Research Licence Inspection Report

Project Title Research Licence Number Person Responsible Nominal Licensee Inspection type Licence expiry date Date Renewal fee paid	**Epigenetic Studies of Preimplantation Embryos and Derived Stem Cells** R0145 Alison Murdoch Mary Herbert **Renewal** 1 August 2006
Project Title Research licence Number Person Responsible Nominal Licensee Inspection type Licence expiry date	**Derivation of human embryonic stem cell lines using nuclear transfer and parthenogenetically activated oocytes** R0152 Alison Murdoch Mary Herbert **Progress** 31 July 2008
Project Title Research licence Number Person Responsible Nominal Licensee Inspection type Licence expiry date	**Mitochondrial DNA Disorders: Is there a way to prevent transmission?** R0153 Mary Herbert Alison Murdoch **Progress** 31 August 2008
Centre Number	0017
Centre Name	**Newcastle Fertility Centre at Life**
Centre Address	Bioscience Centre, International Centre for Life, Times Square Newcastle upon Tyne, NE1 4EP
Treatment centres donating to these research projects	0017 – Newcastle Fertility Centre at Life 0170 - Centre for Assisted Reproduction, Gateshead
Inspection date	11 May 2006
Licence Committee Date	26 July 2006
Inspector	Debra Bloor

About the Inspection:

The purpose of the inspection is to ensure that research is carried out in compliance with the HF&E Act 1990, 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 Licence Committee who makes the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

This report covers the period between 2 June 2005 and 11 May 2006.

Brief Description of the Projects

Project **R0145** entitled "**Epigenetic Studies of Preimplantation Embryos and Derived Stem Cells**" has been licensed since 2003.

The lay summary of the project is as follows:

It is now clearly established that embryonic stem cells offer great potential for the understanding of disease and possibly for future treatments. At present the technology for successfully deriving and growing embryonic stem cells (ES cells) needs to be more reliable and efficient. Furthermore, considerable changes are necessary if the cell lines are to be suitable to use in treatment rather than just for research. The aims of this project are to improve the processes of culture of embryos and derivation of ES cells to meet the European Union Tissues and Cells Directive standards.

Stem cell lines so derived will be made available to the National Stem Cell Bank for further approved studies. The embryos used for this study are those of poor quality which are not suitable for treatment. If not used for research they would otherwise be discarded according to patient's consent.

Project **R0152** entitled "**Derivation of human embryonic stem cell lines using nuclear transfer and parthenogenetically activated oocytes**" has been licensed since 2004.

The lay summary of the project is as follows:

It is recognised that human embryonic stem cells offer a great potential for therapies for many diseases such as diabetes. These stem cells are derived from embryos which are created for IVF treatment but which are not suitable for treatment. If stem cell treatments are to reach their full potential we need to derive stem cell lines which are genetically similar to the recipient so they will not be rejected. This may require the application of techniques such as nuclear transfer and parthenogenic activation. Nuclear transfer involves the transfer of genetic material from adult skin cells to eggs which have had the cell's nucleus removed. Parthenogenic activation involves an egg being artificially stimulated by chemical or electronic means in order to make the egg start embryo development. The present application is to undertake some of the initial studies that are needed to understand methods that will develop

this technology.

Project **R0153** entitled "**Mitochondrial DNA Disorders: Is there a way to prevent transmission?**" has been licensed since 2005.

The lay summary of the project is as follows:

Mitochondria are organelles that convert the food we eat into energy. There are many mitochondria in every cell of our body. Each mitochondrion has its own DNA which is separate from 'nuclear' DNA. Nuclear DNA contains genetic information in the cell which influences the make up of the whole body however, mitochondrial DNA only provides instructions on how mitochondria behave. If these genes are damaged an affected person may develop severe disease leading to disability and death. Mitochondrial genes are inherited only through the mother who may pass the disease on to her children. At present no treatment for mitochondrial diseases exists.

