Executive Licensing Panel
24 June 2011 at 10.00am

Centre Name:	Birmingham Women's Hospital
Centre Number:	0119
Project:	R0172
Person Responsible:	Dr Jackson Kirkman Brown

Interim research inspection report of project R0172 at Centre 0119

Papers Enclosed:

- Interim research inspection report, 12 April 2011
- Research Licence Committee Minutes, 18 November 2009, which considered the last renewal of licence.

Research Interim Inspection Report

Date of Inspection: 12 April 2011
Purpose of inspection: Interim Inspection
Length of inspection: 6 hours
Inspectors: Dr Andrew Leonard
Mr Parvez Qureshi

Inspection details:
The report covers the pre-inspection analysis, the visit and information received between 1 January 2010 and the Executive Licensing Panel on the 10 June 2011.

Date of Executive Licensing Panel: 10 June 2011

Centre details

Project Title	Human Gamete Interaction and Signalling
Centre Name	Assisted Conception Unit, Birmingham Women's Hospital
Centre Number	0119
Research licence Number	R0172/2/A
Centre Address	Centre for Human Reproductive Science (ChRS), Research Laboratory – (04-Lab2-009), The Women's Hospital, Edgbaston, Birmingham.
Person Responsible	Dr Jackson Kirkman Brown
Licence Holder	Dr Sarah Connor
Treatment centres donating to this research project	Assisted Conception Unit, Birmingham Women's Hospital (Centre 0119)
Date Licence Issued	1 January 2010
Licence expiry date	31 December 2012
Additional conditions applied to this licence	'That no research must be performed until appropriate ethics committee approval is in place and evidence of this has been provided to the HFEA executive'

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 HFEA Code of Practice 8th edition (CoP) 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 (ELP) which makes the decision about the centre's licence.

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:
Centre 0119 has held research licences since 2004. The research premises comprise the clinical embryology laboratory in the Assisted Conception Unit (ACU), Birmingham Women's Hospital and another laboratory within the ACU which is allocated to the University of Birmingham (04-Lab2-009). The Person Responsible's (PR) office within the ACU, also allocated to the University of Birmingham, is used for the storage of research records, all non-identifiable of the oocyte/embryo donors.

The project was first licensed from 1 January 2006 and was allocated two licence numbers, R0172 at centre 0119 and R0173 at centre 0209. The project was last inspected for renewal on 19 August 2009 and the licence was renewed by the Research Licence Committee (RLC) on the 18 November 2009 for the period 1 January 2010 – 31 December 2012. The licence was renewed for the creation of embryos for research, the use of embryos in research; and the storage of licensed material. The licence at the last renewal was approved to allow research for the following designated purposes, as defined in Schedule 2, paragraph 3A (2) to the HFE Act 1990 (as amended):

- (d) promoting advances in the treatment of infertility,
- (e) increasing knowledge about the causes of miscarriage,
- (g) developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation
- (h) increasing knowledge about the development of embryos.

The RLC at the last licence renewal imposed an additional licence condition: 'That no research must be performed until appropriate ethics committee approval is in place and evidence of this has been provided to the HFEA executive.' This additional condition was requested by the inspection team because the project was extended in scope at the renewal and the ethics approval in place at the time did not cover some elements of the extended project.

Aspects of project R0172 are also performed at Centre 0209 (The Institute of Biomedical Research, School of Medicine, University of Birmingham), located approximately 300 metres from centre 0119) under research project licence R0173 held by that centre.

The PR is a Senior Lecturer with the University of Birmingham, with many years of research experience, and also the Director of Research and Development at the Centre for Human Reproductive Sciences at Centre 0119. The PR has completed the PR entry programme. The Licence Holder (LH) is a Lecturer within the Institute of Biomedical Research, University of Birmingham.

Title of research project:
Human Gamete Interaction and Signalling

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, to recommend the continuation of the centre's licence.

The ELP is asked to note that there are two areas of 'other' practice which require improvement, concerning submission to the HFEA of the annual 'Research information and data sheet' and the ethical approval for the project from the Local Research Ethics Committee (LREC), as discussed below.

