Research Renewal Inspection Report

Date of Inspection: 23 November 2010
Length of inspection: 7 hours
Inspectors: Vicki Lamb (Lead, HFEA)
Bhavna Mehta (Support inspector, HFEA)
Terence Dourado (Observer, HFEA)

Inspection details:
The report covers the pre-inspection analysis, the visit and information received between March 2009 and the date of the Licence Committee.

Date of Licence Committee: proposed date 22 March 2011

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 HF&E Act 1990 (as amended), the Code of Practice, licence conditions and directions and that progress is made towards achieving the stated aims of the project.

The report is used to summarise 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 Licence Committee which makes the decision about the centre's licence renewal application.

Centre details

Project Title	Developing criteria for estimating quality of stem cells derived from human embryos
Centre Name	Guys Hospital
Centre Number	0102
Research licence Number	R0133
Centre Address	Stem Cell and Embryology Research Laboratories Assisted Conception Unit 11th Floor Tower Wing Guy's Hospital London, SE1 9RT
Person Responsible	Professor Peter Braude

Licence Holder	Mr Yacoub Khalaf
Treatment centres donating to this research project	Salisbury Fertility Centre (0197) Chelsea and Westminster Hospital (0158) Herts and Essex Fertility Centre (0030) Lister Fertility Clinic (0006) Sussex Downs Fertility Centre (0015) South East Fertility Clinic (0208) BMI Chelsfield Park ACU (0086) The Woking Nuffield Hospital (0144)
Date Licence Issued	1 May 2008
Licence expiry date	30 April 2011
Additional conditions applied to this licence	None

Contents

Report to Research Licence Committee

Brief description of the centre and its licensing history:

Guy's Hospital has held this HFEA research licence since April 2002.

The centre was last inspected on 26 February 2009 and a Research Licence Committee agreed to the continuation of the research licence in May 2009.

A new research facility has been built on the 11th floor of the Tower Wing, Guy's Hospital. The new premises were inspected on 5 June 2008 and the licence varied to reflect the new address of the premises on 18 June 2008. The new research facility comprises of two dedicated research laboratories situated within the new assisted conception unit. New equipment has also been purchased for use in the new laboratories.

The Person Responsible (PR) is a consultant who has completed the HFEA PR Entry Programme.

The PR recently applied to change the title and lay summary of the project. This application was presented to the Executive Licence Panel on 20 October 2010, and was approved.

Title of research project:

Developing criteria for estimating quality of stem cells derived from human embryos

Summary for licensing decision:

In considering overall compliance, the executive 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 and secure
- the practices are suitable
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, in application for renewal of their licence
- the centre has submitted fees to the HFEA in accordance with requirements

Activities to be licensed

The activities to be licensed are:

- Use of embryos for research
- Storage of embryos
- Creation of embryos in vitro
- Derivation of human embryonic stem cell lines

The above activities have been licensed previously.
None of these 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:

- increasing knowledge about the development of embryos

  HFE Act 1990 (as amended) Schedule 2 3A(2)(h)
- increasing knowledge about serious disease

  HFE Act 1990 (as amended) Schedule 2 3A(2)(a)
- enabling any such knowledge to be applied in developing treatments for serious disease

  HFE Act 1990 (as amended) Schedule 2 3A(2)(b)

These purposes have been licensed previously.

The applicant has also proposed this research be licensed for the following purposes to better reflect the research being undertaken. The reasons for adding each purpose is also briefly explained:

- Increasing knowledge about the causes of congenital disease or congenital medical conditions

  HFE Act 1990 (as amended) Schedule 2 3A(2)(c)

  This is because investigating congenital disease is integral to their research of understanding more about serious genetic and mitochondrial diseases.
- Promoting advances in the treatment of infertility

  HFE Act 1990 (as amended) Schedule 2 3A(2)(d)

  Information on this may be obtained in the course of the research, as some embryos unsuitable for transfer involve infertility as a result specifically of the genetic condition being screened for.
- Developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation

  HFE Act 1990 (as amended) Schedule 2 3A(2)(g)

  Information on this, particularly mitochondrion abnormalities, may be obtained through the research on culturing in different oxygen concentrations. Also, comparing the genetic constitution of inner cell mass isolated for stem cell research and trophectoderm cells will provide information on the consistency of findings between the two types of tissues and thus establish the validity of genetic tests made at the blastocyst stage.

