Research Licence Interim Inspection Report

Centre Name	**Newcastle Fertility Centre at Life**
Centre Number	0017
Centre Address	Bioscience Centre, International Centre for Life, Times Square Newcastle upon Tyne, NE1 4EP
Treatment centres donating to this research project	Newcastle Fertility Centre at Life
Inspection date	10 July 2007
Licence Committee Date	28 November 2007
Inspector(s)	Debra Bloor Chris O'Toole

Project Title Research Licence Number Person Responsible Nominal Licensee Inspection type Licence expiry date	**Epigenetic studies of preimplantation embryos and derived stem cells** R0145 Alison Murdoch Mary Herbert Progress 31 December 2009
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

About the Inspection:
The purpose of the inspection is to ensure that research is carried out in compliance with the HF&E Act 1990, seventh edition Code of Practice, licence conditions and directions.

The report is used to summarise the findings of the inspection highlighting areas of firm compliance and good practice, as well as areas where further improvement is required to meet regulatory standards. It is primarily written for the Licence Committee who make the decisions about the centre's licence. The report is also available to patients and the public following the Licence Committee meeting.

This report covers the period between 11 May 2006 and 10 July 2007.

Brief Description of the Project

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 Newcastle Fertility Centre for Life were closed for refurbishment between January 2006 and July 2007. During this time clinical laboratory work was carried out at licensed premises at the Royal Victoria Infirmary (centre 0248) but activity was reduced during the refurbishment and this impacted on the availability of material for the research programmes. During the refurbishment, the altruistic donation of eggs to research was suspended.

In 2005, the Person Responsible (PR) applied to vary the licence to allow fresh eggs for use in research project R0152 to be sourced in the following ways:

- altruistic donation by a person not undergoing fertility treatment who undergoes stimulation and egg retrieval purely for the purpose of donating eggs to research;
- participation in an "egg sharing arrangement" when part of the costs for a patient undergoing fertility treatment are covered by research funds if the patient agrees to donate a proportion of the eggs which are retrieved to research.

The licence of project R0152 had previously been varied to allow patients undergoing fertility treatment to donate two eggs to research if 12 or more eggs were retrieved.

On 11 July 2006 a Licence Committee of the Authority (LC) agreed to grant the application to permit oocytes to be obtained from patients participating in egg sharing schemes for use in research project R0152 subject to the imposition of the following licence condition:

- Where patients are to be approached about the possibility that they might enter into an egg sharing arrangement in which a proportion of their eggs would be donated for use in research those patients must not receive information, consenting and / or counselling concerning the research from clinical personnel involved in the project of research (with the exception of the Nurse Coordinator).

On 14 September a LC approved a variation to allow women not undergoing fertility treatment to donate eggs for use in research project R0152. This decision was made subject to review of HFEA policy.

There have been some staff changes in the research teams.

A small number of issues were identified in the course of the 2006 inspection which warranted consideration and these are summarised below.

Recommendation	Action taken
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.	A member of the team who had been in post since May 2006 was interviewed in the course of the inspection and reported participation in a comprehensive induction programme. She reported that she had not received mandatory health and safety training in the last year.
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.	Updated staff lists have been submitted to the HFEA in the time since the last inspection.
The persons responsible should ensure that access to any laboratories where viable embryos are left unattended is controlled and limited to licensed personnel only.	All research involving viable embryos is carried out in laboratories where access is limited to licensed personnel.
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.	On the advice of the Head of Research Inspection, it was concluded that if freezing is undertaken as part of the research programmes either to facilitate the batch processing of embryos or for the evaluation of the effects of freezing on the viability of embryos and derivation of stem cells this does not constitute storage of embryos but use in research. In these circumstances it was considered that the gamete providers, having already consented to the use of their embryos in research, would not be required to provide further consent to storage.
The documentation of the witnessing of transfer of embryos or eggs to research could be more formally documented.	Evidence of the documentation of witnessing at the time of transfer to research or disposal was observed in the course of the inspection.
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 6th COP) and the timescales in which it is anticipated that fixed embryos will be discarded. The timescales for the	No secondary research has been carried out in the time since the last inspection and the patient information has not therefore been revised. Patient information should be revised and

disposal of embryos used in secondary research should be documented in protocols.	timescales for the disposal of fixed material should be agreed with those carrying out secondary research if this aspect of the centres research is resumed.
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.	This issue is currently under consideration by the HFEA scientific advances group.