The ELP should also note the additional condition ('That no research must be performed until appropriate ethics committee approval is in place and evidence of this has been provided to the HFEA executive') placed on this research licence by the Research Licence Committee on 18 November 2009. It is the opinion of the inspection team that this additional licence condition will need to remain in place. This is because ethical approval for the extension of the research project approved at renewal has not yet been sought, since no work has been performed on the project since renewal. Revised ethical approval for the extension of the research project and associated patient information and consent forms, is being sought by the PR within the next three months. The PR has assured the inspection team that no work on the project will be performed unless ethical approval has been provided.

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.

The inspection team recommends that the ELP requires that the PR complies with the following recommendations.

Critical areas of concern: None
Major areas of non compliance: None
Other areas of practice that require improvement:

- The PR should ensure that the annual 'Research information and data sheet' for the project is submitted to the HFEA by 31 January of the following year.
- The PR should ensure that LREC approval is sought for the extended research activities added to the project in 2009, and the revised patient information and consent forms.

The inspection team also recommends that the existing additional condition on the licence: 'That no research must be performed until appropriate ethics committee approval is in place and evidence of this has been provided to the HFEA executive', **should remain on the licence** until appropriate ethical approval has been obtained for the project as it is currently licensed and its associated patient information and consent forms.

Summary of project

Lay summary of the research project:

Due to the technical and logistic difficulties of undertaking experimental work on the human egg almost nothing is known about what happens as a sperm moves through the outer egg coats to achieve fertilisation. We now have the technology available to begin to examine this in detail. We hope that the results will inform us about how sperm and eggs may 'talk to each other' and enable us to not only better understand how these things go wrong and may cause infertility but also to devise better future treatments and contraceptives.

In this project we will employ advanced fluorescent imaging (microscopy) techniques to examine in detail the events occurring as human sperm and eggs interact, particularly with reference to concentrations of calcium which we know form a vital part of the signalling that occurs. The data we hope to generate will give new insight into the very early events occurring in fertilisation, we hope that one early outcome for this data may be new treatments to help couples where the sperm lacks the crucial ability to 'activate' the egg and hence normal fertilisation cannot take place.

Objectives of the research:

Summary

The objective of this proposal is to elucidate the events that occur during human sperm and egg interaction at a cellular and molecular level, including methods for achieving improved oocyte activation/fertilisation rates.

Aims

These aims are not mutually exclusive and many may be accomplished at once in single experiments:

- Evaluation of techniques to artificially activate human oocytes, particularly around therapeutic assisted activation focused upon those which would meet and comply with EUTCD requirements.
- Characterisation of the Ca^{2+} responses, motility and other physiological changes induced in human sperm by cumulus oophorus and zona interaction and penetration in zona-enclosed human oocytes.
- Characterisation of any focal or global signalling events generated in cumulus cells due to interaction or presence of human spermatozoa.
- Precise monitoring of the human fertilisation event and understanding of how any calcium signalling events occurring within the sperm may relate to those initiated in the oocyte.
- Examination of whether signals initiated in the periphery of the cumulus, possibly induced by interaction with spermatozoa, propagate to the oocyte itself.
- Accurate examination of the early fertilisation events in the fresh human oocyte.
- Effects of aneuploid state of the oocyte upon any of these signals or their subsequent events.

Donation and use of embryos:

The centre submitted the annual 'Research Information and Data Sheet' for 2010 to the HFEA in accordance with the requirements of General Direction 0002, albeit the submission was after the required deadline. This submission indicated that no embryos or oocytes were used in project R0172 in 2010. The submission also provided a lay summary of the research undertaken which stated:

'Over the past year our research has been focused upon research that is undertaken on the same ethical approval as this licence, and concentrates upon how the human sperm navigates the female tract and responds to the egg. However, the research we have been working on has not used any human eggs.

'This research was focused upon the role of the cumulus oophorus and follicular fluid upon sperm; the role they may have in selecting a 'genetically normal' sperm; and how the cells of the female reproductive tract interact with and modulate sperm motility.

'Our research has not focused upon the egg, in part because our funding has lain elsewhere and in part because we would only use high-quality fresh eggs if we were focused upon a specific question in that field.