Patient information and consent forms

The supplied patient information and consent forms meet the statutory requirements.

Recommendation to the Research Licence Committee:

The inspector considers that overall there is sufficient information available to recommend the renewal of this research licence for a period of 3 years without additional conditions. The inspector also recommends that the licence is varied to add the new research purposes:

- Increasing knowledge about the causes of congenital disease or congenital medical conditions

  HFE Act 1990 (as amended) Schedule 2 3A(2)(c)
- Promoting advances in the treatment of infertility

  HFE Act 1990 (as amended) Schedule 2 3A(2)(d)
- Developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation

  HFE Act 1990 (as amended) Schedule 2 3A(2)(g)

Details of inspection findings

Lay summary of the research project:

Stem cells are unique cell populations that are able to copy themselves exactly and also specialise into new cell types. The most powerful human stem cells can be isolated from the earliest stages of human development and they are termed human embryonic stem cells (hESC). These cells have great potential in regenerative medicine because they can be guided to form various more specialised cell types which then may be of use in treating serious debilitating diseases such as diabetes, or to repair organs following stroke or heart attacks. Another valuable use of these cells is in studying disease progression as well as in the search for new drugs for treatment of serious illnesses.

Although there has been a lot of hype about stem cells, their potential is not yet fully realised. Firstly, methods to generate the cells in a reliable and safe way have to be established. Secondly, the characteristics of the cells have to be precisely defined, which has not yet been achieved - scientists have not been able to fully track and understand changes happening during manipulation of the cells. In this work, we are aiming to use the most advanced technologies to address these uncertainties. We wish to define norms and standardise protocols that would assure quality and reliability of these cells.

We plan to accurately analyse how the cells copy themselves and what factors make this process more successful, such as the position of each cell in a population or the addition of external supplements. This understanding will enable us to improve the methods we use to grow the cells.

Objectives of the research:

The primary objective of the proposed research is to adapt rapid throughput technology to perform comprehensive quantitative assessments requisite for the establishment of normal and disease-specific cell line identity.

This is a cross-disciplinary biotechnology approach that has not previously been applied to the study of either human embryonic stem cells (hESC) or induced pluripotent stem cells (iPSC), and which will significantly facilitate the use of these cells by researchers in academia and particularly by end-users in industry and the commercial sector.

Human embryonic stem cells not only differ from animal derived stem cells, but they also seem to be dissimilar from induced pluripotent cells (adult cells) which have recently received a lot of attention. Furthermore and most importantly, human cell lines may differ from each other, and individual clones derived from any one inner cell mass may also differ significantly. This requires specifically the use of human embryos if we are to understand the origin of this variation in human stem cells, and will need to use embryonic stem cells that have features

that can be well characterised. We will begin with the studies focusing on Huntington's and Von Hippel-Lindau for which we already have lines, and then to apply to lines newly derived taking into account the means of derivation (culture conditions and manipulation). If we are successful with this novel methodology and technology, its application will then be made accessible internationally to the research community and commercial sector whilst retaining the IP rights in the UK.
To achieve this objective we propose to:

- Optimise protocols for array comparative genomic hybridization to be able to identify chromosomal imbalance and submicroscopic copy number variants in hESC and iPSC.
- Develop methods for using automated fluorescence microscopy combined with single cell image analysis to quantitatively assess self-renewal capability.
- Generate robust protocols to use dynamic array integrated fluidic platforms to determine differentiation propensity.

This biotechnological approach will result in the UK Stem Cell Bank (UKSCB) being supplied with lines with detailed and robust characterisation, which will facilitate and accelerate the banking process, accelerating the rate at which cells can be made available to end users. In addition, as the complete cell line identity profile will be made available with the cells through the UKSCB, the end users will be able to select the most appropriate line for their application, thus improving efficiency and streamlining the route to manufacturing therapeutics.