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

C	Licence R0153 was issued with an additional condition requiring the submission of six monthly progress reports to the HFEA.
A	**Complied Y** Progress reports for project R0153 have been submitted as required.

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.

Action has been taken in relation to the recommendations of the previous report.

The executive supports the continuation of the licences for research projects R0145, R0152 and R0153.

Proposed licence variations

None

Report of Inspection findings

1. **Organisation**
   Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

   Summary of findings from inspection
   Evidence of:
   - Leadership and management
   - Organisation of the centre
   - Staffing
   - Funding
   - Research governance

Full time equivalent staff

Principal investigator	Alison Murdoch, Mary Herbert
Scientists	3 PhD students, 2 research associates, 1 junior research associate, 1 research student
Laboratory technicians	1
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
There have been some staff changes in the time since the last inspection and the HFEA has been provided with updated staff lists. Bi-annual progress reports for all of the research licenses under consideration were submitted to the HFEA as required. Minutes of management meetings are posted on a notice board in a staff rest area: the minutes reviewed documented discussions related to research, risk management and quality management. The minutes that were reviewed documented the attendance of both research PRs. A recently appointed member of the research team reported receiving induction training similar to that undertaken by members of the embryology team of centre 0017. The programme includes training in the requirements of the HFEA. It was reported the projects under consideration have ongoing funding. The reporting of adverse incidents was discussed in the course of the inspection. It was reported that no adverse incidents have occurred in the course of the research although there

was awareness of incident reporting requirements among members of the research team. Centre 0017 has a documented adverse incident reporting protocol and the requirements of incident reporting are discussed in the course of the induction of new staff members.
Issues for consideration
The member of staff interviewed in the course of the inspection had not received mandatory health and safety training in the last 12 months. The member of staff reported that suitable training is available and the PRs should ensure that all staff participate in annual mandatory health and safety training. The updated staff list provided to the HFEA provided information on staff changes that occurred up to twelve months prior to the submission of the update. In the course of the inspection, the persons responsible agreed to provide more frequent updates of staff changes.
Executive recommendations for Licence Committee
None
Areas not covered in this inspection
Resource management

2. Premises and equipment

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

Summary of findings from inspection: *(Delete areas not being reported on)*

- Suitability of premises
- Safety of equipment
- Servicing and maintenance of equipment

Highlighted areas of firm compliance
The laboratories at the Centre for Life were closed for refurbishment between January 2006 and July 2007. During this time, clinical work was reduced and the altruistic donation of eggs to research was suspended. This impacted negatively on the availability of material to the research programmes. During the refurbishment, research activity took place in laboratories within the Institute of Stem Cell Biology and Regenerative Medicine at the Centre for Life. Following completion of refurbishment works, from July 2007, research has taken place in specially designed facilities within the Centre for Life. It was reported that no viable material will be removed from the unit access to which is limited to licensed personnel. At the time of the inspection, the laboratories appeared to be suitably equipped. The research facilities include a designated isolator allowing all aspects of the culture and manipulation of embryos to be carried out in a controlled atmosphere: this is expected to have a positive impact on embryo quality. Evidence of ongoing maintenance of key equipment was observed in the course of the inspection. Cryopreserved embryos donated to research are transferred to designated storage vessels upon transfer to the research programme. The bring forward system used to identify embryos for which the consent to storage is due to expire was demonstrated in the course of the inspection of centre 0017 and was considered robust. It was reported that Health and Safety inspection of the research laboratories is carried out by the University of Newcastle.
Issues for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered in this inspection
Storage facilities

3. Donation of material

Desired outcome: Ensure donors are recruited in a proper way and their consent is respected.

Summary of findings from inspection: *(Delete areas not being reported on)*

Highlighted areas of firm compliance
Issues relating to the recruitment of donors were considered in some depth in the inspection carried out in May 2006 when the systems in place were considered robust. Donation is coordinated by a designated individual who is not directly involved in the patient's treatment. It was reported that there have been no changes to recruitment procedures and these issues were not revisited. Evidence was seen that the witnessing of the transfer of embryos to research is documented. There is a robust system for tracking the fate of embryos used in the research programmes. The system was demonstrated in the course of the inspection when the fate of two embryos was tracked successfully.
Issues for consideration
Although the transfer to research or disposal of embryos is witnessed and the procedure documented at the time of the inspection it was noted that a copy of the record was not placed in the patient record as recommended in section G13.2.1 of the 7th Code of Practice. This was discussed with a member if the embryology team and it was agreed that a copy of the record would be included in the patient records.
Executive recommendations for Licence Committee
None
Areas not covered in this inspection
Recruitment of donors Ensuring prospective donors have access to further guidance Ensuring prospective donors have time to consider donation properly Prevention of coercion of prospective donors