Previous studies in mice have shown it is possible to prevent the transmission of mitochondrial disease by moving the pronuclei (pronuclei ultimately develop into an embryo's nucleus containing the embryo's 'nuclear' DNA) from an egg containing bad mitochondria to another egg which only contains good mitochondria.

In experiments conducted on mice, eggs developed normally and non affected mice were born after the procedure. These experiments are very encouraging but there are many differences between mouse and human eggs.

We are proposing to determine if moving the pronuclei could ever be used for our patients by taking abnormally fertilised human eggs (which cannot be used for treatment) and transferring the pronuclei from one egg to another. Following this transfer we would monitor the possible carry-over of mitochondria between eggs and will determine whether the egg then develops normally.

We hope that these studies will provide vital information as to whether we could ever prevent the transmission of mitochondrial diseases from mother to child.

		R0145	R0152	R0153
Research activities	Use of donated embryos for research	✓	✓	✓
	Storage of licensed material	✓	✓	✓
	Creation of embryos in vitro		✓	✓
	Derivation of human embryonic stem cells	✓	✓	
	Cell nuclear replacement		✓	

Changes/ improvements since last inspection

The laboratories at the Centre for Life have been closed for refurbishment since January 2006 and clinical embryology work has been taking place at the Royal Victoria Infirmary (centre 0248). Clinical work has been reduced during the refurbishment and this has impacted on the availability of material for the research programmes. During the refurbishment, the altruistic donation of eggs to research has been suspended.

There have been some staff changes in the research teams.

Additional licence conditions and recommendations and actions taken by centre since last inspection

Licences R0145, R0152 and were issued without additional conditions. Licence R0153 was issued with an additional condition requiring the submission of six monthly progress reports to the HFEA.

Summary for Licence Committee

Progress has been achieved in relation to the stated aims of the research projects. All aspects of practice that were reviewed in the course of the inspection were found to be largely compliant with the requirements of the HF&E Act 1990, Code of Practice, licence conditions and directions.

A small number of issues were identified in the course of the inspection which warrant consideration and these are summarised below:

- Not all members of the research team maintain formal records of training and CPD opportunities;
- There may have been staff changes in the team of which the HFEA has not been notified;
- Minor improvements could be made to the witnessing of the transfer of material to research;
- Patient information for project R0153 could be clarified by the inclusion of information on the use of embryos in secondary research.

The persons responsible for both projects should consider the recommendations made in the report and implement any changes that are considered necessary.

The application for renewal of licence R0145 was supported by an external peer reviewer.

The inspector supports the renewal of licence R0145 and the continuance of research licences R0152 and R0153.

Proposed licence variations

None

Report of Inspection findings

1. **Organisation**

Desired Outcome: The research is well-organised and managed and complies with the requirements of the HFE Act.

Summary of findings from inspection
Evidence of:

- Leadership and management
- Staffing
- Funding

Staff

Principal investigators	Alison Murdoch, Mary Herbert
Scientists	1 clinical research associate, 1 clinical scientist, 2 research associates, 2 PhD students, 1 research assistant, 1 placement student
Research nurse (donor co-ordinator)	1
Support staff (receptionists, record managers, quality and risk managers etc)	Staff at centre 0017

Highlighted areas of firm compliance
The PR of research licences R0145 and R0152 has extensive knowledge of the regulatory requirements of the HFEA as she was previously the PR for the treatment and storage licence for centre 0017 and remains an accredited consultant at centre 0017. The PR has managed the projects since their inception. She has considerable experience in research and an extensive relevant publication history. The CV of the PR for project R0153 documents appropriate experience and publishing history. New members of the research team are provided with training and induction similar to that undertaken by members of the embryology team of centre 0017. The programme includes training in the requirements of the HFEA and Association of Clinical Embryologists (ACE) and also covers mandatory health and safety training. Not all members of the research team who met with the inspector were able to provide documented evidence of training and CPD and it was suggested that all staff maintain formal training records. One member of the research team reported receiving fire training and basic life support training in the time covered by this report and training records were made available to the inspection team. Evidence was also provided that the research nurse with responsibility for recruiting donors is registered with the Nursing and Midwifery Council and has undertaken

counselling training. She also provided evidence of having undergone a criminal records bureau screen (CRB) prior to her employment.

