preimplantation embryos, and increasing knowledge of the biology and genetics of early embryo development, with a view to understanding the basis of successful pregnancies and improving the chances of healthy offspring for couples undergoing preimplantation genetic diagnosis (PGD) and IVF procedures. We intend to work over the next three years, further developing this approach. Our aims will be: a) Improve the chances of healthy offspring by introducing and developing better strategies and protocols for embryo culture and testing b) Explore new avenues in modelling early human development to understand biology and genetics of human embryos.

Objectives of the research:

We wish to continue to improve our PGD and IVF programmes by introducing and developing better strategies and protocols for embryo culture and testing. We also wish to understand more about the biology and genetics of early human embryos. The last several years we explored embryo twinning. The blastomere separation technique of embryo splitting seems to be unsuitable for either clinical or research purposes; however, embryo bisection, a preferable method of cloning in veterinary medicine, has not yet been tested on human embryos. We would like to investigate this approach in more detail.

Donation and use of embryos:

In the period from 1 January 2019 to 31 December 2019, the centre reported the use of 35 frozen embryos in this research project. The centre has not taken consent to donate embryos to research from any patients since July 2019, but have 404 frozen embryos remaining in storage.

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 August 2018 for the following activities:

- creation of embryos in vitro;
- keeping embryos;
- storage of embryos;
- using 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
- Increasing knowledge about the causes of any congenital disease or congenital medical condition that does not fall within paragraph (a)
- Promoting advances in the treatment of infertility
- Developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation
- 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.

Evidence that the research project has been approved by an ethics committee was provided to the HFEA in 2018 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 Person Responsible (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 2018, a recommendation for improvement was made in relation to one major area of non-compliance.

The PR provided information and evidence that the recommendation to address this was fully implemented within the agreed timescale.

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the inspector 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