4. Patient information and consents

Desired outcome: Ensure that patients are informed in order to give informed consent

Summary of findings from inspection:

- Ensuring patient consent is not breached

Outcome of audit of records
The records of two sets of patients were reviewed. Consent forms were present and consistent with the use of the embryos in research.
Highlighted areas of firm compliance
Patient information was reviewed in depth at the time of the last inspection when it was considered to be compliant with requirements. However, it is recommended that information provided to patients is reviewed to ensure compliance with the revised 7th Code of Practice.
Issues for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered in this inspection
Patient information Consent forms Patient information for projects deriving embryonic stem cells Consent forms for projects deriving embryonic stem cells

5. Scientific practice R0145

Desired outcome: Procedures are robust to ensure material is used appropriately

Summary of findings from inspection:

- Minimisation of material loss and wastage
- Ability to achieve set aims and objectives

Use of material
The purposes for which the research is licensed 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. 706 fresh and 10 frozen embryos were donated and used in the research project between 30

April 2006 and 30 April 2007. This represents a reduction in the number of embryos used when compared to 2005/6 when a total of 1471 embryos were used in the project. It was predicted in the 2006 renewal application that 400 fresh and 100 frozen embryos would be used.

It should be noted that at this unit, all of the embryos that are transferred to research are logged as "used" in the research. This includes poor quality embryos that fail to cleave and/or arrest at early stages of development. The use of embryos was discussed with the PR and it was reported that embryos are used in all aspects of the work including derivation of stem cells, development of procedures and peripheral studies as outlined in the research proposals. For this reasons it is considered inappropriate by the PR to identify human embryonic stem cell (hESC) derivation rates.

Project objectives

1. To optimise good manufacturing practice (GMP) compatible methods for derivation, expansion and cryopreservation of hESC. This requires the provision of facilities compatible with the European Union Cells and Tissues Directive (EUTD) and the development of feeder free and animal product free system for culturing hESC.

   It was reported that the GMP laboratory is nearing completion; equipment and standard operating procedures have been drafted; commissioning and testing of the isolators and incubators are nearly completed.

2. To optimise blastocyst culture, determine the optimum time for the isolation of the inner cell mass (ICM) and refine the mechanical methods of ICM isolation.

   Progress towards achieving this objective was reported as ongoing.

3. To define the pluripotent population within the ICM to gain insights into the nature of the stem cell niche in the context of the human blastocyst.

   It was reported that progress towards achieving this objective is ongoing and it is expected that the results may be ready for publication at the end of the summer of 2007.

4. To optimise methods for blastocyst cryopreservation and thawing and to determine the effect of freeze/thaw on the potential to produce stable hESC. A secondary benefit will be to enable the evaluation of the efficacy of blastocyst cryopreservation as a possible alternative to cleavage stage freezing in the clinical IVF programme.

   This objective has not yet been addressed.

5. To better understand the nature and origin of chromosomal instability in hESC and to assess the effect of environmental conditions on the maintenance of genomic integrity. This is important because the acquisition of chromosomal abnormalities by hESC will be a major limitation to their therapeutic application.

   It was reported that work is ongoing to characterise the checkpoint protein function in hESC using knockdown technologies.

6. To characterise the epigenetic status of blastocysts and hESC. This will advance the understanding of the epigenetic control of pluripotency and differentiation and will also yield insights into the effect of environment on epigenetic stability.

   It was reported that this work is ongoing

7. To evaluate new developments in the derivation of hESC to determine, for example, whether hESC can be derived from the individual blastomeres removed from 4 to12 cell embryos.

   It was reported that this objective has not yet been addressed

8. To continue to monitor and improve the process of giving information to and taking consent from patients for this research.

   It was reported that this work is ongoing.

It was expected that refurbishment of the laboratory facilities would be complete in October 2006. Refurbishment was not completed until June 2007 and this had some negative effect on the progress of the research.

Nine stem cell lines have been derived in the course of the research to date.