It is reported the projects under consideration have ongoing funding.

A brief report was submitted documenting the progress made in research undertaken under the auspices of research licences R0145 and R0152 in February 2006.

It is a condition of licence R0153 that the HFEA is provided with six monthly progress reports: this project commenced in October 2005 and a progress report was received in May 2006. The PR for licence R0153 should ensure that progress reports are submitted in accordance with the licence condition.

Issues for consideration

All staff should receive opportunities for continued professional development and mandatory health and safety training and training should be documented. Staff training records should be made available during future inspections.

The staff list and information provided in applications includes the names of a number of individuals who are not listed on the HFEA centre's database. This may indicate that HFEA has not been advised of staff changes in the research team. The persons responsible should ensure that the HFEA is advised of the names of all staff who may have access to confidential identifying information in the course of their work in compliance with the requirements of Chair's letter CH(01)08 and Section 17(2)b of the Human Fertilisation and Embryology Act 1990 (HF&E Act).

Executive recommendations for Licence Committee

None

Areas not covered in by this inspection

Organisation of the centre
Resource management
Research governance

2. Premises and equipment

Desired Outcome: The premises and equipment are safe, secure and suitable for their purpose.

Summary of findings from inspection:

- Suitability of premises

Highlighted areas of firm compliance
The research laboratories are housed within the Institute of Stem Cell Biology and Regenerative Medicine at the Centre for Life. Researchers have the exclusive use of two laboratories which are likely to be used for manipulation of viable embryos (although this was not happening at the time of the inspection) and access to shared space in a multi user laboratory. It was confirmed that no viable embryos will be manipulated in the shared laboratory.
Issues for consideration
The persons responsible should ensure that access to any laboratories where viable embryos are left unattended is controlled and limited to licensed personnel only.
Executive recommendations for Licence Committee
None
Areas not covered in by this inspection
Servicing and maintenance of equipment

3. Donation of material

Desired outcome: Donors are recruited appropriately and any research carried out on their embryos is in accordance with their consent.

Summary of findings from inspection:

- Recruitment of donors
- Ensuring prospective donors have access to further guidance
- Ensuring prospective donors have time to consider donation properly
- Donor and patient records

Highlighted areas of firm compliance
Donation is coordinated by a designated individual who is not directly involved in the patient's treatment. During the first consultation, patients are asked if they would consider donating to research and their response is documented in the patient's notes. The donor coordinator reviews the notes of all patients starting treatment and if the patients have agreed to consider research, a research information pack is inserted in the notes and this is given to patients when they attend for their first ultrasound scan. One week later, the coordinator schedules an introductory five minute appointment with patients to ask if they would agree to meet with the coordinator on the day of their scheduled egg collection On the day of egg collection (prior to the procedure) the nurse coordinator discusses the research in detail and patients complete consents if they decide to participate. This process ensures that patients have an adequate opportunity to consider their participation and to ask questions and seek further information. Patient information provides contact details for the donation coordinator and principle investigators ensuring that prospective donors can obtain further information if required. Centrally held records reviewed in the course of the inspection contained necessary information to allow tracking of individual embryos and cross reference to patient records.
Issues for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered in by this inspection
Prevention of coercion of prospective donors

4. Patient information and consents

Desired outcome: Patients are provided with appropriate information which allows them to give informed consent.

