Executive Licensing Panel - minutes

Centre 0021 (Hull IVF Unit)

Interim Inspection Report - Research Project R0067

Friday, 17 November 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Anna Quinn Helen Crutcher	Director of Strategy and Corporate Affairs Scientific Policy Manager Risk and Business Planning Manager
Members of the Executive	Dee Knoyle Erin Barton	Secretary Policy Manager (Observer)
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 considered the papers, which included a report and licensing minutes for the last three years.

1.2. The panel noted that Hull IVF Unit holds both a treatment and storage licence and a research licence. The research licence is for project R0067, entitled ‘Biochemistry of early human embryos’. The panel noted that this research project has been licensed by the HFEA since 1995.

1.3. The panel noted that the current licence is due to expire on 31 January 2019.

1.4. The panel noted that all licensed material used in the project will be obtained from Hull IVF Unit.

1.5. The panel noted that no embryos have been used or stored for research since the licence was renewed in February 2016. However, research activities are due to commence in the near future.

1.6. The panel noted that an inspection was carried out on 21 September 2017 and there were no areas of practice that required improvement.

1.7. 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

Juliet Tizzard

Date

27 November 2017

Research Interim Inspection Report

Date of Inspection: 21 September 2017
Purpose of inspection: Interim inspection of research licence
Length of inspection: 4 hours
Inspectors: Dr Andrew Leonard

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

Date of Executive Licensing Panel: 17 November 2017

Centre details

Project title	Biochemistry of early human embryos
Centre name	Hull IVF Unit
Centre number	0021
Research project number	R/0067/10/a
Centre address	Women's and Children's Hospital, Hull Royal Infirmary Anlaby Road, Hull, HU3 2JZ
Person Responsible (PR)	Henry Leese
Licence Holder (LH)	Roger Sturmey
Treatment centres donating to this research project	Hull IVF Unit (centre 0021)
Date licence issued	01/02/2016
Licence expiry date	31/01/2019
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:
The Hull IVF Unit is licensed to provide treatment and storage services and is also licensed to undertake research project R0067: Biochemistry of early human embryos. This project seeks to evaluate changes in the media of cultured embryos resulting from their metabolism and to correlate those changes with embryo viability and potential for live birth, as well as with secondary factors such as patient health. The project was first licensed in 1995.

The research project was last inspected on 11 August 2015 when no non-compliances were found. The research licence was subsequently renewed on 1 February 2016 and is due to expire on 31 January 2019. There are currently 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.

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:

To identify quantitative biomarkers of oocyte and embryo quality.
To discover the influence of female Body Mass Index (BMI) on embryo metabolic health and determine ways to identify the most viable embryos for embryo transfer.

Objectives of the research:

This research will provide information essential to understand the extent to which embryo metabolism can influence onward development to the blastocyst, the success of ART procedures and, crucially, the potential impact on key developmental events that may persist beyond birth. Through many years of research we have demonstrated that, in metabolic terms, a 'quiet embryo' is the most viable and we continue to pursue noninvasive biomarkers of embryo potential that have translational capacity. We have now contributed new knowledge on the extent to which maternal physiology [in the form of body weight] can act to change the physiology of the embryo. Building on this, we aim to elucidate links between maternal physiological characteristics and embryo viability. Specifically, we will investigate the effect of Poly Cystic Ovarian Syndrome (PCOS) on embryo metabolism, as well as other maternal metabolic factors. Moreover, since we have demonstrated that maternal body weight induces metabolic adaptation in the early embryo, we will aim to identify strategies that may be undertaken to prevent or reverse such metabolic programming. The desired output will be sound advice, based on empirical scientific findings, that can be given to patients on the impact that their physiology on the developing embryo and how changes might be made to avoid such an impact.

Donation and use of embryos:

In the period from 1 January 2016 to 31 December 2016, the project used no embryos.

The PR advised on inspection that no embryos have been used or stored for research since the licence was renewed on 1 February 2016. Research activities are due to commence in the near future.

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 research project has been approved by the local research ethics committee. Evidence was provided by the PR that this approval remains active.

The centre was granted a renewal of its research licence by a licence committee in November 2015 for the following activities: Keeping embryos; Using embryos; Storage of embryos. The research project does not include any activities that have been prohibited by the HF&E Act 1990 (as amended).

The renewal of the licence was approved by a licence committee to allow research for the following purposes:

- Increasing knowledge about serious diseases 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.

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 have been maintained in the past, and will be maintained in the future, when embryo donation and storage for the research project are re-established.
- 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 in the past have been, and in future will be, only used with the effective consent of the gamete providers and for the objectives authorised by the licence to meet the defined statutory purposes (RLC R5 and R23). This is facilitated by restricting 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. No embryos are currently in storage for use in the project (RLC R39).

The PR has ensured in the past, and will do so in the future when activity is re-established, 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, no recommendations for improvement needed to be 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
We were happy with the report and felt the inspection was a very positive experience.