Research Renewal Inspection Report

Date of Inspection: 20 March 2012
Purpose of inspection: Renewal of Research Licence
Length of inspection: 4 hours
Inspectors: Vicki Lamb
Janet Kirkland

Inspection details:
The report covers the pre-inspection analysis, the visit and information received between 23 November 2010 and 3 July 2012.

Date of Research Licence Committee: 17 July 2012

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
Person Responsible	Dr Dusko Ilic
Licence Holder	Mr Yacoub 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 2009

Licence expiry date	31 August 2012
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 licence renewal 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 Research Licence Committee which makes the decision about the centre's licence renewal application.

Report to Research Licence Committee

Brief description of the centre and its licensing history:
Guy's Hospital has held this HFEA research licence since July 1994.

The licence was last renewed in May 2009. The centre was last inspected on 23 November 2010 and the Research Licence Committee agreed to the continuation of the research licence.

The Executive Licensing Panel agreed to a change of Person Responsible (PR) in April 2011, due to the retirement of the previous PR. The current PR has completed the HFEA Research PR Entry Programme.

Variation to Licence:
The current research licence was approved for several defined research purposes, one of which was 'developing treatments for serious diseases or other serious medical conditions'. In the licence renewal application, the PR has not included this research purpose to be licensed during the new licence period as the research project is no longer aimed at developing such treatments

Title of research project:
Improving methods for pre-implantation genetic diagnosis of inherited genetic disease and predicting embryo quality

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 conclude that:

- the PR is suitable and has discharged his duty under section 17 of the HF&E Act 1990 (as amended)
- the premises are suitable
- the practices are suitable
- the centre has submitted appropriately completed documentation in application for renewal of their licence
- the centre has submitted fees to the HFEA in accordance with requirements

The Research Licence Committee is asked to note that at the time of the inspection there were no areas of practice that required improvement.

The activities to be licensed are:

- creation of embryos in vitro
- keeping embryos
- storage of embryos
- use of embryos

None of the proposed activities are prohibited by the HF&E Act 1990 (as amended).

The use of embryos for research is necessary or desirable for the following purposes. This research project has been licensed previously for all these purposes and the research has not changed significantly since the last licence renewal.

- increasing knowledge about serious disease or other serious medical conditions
  Human Fertilisation and Embryology Act 1990 (as amended) Schedule 2 s3A(2)(a)

The reason for this, as stated by the PR, is: Investigation of the epigenetics of early embryos to understand the relationship between IVF processes and imprinting abnormalities leading to diseases such as Angelman syndrome, Beckwith- Wiedemann syndrome and Russell-Silver syndrome.

The peer reviewer stated: The proposed research does not address this purpose.

- 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 s3A(2)(c)

The reason for this, as stated by the PR, is: Understanding how genomic imbalances and mitochondrial DNA mutations modify phenotypic effects of congenital disease.

The peer reviewer stated: The proposed research described does not address this purpose but seeks to develop PGD for mitochondrial disorders.

- promoting advances in the treatment of infertility
  Human Fertilisation and Embryology Act 1990 (as amended) Schedule 2 s3A(2)(d)

The reason for this, as stated by the PR, is: For assessing efficacy of embryo vitrification procedure.

The peer reviewer stated: Assessing efficacy of embryo vitrification is said to address this purpose but is not described in the research proposed.

- increasing knowledge about the causes of miscarriage
  Human Fertilisation and Embryology Act 1990 (as amended) Schedule 2 s3A(2)(e)

The reason for this, as stated by the PR, is: Use of embryoscopy to correlate early embryo development with implantation and pregnancy loss.

The peer reviewer made no comment about this purpose.

- developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation
  Human Fertilisation and Embryology Act 1990 (as amended) Schedule 2 s3A(2)(g)

The reason for this, as stated by the PR, is: Developing new PGD methodology for detecting genetic abnormalities, particularly for de novo mutation carriers and couples where family members are unavailable or uninformative.

The peer reviewer stated: Research proposed will begin to develop methods of diagnosing mitochondrial disorders in embryos and will also develop molecular methods for the diagnosis of chromosomal translocations and haplotype determination from polar body analysis.

- increasing knowledge about the development of embryos
  Human Fertilisation and Embryology Act 1990 (as amended) Schedule 2 s3A(2)(h)

The reason for this, as stated by the PR, is: Using single cells from disaggregated embryos to study individual cell fate during development to blastocyst.