Lay summary of research undertaken
The current program of research began at the start of the licence in January 2007. Some of the early studies on culturing blastocysts are progressing well and should be ready for submission for publication later this year. Our object to derive therapeutic grade hES cells is progressing well. The new laboratory facilities that meet the required standard opened in June 2007.
Issues for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered in this inspection
Standard operating procedures Quality assurance systems (see section 2)

6. Scientific practice R0152

Desired outcome: Procedures are robust to ensure material is used appropriately

Summary of findings from inspection:

- Minimisation of material loss and wastage
- Ability to achieve set aims and objectives

Use of material
The purposes for which the research is licensed 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. 9 fresh oocytes and 26 oocytes which failed to fertilise and were donated and used in the research project between 30 April 2006 and 30 April 2007. This represents a reduction in the number of oocyes used when compared to 2005/6 when a total of 66 fresh oocytes and 593 oocytes which failed to fertilise were used in the research project. It was predicted that 500 fresh and 300 oocytes which failed to fertilise would be used. 5 embryos were created in the course of research undertaken between 30 April 2006 and 30 April 2007. The reasons given for the discrepancy between the predicted and actual use of material were as follows: • The activation rates of the failed to fertilise eggs were unfeasibly low; • The number of freshly harvested eggs available from follicle reductions was lower than expected; • There was a major delay in obtaining regulatory approval from the HFEA for egg donation for research. The PR is now awaiting the outcome of a decision on funding for the project.
Project objectives
1. To optimise methods for somatic cell nuclear transfer (SCNT) into mature human oocytes. Investigations will focus on techniques used in a. Removal of egg DNA; b. Introduction of somatic cell nucleus into eggs; c. Egg activation; d. Culture of embryos generated by SCNT to the blastocyst stage. It was reported that optimisation of egg activation procedures has been the focus of the work done to date and that progress towards achieving this objective is ongoing. 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. It was reported that this hypothesis is being tested using mouse oocytes.

A major focus of the project in the past year has been addressing the regulatory and funding issues related to the donation of fresh human eggs with the HFEA and the Medical Research Council. As reported, the PR has been successful in obtaining the required licence.
Lay summary of research undertaken
Having determined that an essential element to the successful reprogramming of a nucleus is to use a 'fresh' egg, we have been involved in extensive discussions about egg donation over the past 18 months. Some aspects of this project have consequently been delayed whilst our proposals were approved. In the meantime though improvements have made to protocols and further collaborations established.
Issues for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered in this inspection
Standard operating procedures Quality assurance systems (see section 2)

7. Scientific practice R0153

Desired outcome: Procedures are robust to ensure material is used appropriately

Summary of findings from inspection:

- Minimisation of material loss and wastage
- Ability to achieve set 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 progress report submitted in June 2007 proposes that the project is also licensed for the purposes of increasing knowledge about the development of embryos and the Licence Committee is asked to consider this proposal. 127 fresh embryos were used in the research between 30 April 2006 and 30 April 2007. This represents an increase in the number of embryos used when compared to 2005/6 when 63 fresh and 5 frozen embryos were donated to the project. It was predicted that 200 embryos would be used. It was reported that fewer embryos were made available to the project because of the reduction in the number of treatment cycles carried out by the donating centre during the refurbishment of the laboratory facilities.
Project objectives
1. To determine whether embryos derived from pronuclear transfer zygotes are capable of development to the blastocyst stage. This objective was reported as ongoing with progress having been made in refining the techniques used for the removal of the pronucleus (PN) and karyoplast. 2. To evaluate the cytogenetic, epigenetic and gene expression profiles of embryos derived from pronuclear transfer zygotes Progress towards achieving this objective was reported as ongoing. 3. To determine the extent of mitochondrial DNA carry-over from the donor zygote. This objective was reported as ongoing with progress having been made in identifying the spatial distribution of mitochondria and in identifying the extent of mitochondrial transfer during PN transfer.
Lay summary of research undertaken
This research is progressing. Results are being obtained and will be published when the study is complete. There has been no need to change our protocol based on the results of the study so far.

Issues for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered in this inspection
Standard operating procedures Quality assurance systems (see section 2)

Report compiled by:

Name……Debra Bloor…….

Designation……Inspector…….

Date…6 August 2007……

Appendix A: Centre Staff interviewed

Meetings were held with Mary Herbert, Alison Murdoch and three other members of the research team in the course of the inspection.