Summary of findings from inspection:

- Patient information
- Consent forms
- Patient information for projects deriving embryonic stem cells
- Consent forms for projects deriving embryonic stem cells

Highlighted areas of firm compliance
Patient information and consents largely comply with all of the requirements outlined in standard licence conditions and the 6th Code of Practice (COP).
Summary of audit of patient records
Seven sets of records from patients who donated eggs and embryos for research were reviewed. Consent forms in all of the records were present and consistent with the use of the material in research. Witnessing of the transfer of embryos to research was documented appropriately in the records of patients whose embryos had already been used in research (some embryos had been donated and not used and some were awaiting transfer to research but were still within the consented storage period). The records of two patients whose eggs were donated to research following follicular reduction did not contain documentation of the witnessing of the transfer. The Licence Committee that considered the patient information and consent forms relating to R0153 recommended three changes. The recommended changes have been implemented although the precise wording recommended by the licence committee has not been adopted.
Issues for consideration
Witnessing practices were discussed with the senior embryologist of centre 0017 and it was agreed that procedures would be reviewed to consider how the transfer of embryos or eggs to research could be more formally documented.
Executive recommendations for Licence Committee
None
Areas not covered in by this inspection
None

5. Scientific practice R0145

Desired outcome: Research is carried out in accordance with licence conditions and makes progress towards achieving stated aims

Summary of:

- Use of material
- Progress in achieving aims and objectives
- Peer review

Use of material
The purposes of the research remain unchanged and are as follows: • increasing knowledge about the development of embryos; • increasing knowledge about serious disease; • enabling any such knowledge to be applied in developing treatments for serious disease. 1983 fresh and 38 frozen embryos were donated to the project in the time covered by this report: 1454 fresh and 17 frozen embryos were used in the research project.
Renewed project objectives
The scientific objectives of the project are as follows; 1.To optimise good manufacturing process (GMP) compatible methods for derivation, expansion and cryopreservation of embryonic stem (ES) cells; 2. To optimise blastocyst culture, determine the optimum time for the isolation of the inner cell mass (ICM) and refine the mechanical methods of inner cell mass (ICM) isolation; 3. To define the pluripotent population within the ICM. This will also yield insights into the nature of the stem cell niche in the context of the human blastocyst; 4. To optimise methods for blastocyst cryopreservation and thawing and to determine the effect of freeze/thaw on the potential to produce stable ES cell lines. A secondary benefit will be to enable the evaluation of the efficacy of blastocyst cryopreservation as a possible alternative to cleavage stage cryopreservation in the clinical IVF programme; 5. To better understand the nature and origin of chromosomal instability in ES cells and to assess the effect of environmental conditions on the maintenance of genomic integrity. This is important because the acquisition of chromosomal abnormalities by ES cells will be a major limitation to their therapeutic application; 6. To characterise the epigenetic status of blastocysts and ES cells. This will advance our understanding of the epigenetic control of pluripotency and differentiation and will also yield insights into the effect of environment on epigenetic stability; 7. To evaluate new developments in the derivation of ES cell lines e.g. to determine whether ES cell lines can be derived from the individual blastomeres removed from 4-12 cell embryos; 8. To continue to monitor and improve the process of giving information to and taking consent from patients for this research.
Lay summary of research undertaken
The research carried out under the auspices of licence RO145 has resulted in the derivation

of 6 ES cell lines. The first has been deposited in the UK Stem Cell Bank and the remainder are in the process of being deposited.

The research team has looked at the expression of the genetic code in embryos and ES cells. This work has provided some interesting results but further data need to be collected before this can be published.

The research team has also undertaken some detailed qualitative analysis of the attitudes of patients donating embryos for this research. Information from this study is being analysed in preparation for publication.

Results related to this research have so far been published in 7 peer reviewed papers.

