

Executive Licensing Panel - minutes

Centre 0102 (Guy's Hospital)

Interim Inspection Report

Research Project R0133

Friday, 8 June 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Helen Crutcher Anna Quinn	Director of Strategy and Corporate Affairs Risk and Business Planning Manager Scientific Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Senior Governance 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:

- 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 Guy's Hospital is a treatment, storage and research centre. There are currently two research projects licensed at this centre. Research project R0133, entitled 'Developing criteria for estimating quality of stem cells derived from human embryos', was first licensed in April 2002.
- 1.2. The current licence is due to expire on 31 July 2020 and was renewed, for three years, by a Licence Committee on 13 July 2017. There are no additional conditions on the licence. The research premises were last inspected on 10 December 2015.
- 1.3. The panel noted that at the time of the inspection on 29 March 2018, there was one major area of non-compliance or poor practice regarding the offer of counselling to patients donating embryos about the implications of their donation. Since the inspection, the Person Responsible (PR) has addressed this area of non-compliance.
- 1.4. The panel noted the inspectorate's recommendation for the continuation of the centre's research licence with no additional conditions.

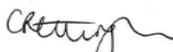
2. Decision

- 2.1. The panel noted that the one major area of non-compliance had been addressed and endorsed the inspectorate's recommendation to continue 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

11 June 2018

Research Interim Inspection Report



Date of Inspection: 29 March 2018
Purpose of inspection: Interim inspection of research licence
Length of inspection: 4 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: 8 June 2018

Centre details

Project title	Developing criteria for estimating quality of stem cells derived from human embryos
Centre name	Guys Hospital
Centre number	0102
Research licence number	R0133
Centre address	11 th Floor, Tower Wing Stem Cell and Embryology Research Laboratories Assisted Conception Unit Guy's Hospital Great Maze Pond London SE1 9RT
Person Responsible (PR)	Dr Dusko Ilic
Licence Holder (LH)	Mr Yakoub Khalaf
Treatment centres donating to this research project	0102 Guys Hospital
Date licence issued	1 August 2017
Licence expiry date	31 July 2020
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.

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Report to Executive Licensing Panel

Brief description of the centre and its licensing history

Centre 0102 is a treatment, storage and research centre. There are currently two research projects licensed at this centre. Research project R0133, entitled 'Developing criteria for estimating quality of stem cells derived from human embryos', was first licensed in April 2002.

The current licence is due to expire on 31 July 2020, having been renewed for three years by a Licence Committee on 13 July 2017. There are no additional conditions on the licence. The research premises were last inspected on 10 December 2015.

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 was one major area of non-compliance which has now been addressed by the PR:

Major area of non-compliance:

- The PR should ensure that patients donating embryos are offered the opportunity to receive counselling about the implications of their donation.

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.

Summary of project

Lay summary of the research project:

Stem cells are unique cell populations that are able to copy themselves exactly and also specialise into new cell types. The most powerful human stem cells can be isolated from the earliest stages of human development and they are termed human embryonic stem cells (hESC). These cells have great potential in regenerative medicine because they can be guided to form various more specialised cell types which then may be of use in treating serious debilitating diseases such as diabetes, or to repair organs following stroke or heart attacks. Another valuable use of these cells is in studying disease progression as well as in the search for new drugs for treatment of serious illnesses. Although there has been a lot of hype about stem cells, their potential is not yet fully realised. Firstly, methods to generate the cells in a reliable and safe way have to be established. Secondly, the characteristics of the cells have to be precisely defined, which has not yet been achieved - scientists have not been able to fully track and understand changes happening during manipulation of the cells. In this project, the researchers wish to define norms and standardise protocols that would assure quality and reliability of these cells. They plan to accurately analyse how the cells copy themselves and what factors make this process more successful, such as the position of each cell in a population or the addition of external supplements. This understanding will enable them to improve the methods they use to grow the cells. They will also look at the number and arrangement of the genetic material in the cells at the beginning of the culture and again several months later to see if any changes have occurred. Even minor alterations are cause for concern and may limit the use of these particular cells. Although hESC can become any other mature cell in an adult organism, they are usually inclined to go one way rather than another and it is not yet understood why. In this project the researchers will allow the cells to differentiate and study which cell types they prefer to become. Knowing the difference in preferences of hESC lines will be of great benefit to all researchers when selecting which cell line to use in experiments. The cells that already prefer to make muscle, for example, can be chosen for work on heart disease, whereas others that would rather make neural tissue can be used in treatment of spinal cord injuries. Lastly they will look for changes that are related uniquely to specific diseases and try to identify ways to prevent or reduce these changes. Detailed characteristics of any lines developed and studied will be logged with the cell line in the UK Stem Cell Bank for the benefit of all researchers and people that will use them in the future.

Objectives of the research:

- 1.To continue derivation of disease-specific hESC lines on demand.
- 2.To utilise hESC-derivation technology in the validation of blastocyst quality.

Donation and use of embryos:

In the period from 1 January 2017 to 31 December 2017, the centre did not use any embryos, and no embryos were created for use in the project. The PR wishes to keep this project active as there are still some embryos in storage that have been consented for use in this research.

A total of 44 cell lines have been derived since the start of this research project. All of these cell lines have been deposited in the Stem Cell Bank.

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 July 2017 for the following activities:

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

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 the causes of any congenital disease or congenital medical condition that does not fall within paragraph (a)
Human Fertilisation and Embryology Act 1990 (as amended) Schedule 2 3A(2)(c)
- Promoting advances in the treatment of infertility
Human Fertilisation and Embryology Act 1990 (as amended) Schedule 2 3A(2)(d)
- Increasing knowledge about the development of embryos
Human Fertilisation and Embryology Act 1990 (as amended) Schedule 2 3A(2)(h)

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 St Thomas's Hospital Ethics Committee. Evidence was provided by the PR that this approval remains active and covers the research activity described in the licence application.

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).

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.

Patients donating frozen embryos to research are given information and provide their consent by post. The patient information provided to them does not mention that they can access counselling about the implications of their donation (RLC R18) (see recommendation 1).

Changes and improvements since the last inspection

Following the desk-based renewal assessment in 2017, no recommendations for improvement were made.

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
1. The patient information does not mention that patients can access counselling about the implications of their donation	The PR should ensure that patients donating embryos are offered the opportunity to receive counselling about the	Our literature for the patients states that counselling is available to patients before, during and after this treatment.	The PR has updated the patient information to include the offer of counselling. The patient information leaflet has

(RLC R18).	implications of their donation. The PR should inform the inspector of the actions taken to ensure counselling is offered to patients by the time this report is considered by the Executive Licensing Panel.	Technically, this availability should cover any aspect of treatment/ storage and fate of embryos that patients need to have support with. Following your suggestion, we specifically mentioned counselling contact in updated version of patient information sheet.	been provided to the inspector. No further action.
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▶ 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