Lay summary of the research undertaken since the last inspection on 26 February 2009:

Continued improvement to the manipulation techniques and culture conditions for derivation of human embryonic stem cells has resulted in a success rate of 40-50% for fresh embryos and 30-35% for cryopreserved-thawed embryos. We have now derived 21 lines, with a further line at early passage of which 11 carry clinically relevant genetic mutations including cystic fibrosis, Huntington disease, myotonic dystrophy and von Hippel-Lindau Syndrome. To achieve this we have used 37 embryos after PGD and a further 19 frozen embryos received from collaborating units.

Significant progress has been made towards the objective of GMP derivation. Our validation master plan is in final draft form and being checked, reviewed and approved by our Quality Manager and external contractors. The framework, paperwork and record systems required by the HTA are nearing completion. This should enable sufficient time to allow us to meet our MRC objective of 5-10 clinical grade lines by the end of the grant in the first quarter of 2012.

Further work has established feeder-free culture systems, particularly for the PGD lines, as this is a prerequisite for disease modelling. Highly sensitive karyotype analysis methods have been developed in conjunction with the Genetics department, which enable a thorough characterisation of the chromosome content of the cells.

Peer review comments:

The peer reviewer considered that the proposed research project is necessary or desirable for the following purposes:

- Increasing knowledge about serious disease or other serious medical conditions
  The reason given by the peer reviewer is that the group proposes to derive ES cell lines from both normal embryos and those carrying genetic defects that will cause disease and use these lines, alongside already existing lines to study diseases such as Huntingdon's and Von Hippel-Lindau
- Developing treatments for serious disease or other serious medical conditions
  The reason given by the peer reviewer is that ES cell lines derived as part of this project will be used in differentiation studies to assess their suitability as model systems for disease modeling in defined tissues; to monitor changes during differentiation and extended culture, and ultimately, for transplantation into diseased tissues. All lines will be freely available.
- Increasing knowledge about the causes of congenital disease or congenital medical conditions
  The reason given by the peer reviewer is that ES cells derived from genetically defective embryos will be differentiated into relevant tissues, which will be used to study the progression of the disease and thereby potentially identify causative effects.
- Promoting advances in the treatment of infertility
  The reason given by the peer reviewer is that the availability of PGD enables couples at risk for specific genetic diseases to produce normal children. Also, the process of ES cell derivation requires culture and close observation of developing embryos, which has already provided useful information about assessment of embryo quality for transfer to patients.
- Developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation
  In addition to the work on ES cell derivation, this group will be using iPS cells made from somatic tissue of patients carrying specific diseases. These will provide tissue that may be used to develop novel detection methods for a broader range of diseases than presently offered.
- Increasing knowledge about the development of embryos
  In addition to monitoring embryo development during culture, this group plans to compare the genetic constitution of ICM cells compared with trophectoderm cells. This may provide information about lineage segregation and compensation for chromosomal abnormalities.

The peer reviewer agrees that the use of human embryos is necessary for this research because embryos are the only source of ES cells. Although there is now the potential to produce iPS cells from affected patients, this procedure is inefficient at present, and it is still not clear how well iPS cells lend themselves to directed differentiation into the full range of tissues that is possible from embryo-derived ES cells. Therefore, it is essential that genetically defective embryos are used to produce tissues for these studies.

The peer reviewer agrees that the number of embryos used and proposed number of embryos to be used in the research is justified.

Donation and use of embryos:

In the period from 1 January 2009 to 31 October 2010, the centre reported the use of 73 fresh embryos and 100 frozen embryos.

The PR estimates that 300 fresh embryos and 150 frozen embryos will be used over the next three years.

Regulatory principles

Focus

- **Protection of the embryo**
- **Good governance and record keeping**
- **Areas of concern** – This inspection is a renewal inspection and therefore all mandatory requirements related to this research licence were assessed for compliance.

▶ 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 (Principle 12).
What the centre does well. The research project received ethics committee approval in June 2006 for the duration of the project. A progress report was submitted to the ethics committee in May 2010, and continued approval for the research was confirmed. Evidence of this was provided to the inspection team. 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 with adult stem cells or induced pluripotent stem cells. 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. No issues identified

Have respect for the special status of the embryo when conducting licensed activities (Principle 3).