Progress

The reduction in clinical work at centre 0017 during the refurbishment of the laboratories has impaired progress of the research to some extent. However, progress has been maintained and can be summarised as follows:

- Having isolated a number of ES cell lines in the first two years of the project, in the last year the team has concentrated on the development of methods for the culture of ES cell lines under conditions that would satisfy GMP rather than continue the development of research grade lines. Some advances have been achieved towards this aim;
- The team has continued to investigate what conditions are required for optimum growth of embryos prior to the derivation of ES cell lines. The role of hyaluronic acid at different stages of embryo development and in ES cells has been studied and this work is being prepared for publication;
- An investigation has been undertaken of genetic imprinting in embryos at different stages of development. More data need to be collected before this work is ready for publication;
- A unique isolator/incubator system for the IVF and stem cell laboratories has been designed which will provide a controlled environment in which gametes and embryos can be manipulated in compliance with the standards of the EU Tissues and Cells Directive and GMP. The installation of the system was in progress at the time of the inspection and it is anticipated that will be completed in October 2006.
- Following the appointment of a full time research nurse in 2004, the team have undertaken an analysis which has shown that the number of donors of surplus embryos increased following the appointment of the research nurse although the demographic and clinical data relating to donors has remained unchanged.
- A study of patient attitudes to donation to research has been completed and the results are being analysed. Publication of the results is anticipated in 2006/7. Some changes to procedures and patient information have been implemented as a result of the study.

Peer reviewers comments

Supported application.

Issues for consideration

In the course of the inspection it was noted that researchers may wish to freeze embryos for research purposes in the future. Current clinical practice at centre 0017 is for patients to

consent to cryopreservation only when it is known that suitable embryos are available. The PR was advised to consider how consent to cryopreservation will be obtained for research embryos: the PR wishes to consider the use of specific consents rather than the usual HFEA 00(6) and 00(7) consent forms. If freezing of research embryos is carried out then it is recommended that forms and procedures for the documentation of consent are developed in consultation with the HFEA. A suitable system for monitoring of the expiry of consents should also be developed.

Epigenetic studies are carried out on fixed embryos at a centre remote from the primary research centre. The PR should consider revising patient information to clarify that embryos may be used in secondary research (as required in part 5.9 (i) of the COP) and the timescales in which it is anticipated that fixed embryos will be discarded. The timescales for the disposal of embryos used in secondary research should be documented in protocols.

Section 3) (a) of the Human Fertilisation and Embryology Act 1990 states that a licence cannot authorise keeping or using an embryo after the appearance of the primitive streak, where the primitive streak is to be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with the day when the gametes are mixed, not counting any time during which the embryo is stored. Where whole embryos are cultured to form outgrowths the centre should consider how it can be demonstrated that they have complied with the Act to terminate culture after 14 days. In relation to this the PR requested clarification of when an outgrowth can be considered a cell line.

Executive recommendations for Licence Committee

None

Areas not covered in by this inspection

None

6. Scientific practice R0152

Desired outcome: Research is carried out in accordance with licence conditions and makes progress towards achieving stated aims

Summary of:

- Use of material
- Progress in achieving aims and objectives

Use of material
The purposes of the research are as follows: • increasing knowledge about the development of embryos; • increasing knowledge about serious disease; • enabling any such knowledge to be applied in developing treatments for serious disease. 66 fresh oocytes and 1224 oocytes which failed to fertilise were donated to the project in the time covered by this report: 66 fresh oocytes and 593 oocytes which failed to fertilise were used in the research project. Before proceeding to work on human oocytes, the group optimises techniques using mouse oocytes. The group is also exploring alternative methods for the procurement of fresh human oocytes and has developed a programme for altruistic donation of oocytes. In this process the eleventh and twelfth oocytes collected are allocated to the research programme. This ensures transparency in the donation process. At the time of the research inspection the programme of altruistic donation had been suspended pending the refurbishment of the laboratories at the Centre for Life. However this programme is expected to resume late in 2006.
Project objectives
1. To optimise methods for somatic cell nuclear transfer (SCNT) into mature human oocytes. Investigations will focus on techniques used in I. removal of egg DNA II. introduction of somatic cell nucleus into eggs III. egg activation IV. culture of SCNT embryos to the blastocyst stage 2. To test the feasibility of performing SCNT with immature oocytes with a view to testing the hypothesis that SCNT into immature human oocytes promotes efficient transcriptional silencing and nuclear reprogramming.
Lay summary of research undertaken
The research team has successfully derived a blastocyst following nuclear transfer. They have identified that a major rate limiting factor in the progress of the research is the source of fresh eggs. The group are continuing to use unfertilised eggs and immature eggs to provide information on the molecular mechanisms underlying the processes and technology necessary to develop nuclear reprogramming. The PR reported that progress has been slow because key publications in the field were identified as false in the time covered by his report. This resulted in two changes in research strategy.