'We wish to maintain our licence in this area, because we believe the questions using eggs will be appropriately timely, but also because occasionally a patient, whose husband has no sperm retrieved, wishes to donate all her fresh eggs to research rather than use donor. If this situation arose we have the questions and techniques ready.'

The inspection team note that the research undertaken in 2010 was non-licensible, and was part of the wider programme of research which includes the licensed research activity and is covered by a common ethics committee approval.

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.

Research project R0172 was granted a renewal of the research licence by a HFEA RLC on 18 November 2009. That renewal application was reviewed by a peer reviewer and the HFEA RLC, who both considered that the centre met appropriate ethical standards and had clear justification for, and no viable alternative to, the use of human embryos in research. The licensed activities approved were the creation of embryos for research, the use of embryos in research and the storage of licensed material. The licence was approved to allow research for the following designated purposes, as defined in Schedule 2 3A (2) to the HFE Act 1990 (as amended):

- 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.

Discussions with the PR on inspection indicated that no oocytes or embryos have been used in the project since the licence was renewed, thus there can be no concerns regarding inappropriate or unlawful use of oocytes or embryos in the project since its renewal on 18 November 2009.

The PR also stated on inspection that the project's aims, objectives and methodologies have not changed since renewal. Thus any future use of oocytes and embryos will be in activities and for purposes which have been approved by the RLC, which considered them to meet appropriate ethical standards and have clear justification. This point is however qualified by the absence of LREC approval for some elements of the project, as discussed below.

What they could do better.

The original research activities of project R0172 were approved by the LREC in 2005. The project at that time investigated intracytoplasmic calcium ion flux within fertilising oocytes in the five hours after sperm-oocyte interaction.

The renewal application in 2009 applied to extend the research activities to include in vitro maturation of immature oocytes, culture of fertilising oocytes for up to 7 days (i.e. embryo culture) and aneuploidy screening of cultured research embryos. The report of the renewal inspection on 19 August 2009 noted that these additional research activities and the revised patient information and consent forms had not been approved by the LREC. The PR assured the inspection team that the new activities would not and could not, lawfully, be performed without LREC approval. The report recommended that the PR

obtain approval from the LREC for the additional research activities and for the associated revised patient information and consent forms. The report also recommended that no work is performed on the project unless it is has LREC approval. The RLC on 18 November 2009 approved the renewal of the licence and placed on it an additional condition: 'That no research must be performed until appropriate ethics committee approval is in place and evidence of this has been provided to the HFEA Executive'.

The PR stated at this inspection that the original ethical approval under which the project was established in 2006, is still in place and will remain so until he informs the LREC that the project has terminated. LREC approval for the additional research activities outlined in the renewal application in 2009, and the revised patient information and consent forms, has still not been obtained, contrary to the recommendation made in the renewal inspection report in 2009. The inspection team note that no research activity has been performed since the licence was renewed in 2009, be it on the original LREC-approved project or the additional research work. Thus the centre has not breached the additional licence condition placed on the licence by the RLC on 18 November 2009.

The PR considered that the lack of activity on the project - due to funding/staffing issues and the concentration of research efforts in other areas - has meant it has been unnecessary to obtain LREC approval. The inspection team is understanding of this reasoning but also consider that the PR agreed to implement the recommendation in the last inspection report concerning obtaining LREC approval for the extended project as licensed by the HFEA. This would have prevented the situation in which a research project has been licensed by the HFEA without LREC approval for some aspects, although work on the project cannot lawfully progress without LREC approval being obtained.

The PR stated that he will be seeking to obtain LREC approval in two months, for the extended research activities (in vitro maturation of immature oocytes, culture of fertilising oocytes/embryos for up to 7 days and aneuploidy screening of cultured research embryos) and for the associated revised patient information and consent forms. This is because research and funding circumstances may be changing such that licensed research activity can be re-commenced. The PR also stated that the licensed research activities will only be commenced when full LREC approval has been obtained, in accordance with the requirement of the additional condition placed on the licence by the RLC on the 18 November 2009.

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.