Appendix B: Licence history for previous 3 years

R0145

Status	Licence	Type	Active From	Expires
Active	R0145/3/a	Research Project	01/01/2007	31/12/2009
Expired	R0145/2/b	Research Project	01/10/2006	31/12/2006
Expired	R0145/2/a	Research Project	01/08/2006	30/09/2006
Expired	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
Active	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

Centre Number…0017 Project R0145, R0152……

Name of PR……Alison Murdoch……Mary Herbert…….

Date of Inspection……10 July 2007……..

Date of Response……7 August 2007……

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

No actions needed other than those agreed during the inspection and documented.

I have read the inspection report and agree to meet the requirements of the report.

Name…….Alison Murdoch…….

Date……7-8-07……

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).

Page 3, 1st paragraph. It is stated that the purpose of the inspection relates to quality service for patients and to 'improve patient services'. Should this not relate to the purpose of a research licence inspection? I presume you mean compliance with the 7th COP.

Page 5, 2ND paragraph. The application for variation was in 2005 not 2006. Also the costs are covered by the research funds not the 'Centre'. This is important because the Centre is funded for treatment by the PCTs and the patient fees so you must not give the impression that the treatment funds the research.

Page 5, para 5, The variation was to research licence RO152 not RO153.

Page 8. The scientific staff are 3x PhD students, 2 x research associates, 1 x junior research associate, 1 x research student.

Page 12. Donated sperm may still be used for non-licensed research at this Centre.

On a separate issue, whilst acknowledging that I signed to agree to the Standard Conditions in the Licence, I have re-read section 3(b) and request clarification from the Licence Committee. All our patients are asked about research. I assume that the Committee are not

suggesting that I have to give up clinical practice if I continue research activity?

Page 14. We have deposited 9 stem cell lines in the UK Stem Cell Bank not 8

Factual inaccuracies documented here were amended in the text of the report before consideration of the report by a Licence Committee.

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

28 November 2007
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 5

Research Projects R0145, R0152, R0153
Newcastle Fertility Centre at Life (0017)
Interim Inspection

Members:
Emily Jackson – Chair, Lay Member
Richard Harries, Lay Member
Clare Brown, Lay Member
Maybeth Jamieson, Consultant Embryologist, Glasgow Royal Infirmary
Neva Haites, Professor of Medical Genetics, University of Aberdeen

In Attendance:
Trish Davies, Director of Regulation/ Deputy Chief Executive
Chris O'Toole, Head of Research Regulation
Claudia Lally, Committee Secretary

Observing:
David Gomez, legal adviser to the HFEA

Providing Clinical Advice:
William Ledger, Professor of Obstetrics and Gynaecology, University of Sheffield

Providing Legal Advice:
Graham Miles, Morgan Cole Solicitors

Conflicts 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:

- papers for Licence Committee (97 pages)
- no papers were tabled.

1. The papers for this item were presented by Debra Bloor, HFEA Inspector. Dr Bloor informed the Committee that the laboratories at the Newcastle Fertility Centre for Life (the donating clinical unit) were closed for refurbishment between January 2006 and July 2007. During this time clinical laboratory work was carried out at licensed premises at the Royal Victoria Infirmary (centre 0248) but activity was reduced during the refurbishment and this had a negative impact on the availability of material for the research programmes. At the time of the inspection the new laboratories had been operational for less than a month. Dr Bloor further

informed the Committee that the centre has now largely complied with the recommendations made following the 2006 inspection.

2. Dr Bloor drew the Committee's attention to the question by the Person Responsible (at page 22 of the Committee papers) asking for clarification about the additional condition applied to licence R0152:

> "Where patients are to be approached about the possibility that they might enter into an egg sharing arrangement in which a proportion of their eggs would be donated for use in research those patients must not receive information, consenting and / or counselling concerning the research from clinical personnel involved in the project of research (with the exception of the Nurse Coordinator)"

Dr Bloor explained that the Person Responsible is seeking clarification about whether this condition means that researchers cannot also participate in clinical practice. The Committee agreed that the condition does not mean that researchers cannot have normal clinical contact with patents, but only that researchers are not involved in the process whereby patients are invited to donate gametes to the research project.

3. Dr Bloor also drew the Committee's attention to a standard licence condition on all research licences (at condition no. 3) which relates to this issue. The Committee asked that the wording of this condition be reviewed to ensure that it does not imply that researchers cannot also have a clinical role.

4. The Committee hoped that more progress would be made in the coming year and agreed that they were happy for the licences to continue with no additional conditions.

Signed..... Date 2.1.08
Emily Jackson (Chair)