The results of initial studies also showed that nuclear transfer success requires the use of fresh eggs. The group have sought to change procedures for the recruitment of donors to ensure a supply of fresh oocytes but this has been slow because of the regulatory process.
Issues for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered in by this inspection
Peer review

7. Scientific practice R0153

Desired outcome: Research is carried out in accordance with licence conditions and makes progress towards achieving stated aims

Summary of:

- Use of material
- Progress in achieving aims and objectives

Use of material

The purposes for which the research was previously licensed are as follows:

- increasing knowledge about serious disease;
- enabling any such knowledge to be applied in developing treatments for serious disease.

The PR proposes that the research should also be licensed for the following purposes:

- promoting advances in the treatment of infertility;
- increasing knowledge about the development of embryos.

63 fresh and 5 frozen embryos were donated to the project in the time covered by this report: 48 fresh and 5 frozen embryos were used in the research project.

The PR reported that fewer abnormally fertilised eggs were made available than was anticipated. This was attributed to the reduction in the number of treatment cycles due to laboratory refurbishments. Very few frozen embryos were used in the research but it is envisaged that the use of frozen embryos will increase once pronuclear transfer techniques have beeen optimised. It is reported that the shortage of material has had a significant impact on progress.

Project objectives

The initial objectives of the project were as follows:

1. To determine whether embryos derived from pronuclear transfer zygotes are capable of development to the blastocyst stage;
2. To determine the extent of mitochondrial DNA carry over following pronuclear transfer;
3. To evaluate the cytogenetic, epigenetic and gene expression profiles of embryos derived from pronuclear transfer zygotes.

Progress has bee made in achieving these objectives. The group has evaluated techniques for pronuclear transfer and has optimised the bore diameter and spike length of the pipettes used for pronuclear extraction and the method of transfer to ensure optimum survival of embryos. Researchers have also assessed the localisation of mitochondria in human zygotes.

The PR reports that at this stage of the project the team intends to focus on the following objective:

4. To increase the supply of material for developing pronuclear transfer techniques by using unfertilised and parthenogenetically activated eggs to practice removal and transfer/fusion of pronulcei.

Lay summary of research undertaken

During the past 6 months, the group have been using abnormally fertilised eggs to optimise pronuclear transfer techniques. They have also used a special stain to show the location of mitochondria inside the eggs. This is important because, the clinical relevance of the pronuclear transfer technique rests on the ability of the team to minimise the carry-over of mitochondria from one egg to another.
Issues for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered in by this inspection
Peer review

Report compiled by:

Name……Debra Bloor…….

Designation……HFEA inspector…….

Date14 June 2006……

Appendix A: Centre Staff interviewed

Alison Murdoch, Person Responsible R0145, R0152
Mary Herbert, Person responsible R0153

Two other members of the team took part in meetings with the inspector.

Appendix B: Licence history for previous 3 years

R0145

Status	Licence	Type	Active From	Expires
Active	R0145/1/a	Research Project	05/08/2003	01/08/2006

No conditions or recommendations have been applied to the licence.

R0152

Status	Licence	Type	Active From	Expires
Replaced by New Version	R0152/2/a	Research Project	01/08/2005	31/07/2008
Expired	R0152/01/a	Research Project	11/08/2004	31/07/2005

No conditions or recommendations have been applied to any of the licences listed above.