Discussions with the PR and LH, review of the centre's research documented procedures and oocyte and embryo usage log, and inspection of the premises and equipment, indicated to the inspection team that the special status of the human embryo is respected. This was evidenced by several observations:

1. The centre has documented procedures for the processes by which patients are informed of the research and their consent is taken, and for preventing the use of oocytes and embryos in activities other than those which are licensed (Licence Condition (LC) R23). These procedures ensure that oocytes and embryos are used

in a respectful manner for only the purposes specified in patients' consents, as required by Schedule 3 to the HF&E Act (1990) as amended.

2. The PR stated that research recruitment practices ensure that no money or other benefit is given to patients donating oocytes to the project, as required by LC R24. This is also clearly stated in the information provided to patients.
3. Centre 0119 has documented procedures, read by all embryology staff, which ensure that treatment and research roles are separated in the clinical embryology laboratory (LC R27).
4. All oocytes donated to the project are anonymised and marked with a clear research code, before being removed from the clinical embryology laboratory to the research laboratory at centre 0119, as required by LC R26.
5. The centre has a procedure which documents that embryos should not be cultured for more than 14 days post-fertilisation. The culture of each oocyte and embryo is recorded on unique experimental log sheets which are, when the project is active, regularly reviewed to prevent culture beyond 14 days post-fertilisation. Together these prevent non-compliance with LC R28.
6. A procedure has been established for oocyte and embryo disposal at the end of experimental use or their statutory storage period, as recommended by CoP Guidance 22.3. Disposal is witnessed and recorded on the experimental log sheet for each oocyte/embryo.
7. The transfer of oocytes to the research project and the disposal of fertilised embryos from the research project are both witnessed.
8. Access to premises is controlled, preventing unlawful access to research consented material by unlicensed staff.
9. There is dedicated equipment for the project, which is well maintained and serviced appropriately.
10. The PR has ensured that appropriate records of oocyte and embryo usage are maintained and that annual usage is reported to the HFEA, as is required by General Directions 0002

What they could do better.

The PR returned the annual 'Research information and data sheet for 2010' which reports annual embryo usage on the project in 2010, after the required date for submission stated in General Directions 0002.

Changes / improvements since the last inspection on 19 August 2009:

Area for improvement	Action required	Action taken
The incident reporting SOP did not include that incidents should be reported, in writing on the appropriate HFEA report form, to incidents@hfea.gov.uk within 24 working hours, non-compliant with Direction 0011.	The PR should amend the incident reporting SOP to include that incidents should be reported, in writing on the HFEA report form, to incidents@hfea.gov.uk within 24 working hours.	An incident reporting SOP was produced after the last inspection and was provided to the Executive. The present version was observed on inspection and was considered compliant with HFEA requirements. No further actions are necessary
Local ethical approval is in place for the research work common to the licence application in 2006 and this renewal application, but the additional research work proposed in this application, e.g. IVM, embryo culture for 7 days and aneuploidy assessment, has not been approved by the local ethics committee, albeit an application is in progress. The PR stated that the new research work will not, and lawfully cannot, be performed until ethics committee approval is place. He is seeking to include the additional research work in this licence renewal so that the HFEA licensing process and the ethics review process can progress in parallel.	The inspectorate notes the PR's obvious commitment to performing research within the regulatory and ethical framework in a compliant manner. The inspectorate recommends ethical approval is obtained for the additional work proposed, at the earliest opportunity and that the proposed additional work is not performed until that ethical approval is in place.	This issue has been discussed in 'Details of Inspection Findings - Ensure that all licensed research by the centre meets ethical standards….' on page 7.
The patient information had not been reviewed to include the new additional research proposed in this application, and therefore would not provide patients before consenting with 'all relevant information as is proper' as required by HFE Act (1990)	The inspectorate recommends the patient information is updated to describe the future research programme and that local ethical approval is obtained for its use at the earliest opportunity and that the proposed	This issue has been discussed in 'Details of Inspection Findings - Ensure that all licensed research by the centre meets ethical standards….' on page 7..