What the centre does well.

Research and training (Guidance note 22)
The centre has a documented procedure for ensuring that embryos do not develop beyond 14 days (Licence Condition R28). An audit of a sample of laboratory records performed in the course of the inspection confirmed compliance with this requirement. Evidence of this was also seen in the laboratory book.

Although the research centre is associated with a treatment centre, only two of the research staff have clinical roles. In discussion with the research staff they are aware of the need to separate their research and clinical roles.

Centre staff confirmed that embryos are witnessed by two staff members when transferred to research and evidence of this was seen on inspection. Additionally, the inspectorate saw laboratory books during the inspection that demonstrated each embryo is uniquely labelled (Licence Condition R26). Embryos obtained for research cannot be used for another purpose (Licence Condition R23), or transferred back for treatment once they have been allocated to research.

There is a facility monitoring system to record the conditions within the incubators and dewars. The laboratory cleaning rota was seen by the inspection team. Keypad locks and swipe card access were seen to be in place on doors to critical areas. Staff confirmed that records are kept securely.

What they could do better.

No issues identified

▶ Give prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions (Principle 5).
What the centre does well. **Research and training (Guidance note 22)** 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, donate to other couples for treatment or to 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 research coordinator will answer any questions that patients have in relation to the research. The centre's patient information and consent forms were reviewed at inspection and were considered to be compliant with Licence Conditions R19 and R20. The PR confirmed that the time between the patients receiving information about the research and being asked to give consent is generally between two and eight weeks.
What they could do better. No issues identified

▶ Ensure that patients and donors have provided all relevant consents before carrying out any licensed activity (Principle 6).
What the centre does well. **Research and training (Guidance note 22)** 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. The PR confirmed at inspection that he is satisfied that the consenting procedures at the donating centres are robust. A sample of five records of consent were reviewed at inspection. All consents were present and appropriately completed. There is an SOP to cover the need to check donor consents when the embryos have been created from donor gametes. The form recording the fate of every embryo used for research was seen by the inspection team, and evidence of this form being used in practice was seen during the inspection of the premises. This form includes the witnessing step to confirm the identity of the embryos has been checked and that the patient has given written informed consent. The consented storage periods for embryos in store for research were checked and all embryos were seen to be stored within their consented storage periods (Licence Condition R39).
What they could do better. No issues identified

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 (Principle 13).

What the centre does well.

Research and training (Guidance note 22)
The PR confirmed that all hESC lines derived at the centre have been deposited, or are in the process of being deposited, with the UK Stem Cell Bank (Licence Condition R30).

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.

Centre staff are aware of the requirement to report adverse incidents to the HFEA.

An organisation chart is in place for the research centre and was provided to the inspection team.

Premises and facilities (Guidance note 25)

The inspection team considered the premises to be suitable for the activities carried out (Licence Condition R10). The premises were seen to have appropriate security measures, appropriate equipment, including monitoring and personal protective equipment, and appeared adequately resourced.

The research licence was displayed at the licensed premises (Licence Condition R4).

What they could do better.

No issues identified

Changes / improvements since the last inspection on 26 February 2009:

Area for improvement	Action required	Action taken as evidenced during this inspection
Progress reports have not been submitted at six monthly intervals.	Timely submission of progress reports.	This is no longer a requirement. No action 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	Reference	Action required	Timescale for action	PR Response	Executive Review
None noted at this inspection					Email received from PR on 10 January 2011 stating: We are content with the reports.

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	Reference	Action required	Timescale for action	PR Response	Executive Review
None noted at this inspection					

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	Reference	Action required	Timescale for action	PR Response	Executive Review
None noted at this inspection					

Additional information from the Person Responsible

HFEA Research Licence Committee Meeting

22 March 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 1

Centre 0102 (Guy's Hospital) - Renewal Inspection Report for Research Project R0133

Members of the Committee:	Committee Secretary:
Clare Lewis-Jones (lay)– Chair Andy Greenfield (Professional) Neva Haites (Professional)	Terence Dourado Legal Adviser: Graham Miles, Morgan Cole

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:

- Inspection Report
- Renewal Application
- Peer Review
- Executive Licence Panel minutes: 20 October 2010
- Licence Committee minutes:
  - 20 May 2009
  - 11 March 2009
  - 18 June 2008
  - 02 April 2008

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
- Update on SCAAC recommendations concerning alternative methods for deriving human embryonic stem (hES) cells or hES-like cells

Background

1. The Centre has held a licence for research project R0133 since April 2002. In October 2010 the Executive Licensing Panel approved an application to change the title of the research project to 'Developing criteria for estimating quality of stem cells derived from human embryos'. The objective of the project is to improve the methods used to grow stem cells by 'accurately analysing how [stem] cells copy themselves and what factors make this process more successful.'

Consideration of Application

2. 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 as the Executive noted that the Centre has submitted the appropriate fees in accordance with the HFEA's requirements. The Committee noted that the application was made by the current designated Person Responsible ("PR").

3. The Committee was satisfied that the PR possesses the required qualifications and experience and that his character 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 (7th Code of Practice edition) and is suitably qualified and experienced to undertake the role. The PR has been in post for a considerable time and he has a history of compliance with the HFEA's legal and regulatory framework.

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

5. The Committee was satisfied that the licence application involved the authorisation of activities for the purpose of research, and that it did not involve the use of embryos for training purposes or the testing of embryos.

6. The Committee was satisfied that the renewed licence would not apply to more than one project and that the activities of the licence, permitted under the Act, comprise the ‘creation of embryos in vitro’; ‘use of embryos for research’; ’storage of embryos’, and; the ‘derivation of human embryonic stem cell lines’.

7. The Committee noted the Peer Reviewer’s support for the application and was satisfied that the activity to be licensed is 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 Committee considered the activity to be licensed is desirable for this purpose because the research aims to derive and use ES cell lines from normal embryos and embryos carrying genetic defects to study genetic diseases
    - *Developing treatments for serious disease or other serious medical conditions* (Schedule 2 paragraph 3A(2)(b) to the Act) ; the derived ES cell lines will be used in differentiation studies to assess their suitability as model systems for disease modelling in defined tissues; to monitor change during differentiation and extended culture, and for transplantation into diseased tissues.
    - *Increasing knowledge about the causes of congenital disease or congenital medical conditions* (Schedule 2 paragraph 3A(2)(c) to the Act)*;* ES cells derived from genetically defective embryos will be differentiated into relevant tissues, which will be used to study the progression of the disease and thereby potentially identify causative factors.
    - *Promoting advances in the treatment of infertility* (Schedule 2 paragraph 3A(2)(d) to the Act)*;* The process of ES cell derivation requires culture and close observation of developing embryos, which provides useful information about assessment of embryo quality for transfer to patients.
    - *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 research will use iPS cells made from somatic tissue of patients carrying specific diseases which may be used to develop novel detection methods for a broader range of diseases than is presently offered.
    - *Increasing knowledge about the development of embryos* (Schedule 2 paragraph 3A(2)(h) to the Act); an aim of the research is to compare the genetic constitution of inner cell mass cells with trophectoderm cells. This may provide information about lineage segregation and compensation for chromosomal abnormalities.

8. The Committee was satisfied that the proposed use of embryos is necessary because although there is now a potential to produce induced pluripotent stem cells (iPS) from affected patients, the procedure at

present is inefficient, and it is still not clear how well iPS cells lend themselves to directed differentiation into the full range of tissues that is possible from embryo-derived ES cells. Therefore, it is essential that genetically defective embryos are used to produce tissues for these studies. Furthermore, the Committee agreed with the peer review that the number of embryos used and proposed number of embryos to be used in the research is justified.

9. The Committee was satisfied that the research project had received approval from the LREC St Thomas' Hospital Ethics Committee. It also noted that the Executive have seen the patient information and consent forms, and that these met the statutory requirements.

Decision

10. As it was satisfied regarding all the requirements set out above, the Committee agreed to renew the Centre's licence for a period of three years without additional conditions. The Committee was satisfied that a three year period would be appropriate because the research project had previously been licensed, it is a well established project and the Centre has a history of good regulatory compliance.

Signed: Date:

1/4/11

Clare Lewis-Jones (Chair)