The peer reviewer stated: Novel methods of evaluation of the status of mitochondrial mutations will be developed and PCR based methods will be developed to detect unbalanced products of translocation and specific haplotypes from polar bodies.

The use of human embryos is necessary because this research is concerned with the work up of PGD testing as well as investigating whether the genetic make up of human embryos is the same in both the trophectoderm and inner cell mass. The peer reviewer confirms that since human diseases are being targeted human embryos must be used.

The patient information and consent forms meet the statutory requirements.

Recommendation to the Research Licence Committee:

The inspection team considers that overall there is sufficient information available to recommend the renewal of this centre's licence for a period of 3 years without additional conditions. In making this recommendation it is noted that there were no recommendations to the PR made in this inspection report.

The inspection team note that if the research licence is renewed, 'developing treatments for serious diseases or other serious medical conditions' will no longer be a defined purpose of the research project.

Summary of project

Lay summary of the research project:

Preimplantation genetic diagnosis (PGD) is a reproductive option for couples at substantial risk of conceiving a pregnancy affected with a known genetic disease who wish to avoid the emotional burden associated with an affected child, termination of pregnancy or recurrent miscarriages. PGD has been offered as a service at Guy's and St Thomas' for over ten years, and it is now the busiest and most successful unit in the country.

For single gene diseases, one cell is removed from a 3-day old embryo and tested for the mutation. A separate PGD test has to be developed for every different mutation, requiring substantial resources not always available in state-run medicine. In addition, these tests are technically difficult and very sensitive to contamination with non-embryo DNA.

The centre intends to work over the next three years, further developing this approach for a wider range of genetic disorders. Their 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 PGD and IVF couples.

Objectives of the research:

To continue to improve PGD and IVF programmes by introducing and developing better strategies and protocols for embryo culture and testing. Also to understand more about the biology and genetics of early human embryos.

Lay summary of the research undertaken since the last inspection on 23 November 2010:

Work last year concentrated on developing and improving methodologies for culturing and testing early embryos.

1. To improve the accuracy of PGD and to estimate reliability of those diagnoses staff have:

a. Used DNA extracted from research embryos using different commercial kits as they have become available, to see if these new kits provide better quality DNA for our diagnostic tests. To date, no kits have been identified which provide improved performance over the existing kits.

b. Trialled the collection of biopsied cells from research embryos into different collection media. One such medium was found to improve DNA amplification efficiency, and this new medium is now in routine use for PGD cycles at the centre. Another benefit of this new medium is that it will allow the stable storage of biopsied material for longer periods, potentially allowing batching of testing and reduced test errors due to DNA degradation.

c. Current methodology for PGD for chromosome rearrangements uses fluorescent probes to count chromosome segments in biopsied cells. This technique has an error rate associated with the difficulty of interpreting fluorescent signals by microscopic

visualisation. Staff are therefore developing a new approach, based on testing for specific DNA sequences on the rearranged chromosomes. They have used research embryos to test and validate this new approach, by comparing the sequences in the research embryos with sequences from blood samples from consenting couples.
This work is still in progress, and will continue in the next licence period. When complete, they hope to incorporate this new approach into existing work streams to allow more efficient and accurate diagnosis.

2. In order to develop accurate PGD for mitochondrial diseases, researchers initiated the following preliminary pilot studies:
a. Absolute quantification of mitochondrial content in embryos at different developmental stages.
b. Differences in mitochondrial quality and extent of heteroplasmy between blastomeres of the same embryo.
c. The effect of cryopreservation on mtDNA integrity and function.
This work will continue using various stages of human embryos.

3. Blastocysts for transfer or cryopreservation following embryo biopsy for PGD or during routine IVF are selected on the basis of morphological criteria. However, other than outcome following transfer, there has been little attempt to assess developmental potential other than by estimates of efficiency for stem cell derivation. By examining embryos deemed unsuitable for freezing, and hence would be discarded, using fluorescent staining techniques the researchers have been continuously refining selection criteria enabling more embryos to be frozen for patient use.

Peer review comments:
The peer review regarding the renewal application provided an opinion that it was appropriate to carry out the proposed research.

The peer reviewer provided statements, as detailed above in the ‘Summary for licensing decision’, in relation to the project addressing the statutory purposes (as defined in Schedule 2 3A (2) to the HF&E Act 1990 (as amended)) specified in the renewal application.