as amended, Schedule 3, 3(1)b. The PR informed the inspectorate that patient information is being updated and submitted to the local research ethics committee.	additional work is not performed until that ethical approval is in place.	
The research tissue culture incubator has been recently repaired and has not been validated, albeit this is not a breach of the centre's research licence conditions.	It is suggested that the research tissue culture incubator is validated before use in research experiments	The incubator was seen to have been validated, by temperature monitoring, and serviced as required. No further actions are necessary
The patient information states that withdrawal of consent can be made at any time up to egg collection without it affecting future treatment and 'You must ensure that this has been documented and signed by a member of staff'. It does not state the contact details for a named individual through whom this can be achieved, just that it can be discussed with any member of staff.	The inspectorate consider the patient information is compliant with research licence conditions, but suggest that the information also provides contact details for a named individual through whom withdrawal of consent can be achieved, as well as stating that it can be discussed with any member of staff.	The PR and research recruiter/consenter discuss variation and withdrawal of consent with all patients. Patients are advised that they should contact the PR or the research recruiter/consenter if they wish to vary or withdraw their research consent and are shown the contact details for the PR in the patient information. These discussion points are included in the consenting checklist. No further actions are needed

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	PR Response	Executive Review
The licence renewal application in 2009 applied to extend the research activities to include in vitro maturation of immature oocytes, culture of embryos for up to 7 days and aneuploidy screening of cultured research embryos. The inspection team in 2009 recommended that the PR obtain LREC approval for these changes to the research project. At this inspection it was found that LREC approval has still not been obtained for the extended research activities and revised patient information and consent forms.	The PR should ensure that LREC approval is sought for the extended research activities and revised patient information and consent forms by 12 October 2011. The PR must continue to comply with the additional condition on the centre's licence: 'That no research must be performed until appropriate ethics committee approval is in place and evidence of this has been provided to the HFEA executive.'	We are currently expecting a PhD student to start research on this project in October 2011 and are preparing the revised ethical submission for this work. Evidence of the approval will be provided to the HFE	
The PR returned the annual 'Research information and data sheet' for 2010, after the required date for submission stated in General Directions 0002.	The PR should ensure that the annual 'Research data and information sheet' is submitted to the HFEA by 31 January of the following year.	agreed	

Additional information from the Person Responsible

Research Licence Committee Meeting

18 November 2009
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 2

Research Project RO173: Human Gamete Activation, Interaction and Signalling (0209) (0119)
Research Licence Renewal Inspection Report

Members of the Committee:	In Attendance:
Emily Jackson, Lay Member – Chair	Joanne Anton – Minute taker
Richard Harries, Lay Member	Maria Cesay - Observer
Neva Haites, Professor of Medical Genetics, University of Aberdeen	Providing Legal Advice to the Committee: Graham Miles, Morgan Cole

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

The following papers were considered by the Committee:

- Inspection report
- Anonymised peer review
- Renewal application form
- Email for PR submitting the renewal application form
- CV for the new Licence Holder – Dr Sarah Connor
- Licence Committee minutes initially for project R0160 on 25th November 2005, then for the same project, renumbered to R0173, on 16th September 2008
- Publications x 2
- no papers were tabled.

1. The Committee noted the inspection report findings and the Person Responsible's response, as appended at page 31 of the inspection report. The Committee noted the Person Responsible's intention to revise their incident reporting SOP to reflect that this should now be undertaken via email. The Committee also noted that if approval is granted for the additional growing of embryos on through to blastocyst; that the Person Responsible will immediately apply for ethical approval with appropriate information. The Committee also noted that since the date of inspection all fire-damaged chemicals and materials have been disposed of and have been replaced.

2. The Committee noted the following 3 suggestions for best practice as outlined in the inspection report which have not yet been addressed by the Person Responsible:

- The personnel records for the Research Associate were reviewed. Evidence of induction activities and training were observed, however it was noted that the worker had not undergone the hospital trust induction course. It is suggested that the Research Associate undergo this course to facilitate his ability to perform effectively in the hospital environment.
- It is suggested that the research tissue culture incubator in Centre 0209 is validated before use in research experiments
- The patient information clearly states that withdrawal of consent can be made at any time up to egg collection without it affecting future treatment. It is suggested that the patient information sheet provides contact details for a named individual through whom this can be achieved, as well as stating that patient information can be discussed with any member of staff.

