Executive Licensing Panel - minutes

Centre 0102 (Guy's Hospital) Interim Research Inspection Report – Research Project R0075

Friday, 26 February 2016

HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Panel members	Juliet Tizzard (Chair) Nick Jones Anna Rajakumar	Director of Strategy & Corporate Affairs Director of Compliance & Information Scientific Policy Manager
Members of the Executive	Dee Knoyle	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. Guy's Hospital, centre 0102, is a treatment and research centre. Research project R0075, entitled 'Improving methods for preimplantation genetic diagnosis of inherited genetic disease and predicting embryo quality', was first licensed in July 1994.

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

1.3. The panel noted that donated embryos used in the project are obtained from the following centres:

- Sussex Downs Fertility Centre, centre 0015
- Herts and Essex Fertility Centre, centre 0030
- BMI Chelsfield Park ACU, centre 0086
- Bourn Hall Clinic, centre 0100
- The Woking Nuffield Hospital, centre 0144
- Chelsea and Westminster Hospital, centre 0158
- Salisbury Fertility Centre, centre 0197
- South East Fertility Clinic, centre 0208

1.4. The panel noted that at the time of the inspection on 10 December 2015, there were no areas of practice that required improvement.

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 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

Juliet Tizzard

Date

10 March 2016

Research Interim Inspection Report

Date of Inspection: 10 December 2015
Purpose of inspection: Interim inspection of research licence
Length of inspection: 4 hours
Inspectors: Vicki Lamb and Polly Todd

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

Date of Executive Licensing Panel: 26 February 2016

Centre details

Project title	Improving methods for preimplantation genetic diagnosis of inherited genetic disease and predicting embryo quality
Centre name	Guy's Hospital
Centre number	0102
Research licence number	R0075
Centre address	11th Floor, Tower Wing Stem Cell and Embryology Research Laboratories Assisted Conception Unit Guy's Hospital Great Maze Pond London SE1 9RT
Person Responsible	Dr Dusko Ilic
Licence Holder	Mr Yakoub Khalaf
Treatment centres donating to this research project	Sussex Downs Fertility Centre (0015) Herts and Essex Fertility Centre (0030) BMI Chelsfield Park ACU (0086) Bourn Hall Clinic (0100) The Woking Nuffield Hospital (0144) Chelsea and Westminster Hospital (0158) Salisbury Fertility Centre (0197) South East Fertility Clinic (0208)
Date licence issued	1 September 2015
Licence expiry date	31 August 2018
Additional conditions applied to this licence	None

Doc name: Interim research report R0075 0102, December 2015
TRIM reference: 2015/021564

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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 0102 is a treatment and research centre. The current research project, entitled 'Improving methods for preimplantation genetic diagnosis of inherited genetic disease and predicting embryo quality' (R0075), was first licensed in July 1994.

The current licence is due to expire on 31 August 2018, having been renewed for three years by a Licence Committee on 7 May 2015, following a desk-based assessment. There are no additional conditions on the licence. The centre was last inspected on 17 December 2013.

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.

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:

Understanding fully the molecular events during implantation is necessary in order to manipulate them in a creative way, developing translational strategies to improve implantation rates and lead to higher pregnancy rates in assisted conception procedures. The researchers will continue to build molecular level databases on normal development of preimplantation embryos. Over the past 50 years steady progress in improving mammalian embryo culture media has been achieved, however current culture media still remains sub-optimal. To decrease the number of embryos used in validation of new media or techniques, the researchers intend to introduce an embryo-splitting technique. If successful, they will be able to obtain genetically identical twin embryos. One of them can be used as a control, whereas other can be cultured under new conditions. In such a way, they will avoid genetic background bias that can lead to misinterpretation of the data and that increases the number of embryos needed to validate the process. If the researchers can prove that the technique yields embryos of a quality indistinguishable from non-manipulated embryos, other researchers may also wish to adopt the same practice, particularly in the validation of new media or laboratory techniques.

Objectives of the research:

The researchers wish to continue to improve their PGD and IVF programmes by introducing and developing better strategies and protocols for embryo culture and testing. They also wish to understand more about the biology and genetics of early human embryos.

Donation and use of embryos:

In the period from 1 January 2014 to 31 December 2014, the centre reported the use of 142 frozen embryos. Seventy embryos created by splitting were used in the project.

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 May 2015 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;
- increasing knowledge about the causes of miscarriage;
- 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 2015 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 use documented practices which ensure 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 desk-based renewal in March 2015, 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
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
I have nothing to add or comment.