Regarding the work so far undertaken, the peer reviewer reported: Research to date has mainly concentrated on improving basic methods for the efficient application of PGD to an increasing number of disorders.

Regarding the use of embryos on the project and whether it was justified, the peer reviewer stated: Since human diseases are being targeted human embryos must be used.

The peer reviewer considered that the number of embryos already used in the project and the number proposed to be used in the project is justified.

Regarding how the use of human embryos in the proposed research project would address the stated purposes of the research, the peer reviewer stated: Embryos will be used to develop basic methods to enable PGD to be offered for mitochondrial disorders. Results obtained from molecular analysis in cases of translocations will be compared with those obtained by standard FISH methodology.

Regarding how the objectives of the research project would address the stated purposes of the research, the peer reviewer stated: Since diagnosis of mitochondrial disorders in human embryos is technically very difficult it is first necessary to carry out the proposed basic research. Molecular approaches to the PGD of translocations need to be validated by comparison with results from standard methods.

Donation and use of embryos:

In the period from 1 January 2011 to 31 December 2011 the centre reported the use of 86 fresh embryos and 146 frozen embryos. The figures for frozen embryos are in line with the centre's anticipated usage of 150 embryos. The figures for fresh embryos are slightly less than the centre's anticipated usage of 150 embryos. This was due to the donation of slightly fewer embryos than anticipated, but useful progress with the project was still made.

The PR estimates that 150 fresh embryos and 150 frozen embryos will be used each year over the next three years.

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 received ethics committee approval in May 1993. More recently, a progress report was submitted to the ethics committee in August 2011, and continued approval for the research was confirmed. Evidence of this has been provided to the executive.

In the opinion of the inspection team, the PR has provided appropriate justifications that the activities to be licensed are necessary or desirable for the statutory purposes.

The peer reviewer for this renewal application agreed that the use of human embryos is necessary and justified for the proposed research and that the same results could not be obtained using another method. The peer reviewer also agreed that the proposed number of embryos to be used in the research project is justified.

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.

There is appropriate recording of the use of embryos in research. The form recording the fate of every embryo used for research was seen by the inspection team. This form includes the witnessing step to confirm the identity of the embryos has been checked and that the gamete providers have given written informed consent for use of their embryos in research (SLC R18). Five records were reviewed during the inspection and all five demonstrated appropriate recording of the fates of the embryos.

All embryos used in this research project are uniquely labelled and are traceable throughout the research (SLC R26). Evidence of this was provided to the inspection team.

Centre staff confirmed that embryos are witnessed by two staff members when transferred to research and evidence of this was seen on inspection. Embryos obtained for research cannot be used for any other purpose (SLC R23).

Embryos for use in this research project are only received from HFEA licenced centres (SLC R33).

The centre has a documented procedure for ensuring that embryos are not allowed to develop beyond 14 days post-fertilisation (SLC R28). An audit of a sample of laboratory records performed during the inspection confirmed compliance with this requirement.

The inspection team considered the premises to be suitable for the licensed research activities (SLC R8a and R10). The premises were seen to have appropriate security measures, appropriate equipment, including monitoring and personal protective equipment, and appeared adequately resourced. Staff confirmed that records are kept securely and no evidence to the contrary was observed during the inspection.

Equipment used for research is appropriately maintained and serviced and evidence of this was provided to the inspection team. The incubators had all been validated.

What they could do better.

Nothing noted

Give prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions and ensure they have provided all relevant consents before carrying out any licensed activity (Guidance note 4)

What the centre does well.

Frozen embryos that are no longer required by patients for treatment purposes may be donated to this research project. Patients are contacted as part of the donating centres' bring-forward systems prior to the expiry of the embryos' consented storage period. The "decision form" sent to these patients gives the option to either extend storage for treatment (where possible), allow to perish or donate to research. If patients choose to donate to the project, the research co-ordinator for centre 0102 sends them the specific patient information and consent form related to this project. She speaks to the patients about the research, answers any questions and ensures the consent forms are completed. Fresh embryos are only obtained from centre 0102. The PR confirmed that the time between the patients receiving information about the research and being asked to give consent to the use of fresh embryos in research is generally between two and eight weeks.