The Committee's Decision

3. The Committee applied the licensing decision tree in consideration of the application.

4. The Committee identified the activities to be authorised by the licence as the storage of oocytes; the storage of oocytes in ovarian tissue; the creation of embryos for use in research and the use of donated embryos in research. The Committee agreed that they were satisfied that these activities are not prohibited under the Human Fertilisation and Embryology Act 1990 (as amended).

5. In considering stage 18(a) of the decision tree which requires that the activity is necessary and desirable for the purposes specified in paragraph 3A(2) of Schedule 2 to the Act, the Committee considered the purpose of the research project in relation to these requirements.

6. The Committee agreed that the activities are necessary or desirable for the following specified purposes:

- Promoting advances in the treatment of infertility *Human Fertilisation and Embryology Act 1990, as amended Sch 2 3A (2)(d))*
- Increasing knowledge about the causes of miscarriages *Human Fertilisation and Embryology Act 1990, as amended Sch 2 3A (2)(e)*
- Developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation *Human Fertilisation and Embryology Act 1990as amended Sch 2 3A (2)(g)*

- to increase knowledge about the development of embryos
  Human Fertilisation and Embryology Act 1990 , as amended Sch 2 3A2(h)

7. The Committee agreed that the proposed use of human embryos is necessary for the purposes of the research in order to test the downstream effects of specific oocyte and sperm activation protocols on subsequent embryo viability.

8. The Committee noted that the applicant has not provided evidence of ethics committee approval, as required by Stage 18g(i) of the licensing decision tree.

9. The Committee decided to grant a 3 year licence subject to an additional licence condition: that no research must be performed until appropriate ethics committee approval is in place and evidence of this has been provided to the HFEA executive.

Signed..... Date 9.12.09
Emily Jackson (Chair)

HFEA Executive Licence Panel Meeting
24 June 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 4

Centre 0119 (R0172) (Birmingham Women's Hospital) – Interim Inspection Report (Research)

Members of the Panel: Mark Bennett, Director of Finance & Facilities (Chair) Nick Jones, Director of Compliance Juliet Tizzard, Head of Policy	Committee Secretary: Joanne McAlpine

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that this centre is a research centre and has held a licence since 2004.

2. The Panel noted that the research premises comprise the clinical embryology laboratory in the Assisted Conception Unit (ACU), Birmingham Women's Hospital and another laboratory within the ACU which is allocated to the University of Birmingham.

3. The Panel noted that the research project was first licensed from January 2006 and was allocated two project numbers R0172 at this centre and R0173 based at the Institute of Biomedical Research (centre 0209).

4. The Panel noted that this research project was last inspected for renewal on 19 August 2009 and the licence was renewed by the Research Licence Committee (RLC) on 18 November 2009, for two years.

5. The Panel noted that, at the time of the inspection, there were two areas identified by the Inspectorate that require improvement, concerning the submission to the HFEA of the annual 'Research information and data sheet' and ethical approval for the project from the Local Research Ethics Committee (LREC).

6. The Panel noted that an additional condition was placed on the licence by the RLC on 18 November 2009, 'that no research must be performed until appropriate ethics committee approval is in place and evidence has been provided to the HFEA Executive'. The Panel noted that the Inspectorate considers it appropriate that this condition remains in place as this requirement has not yet been met.

7. The Panel noted that that the Person Responsible (PR) has taken steps to obtain (LREC) approval and urged him to continue to do so, before the condition becomes urgent or restrictive.

8. The Panel noted that the PR is a Senior Lecturer at the University of Birmingham, with many years of research experience.

9. The Panel noted the Inspectorate's recommendation to continuation of the centre's licence with no additional conditions, and that the current additional condition should remain.

Decision

10. The Panel noted the evidence before it, and agreed to continue the centre's licence with the current additional condition and no new additional conditions. The Panel agreed to the Inspectorate's recommendations and associated timescales, particularly timely submission of the annual return (even if 'nil').

Signed: Date: 6 July 2011
Mark Bennett (Chair)