R0153

Status	Licence	Type	Active From	Expires
Active	R0153/1/a	Research Project	08/09/2005	31/08/2008

The licence committee that granted the licence imposed an additional condition requiring the submission of six monthly progress reports.

Appendix C:
RESPONSE OF PERSON RESPONSIBLE TO INSPECTION REPORT – **R0145, R0152**

Centre Number……0017……

Name of PR……Alison Murdoch…….

Date of Inspection……11 May 2006……..

Date of Response……

Please state any actions you have taken or are planning to take following the inspection with time scales

Signed……

Name…….

Date……

2. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

RESPONSE OF PERSON RESPONSIBLE TO INSPECTION REPORT – **R0153**

Centre Number…0017……

Name of PR Mary Herbert…….

Date of Inspection…11May 2006……..

Date of Response……

Please state any actions you have taken or are planning to take following the inspection with time scales

Signed……

Name…….

Date……

2. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

We also welcome comments about the inspection on the inspection feedback form, a copy of which should have been handed out at the inspection. If you require a copy of the feedback form, please let us know.

Please return this section of the report to:
Dr Chris O'Toole
Head of Research Regulation, HFEA
21 Bloomsbury Street
London
WC1B 3HF

Research Licence Committee Meeting

26 July 2006
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 5

Research Project R0145 Epigenetic Studies of Preimplantation Embryos and Derived stem cells, based at Newcastle Fertility Centre at Life (0017) Licence Renewal
Also, progress reports were presented on projects R0152 and R0153

Members:
Emily Jackson, Lay Member – Chair
Ivor Brecker, Lay Member
Richard Harries, Lay Member
Clare Brown, Lay Member
Maybeth Jamieson, Consultant Embryologist, Glasgow Royal Infirmary

In Attendance:
Chris O'Toole, Head of Research Regulation
Claudia Lally, Secretary to the Committee

Providing Legal Advice:
Graham Miles, Morgan Cole Solicitors

Providing Scientific Advice:
Neva Haites, Professor of Medical Genetics, University of Aberdeen

Conflicts of Interest: members of the Committee declared no conflicts of interest in relation to this item.

The following papers were considered by the Committee:

- papers for Licence Committee (127 pages)
- 1 paper was tabled: peer review (3 pages)

1. The papers for this item were presented by Chris O'Toole, Head of Research Regulation. Dr O'Toole informed the centre that this project involves the derivation of stem cell lines. The project has been licensed for 3 years. In this time the project has used 1454 fresh embryos and 17 frozen embryos. The research has generated 6 stem cell lines, two of which have been deposited in the UK stem cell bank, and 7 academic papers have been produced by the researchers. The centre are building new premises with an isolation chamber, all to GMP standards.

2. The Committee noted that the peer reviewer had raised the question of whether or not the use of this number of embryos is necessary. They noted the

centre's response to this comment (at page 56 of the committee papers), and also the reply from the peer reviewer.

3. The Committee agreed that it required more information before making the decision about what number of embryos is a suitable number for use in this research project. The Committee noted that the current research licence is due to expire at the end of July, and decided to issue a two month licence whilst the Executive gathered more evidence on this issue. The licence renewal could then be reconsidered at the next research Licence Committee, due to take place on 13 September.

4. The other issue noted by the Committee was the comments at page 13 of the inspection report about the fact that, in the creation of stem cell lines, centres are allowing the inner cell mass of the embryo to naturally outgrow, rather than extracting it mechanically. The Committee agreed that it would be useful for this technique to be referred to the Authority's Scientific Advances Group.

5. The Committee noted the progress reports relating to projects R0152 and R0153. Members of the Committee noted with concern the findings of the inspection report that the centre is failing to advise the Authority of staff changes, that labs are sometimes left unattended and that witnessing is not always correctly carried out. The Committee requested that these issues are followed up with the centre.

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