The research co-ordinator travels to the donating centres when the embryos are being transferred to research to compare the patient signatures in the records held at the donating centre and those on the consent to research. Two members of staff at centre 0102 witness the receipt of the research embryos.

Information for patients considering donating embryos to this research project was provided to the inspection team. This contained information on:

- the nature of the research project;
- that the decision whether to donate will not affect their treatment in any way;

- that they can vary or withdraw the term of their consent until the point the embryos are used in the project of research;
- whether the embryos will be reversibly or irreversibly anonymised, and the implications of this;
- whether any information will be fed back to them;
- how the research is funded.

The patient information was considered to be compliant with SLC R19.

Patients who donate embryos to this research project receive no financial or other benefit, and this is made clear in patient information (SLC R24).

There is a research co-ordinator who is able to discuss the research with patients considering whether to donate their embryos to this research project (SLC R21 and R22). The patients are also able to discuss donating embryos to research with a counsellor.

Five records were reviewed at inspection and all five demonstrated that appropriate consent for use in research had been provided by all gamete providers and all embryos stored for use in this research project were within their consented storage period (SLC R18, R36 and R39).

The PR and research staff stated that embryos will only be used in the licensed project and would not be provided to other researchers for other purposes, to ensure that embryos will be used in accordance with the research donors' consents, as required by Schedule 3 to the HF&E Act (1990) as amended.

What they could do better.

Nothing noted

Conduct all licensed activities with regard for the regulatory framework governing treatment and research involving gametes or embryos within the UK, including:
maintaining up-to-date awareness and understanding of legal obligations, responding promptly to requests for information and documents from the HFEA, co-operating fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare
(Guidance note 2, 12, 16, 17, 19, 23, 24, 27, 28)

What the centre does well.

The inspection team were satisfied that research activities are carried out only on the premises specified on the licence and under the supervision of the PR (SLC R1). Additionally, the inspection team were satisfied that only the activities specified on the licence are undertaken at the centre (SLC R5).

Information requested in support of the renewal application was provided to the Executive in a timely manner (SLC R3 and R8e), and all members of the research team co-operated fully with the inspection (SLC R2 and R8b).

Research information and data sheets for this research licence have been submitted to the Authority by 31 January each year, as required by General Directions 0002 (SLC R8d and R14).

The fee has been paid for the renewal of the licence (SLC R8c).

Records provided to the inspection team were seen to be well maintained and contained all relevant information (SLC R13 and R15).

There is a procedure for separating research and clinical work. Only one member of research staff is also involved in clinical work. This member of staff explained that she is not involved with the same patients for both treatment and research purposes. Therefore there is a separation of her treatment and research duties (SLC R27).

The training file of one member of the team was seen. Training and competence assessments had been signed off. All research staff have a formal induction prior to starting work on the research and annual competency training is undertaken. Standard operating procedures are in place and staff sign them to confirm they have read and understood them.

Staff are aware of the requirement to report to the HFEA and investigate serious adverse incidents (SLC R40).

What they could do better.

Nothing noted

Changes / improvements since the last inspection on 23 November 2010:

Area for improvement	Action required	Action taken as evidenced during this inspection
None required		

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

Other areas of practice that require 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	PR Response	Executive Review
None			

Additional information from the Person Responsible

HFEA Research Licence Committee Meeting

17 July 2012

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

Minutes – Item 1

Centre 0102 (Guys Hospital) - Renewal Inspection Report for Research Project R0075

Members of the Committee:	Committee Secretary:
Emily Jackson (lay) – Chair Andy Greenfield (Professional) Sally Cheshire (lay)	Joanne McAlpine Legal Adviser: Juliet Oliver, Field Fisher Waterhouse LLP

Declarations of Interest: 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:

- Renewal Research Inspection report, 20 March 2012
- Renewal Application form
- Anonymised Peer Review form
- Publications arising from the research
- ELP minutes 1 April 2011, variation to change the Person Responsible
- ELP minutes 18 February 2011, interim inspection report

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 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 Directions 0000 – 0012

- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Background

1. Centre 0102 received its first research licence for research project R0075 'Improving methods for preimplantation genetic diagnosis of inherited genetic disease and predicting embryo quality' in July 1994.

Consideration

2. A Research Licence Committee last renewed the centre's licence in May 2009.

3. The Committee noted that at the time of the renewal inspection, there were no areas of practice that had been identified by the inspectorate that required improvement.

Decision

4. The Committee had regard to its Decision Tree. The Committee was satisfied that the application was submitted in the form required, and contained the supporting information required by General Direction 0008. Furthermore, it was satisfied that the appropriate fee had been paid. The Committee noted that the application was made by the proposed Person Responsible ("PR") for Research.

5. The Committee was satisfied that the PR possesses the required qualifications and experience and that the character of the PR is such as is required for supervision of the licensed activities. It was further satisfied that the PR will discharge his duties under section 17 of the Act. The Committee noted that the Inspector was satisfied the PR had satisfactorily completed the PR entry programme and is suitably qualified and experienced to undertake the role.

6. The Committee was satisfied that the premises to be licensed are suitable for the conduct of licensed activities as the Inspector confirmed that the premises were suitable and secure.

7. The Committee was satisfied that the licence application involved the authorisation of activities for the purpose of research.

8. The Committee was satisfied that the renewed licence would not apply to more than one project and that the activities to be licensed, none of which

are prohibited under the Act, are: ‘creation of embryos in vitro’, ‘keeping embryos’, ‘storage of embryos’ and ‘the use of embryos for research’.

9. The Committee noted the Peer Reviewer’s support for the application and was satisfied that the activities to be licensed are necessary or desirable for the following purposes, specified in Schedule 2 paragraph 3A(2) to the Act, for the following reasons:

    - *Increasing knowledge about serious disease or other serious medical conditions* (Schedule 2 paragraph 3A(2)(a) to the Act): The reason for this is: The research investigates the epigenetics of early embryos in order to understand the relationship between IVF processes and imprinting abnormalities leading to diseases such as Angleman syndrome, Beckwith–Wiedemann syndrome and Russell-Silver syndrome. Further, this is a wide-ranging study which includes, but is not limited to, the transmission of defective mitochondrial genomes and their detection, which is likely to increase knowledge about serious disease.
    - *Increasing knowledge about the causes of any congenital disease or congenital medical condition that does not fall within paragraph (a) (Schedule 2 paragraph 3A(2)(c) to the Act): The reason for this is:* Researchers aim to categorise chromosome abnormalities that occur simultaneously in different regions of the gene. The interaction between these lends itself to an understanding of how genomic imbalances and mitochondrial DNA mutations modify phenotypic effects or congenital disease. Researchers aims to categorise chromosome abnormalities that occur simultaneously at different locations of the genome and examine interactions that may affect phenotypic expression
    - *Promoting advances in the treatment of infertility* (Schedule 2 paragraph 3A(2)(d) to the Act): The reason for this is: As part of this project, evidence of efficacy of embryo vitrification is likely to emerge.
    - *Increasing knowledge about the causes if miscarriage* (Schedule 2 paragraph 3A(2)(e) to the Act): The reason for this is: Investigating the early development of embryos from women with recurrent miscarriage would permit a correlation to be made between early embryo development and implantation and pregnancy loss.
    - *Developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation* (Schedule 2 paragraph 3A(2)(g) to the Act): The reason for this is: The research proposed will begin to develop methods of diagnosing mitochondrial disorders in embryos and will also develop molecular methods for the diagnosis of chromosomal translocations and haplotype determination from polar body analysis.
    - *Increasing knowledge about the development of embryos (Schedule 2 paragraph 3A(2)(h) to the Act):* The reason for this is: The research uses single cells from disaggregated embryos to study individual cell fate during development of embryos.

10. The Committee was satisfied that the proposed use of embryos does not involve mixing sperm with the egg of an animal. It was satisfied that the use of human embryos is necessary because the research is investigating the genetic make up of early human embryos. Since human diseases are being targeted, human embryos must be used.

11. The Committee was satisfied that the inspector had previously seen the patient information and consent forms, and that these met the statutory requirements.

12. The Committee was satisfied that the research project had received the necessary approval from the Research Ethics Committee.

13. The Committee noted the recommendation from the Inspectorate to renew the centre's research licence for a period of 3 years without additional conditions. The Committee also noted that 'developing treatments for serious diseases or other serious medical conditions' will no longer be a defined purpose of the project.

Decision

14. The Committee agreed to renew the research licence for project (R0075) for a period of three years with no additional conditions.

Signed: Date: 25/7/2012

Emily Jackson (Chair)