Research Licence Inspection Report

Project Title	**In vitro Development and Implantation of Normal Human Pre-embryos and Comparison with Uni- and Poly-pronucleate Pre-embryos.**
Research Licence Number	**R0026**
Person Responsible	**Daniel Brison (Centres 0067 & 0033)** **Susan Kimber (Centre 0175)**
Nominal Licensee	**Susan Kimber (Centre 0067)** **Brian Lieberman (Centre 0033)** **Daniel Brison (Centre 0175)**
Inspection type Licence expiry date Date Renewal fee paid	**Renewal** **31/01/2007** **Not billed yet**
Project Title	**Derivation of human embryonic stem cell lines from embryos, including those created from clinically unused oocytes or abnormally fertilised embryos**
Research licence Number	**R0170/R0171**
Person Responsible	**Daniel Brison (Centres 0033, 0067 & 0175)**
Nominal Licensee	**Brian Lieberman (Centres 0033 & 0067)** **Susan Kimber (Centre 0175)**
Inspection type Licence expiry date	**Progress** **31/12/2009**
Centre Number	**0067, 0033 & 0175**

Centre Name and address	**Centre 0067 NHS - treatment and research** Department of Reproductive Medicine St Mary's Hospital, Manchester M13 OJH **Centre 0033 Private – treatment and research** Manchester Fertility Services 120 Princess Road, Manchester M15 5AT **Centre 0175 University - research only** Faculty of Life Sciences, University of Manchester, Floor 2 Core Technology Facility, 46. Grafton St Manchester M13 9NT
Treatment centres donating to these research projects	Centres 0033 & 0067
Inspection date	19 September 2006
Licence Committee Date	29 November 2006
Inspector(s)	Chris O'Toole

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 01/07/2005 and 30/06/2006

Brief Description of the Projects

Project **R0026** entitled: "In vitro Development and Implantation of Normal Human Pre-embryos and Comparison with Uni- and Poly-pronucleate Pre-embryos", has been licensed since 1991.

The lay summary of the project is as follows:

In spite of the fact that clinical in vitro fertilisation (IVF) has been used as a treatment for infertility for more than 20 years, human embryos created by IVF continue to develop poorly in the laboratory, and the success rate of IVF is low. Only one in every 5 or 10 embryos goes on to form a baby after transfer to the womb.

The aim of this research is to investigate the way normal human embryos develop in the laboratory, and compare them to embryos which develop abnormally. This will help us to improve laboratory conditions to allow normal embryo development, which will increase success rates of IVF.

We are looking particularly at genes and proteins which control cell death in embryos, and the ability of cells in the embryo to stick to one another, and make contact to the wall of the womb, in order to implant and develop.

We are also studying master genes which control other genes, particularly those which are involved in giving cells in the embryo the ability to go on to form any cell in the adult body.

Project **R0170/0171** entitled: "Derivation of human embryonic stem cell lines from embryos, including those created from clinically unused oocytes or abnormally fertilised embryos", has been licensed since 1994.

The lay summary of the project is as follows:

Human embryo stem (hES) cells can be made to develop into a variety of specific cell types and as such have many potential medical uses, including the treatment of degenerative diseases by the replacement of defective cells, the safety testing of new medicines and

treatments, and the study of disease. These cells can be isolated from the inner cells of early embryos produced during in vitro fertilisation treatment before they are transferred to establish a pregnancy. A variety of hES cell lines are required to understand both their biological properties and limitations. Large numbers of hES cell lines will be required for research and for their use in medical treatments, in order to provide the correct tissue match, similar to existing organ transplantation programmes.

To date hES lines have only been derived from embryos left over from IVF treatment programmes. These so-called "spare" embryos are in great demand for the couples' own treatment, for donation to other couples that do not have healthy eggs, and for research into infertility and improving IVF treatment. As a result, embryos donated for hES cell derivation are very scarce and this essential research is progressing very slowly. Although the first hES cell lines were reported in 1998, so far relatively few additional lines have been derived in the UK. To avoid many of the ethical and practical problems associated with the use of "spare" IVF embryos, we plan to use eggs (oocytes) that cannot be used for treatment, and are currently discarded, to create embryos specifically for hES cell derivation. Two groups of eggs will be used; those that are immature, and cannot be used safely for treatment, and those that have failed to fertilise after insemination. About 30-40% of all eggs (3-4 from each cycle of IVF treatment) fall into this category and are normally discarded. We plan to activate these eggs, or use sperm from a fertile donor, to "recover" these eggs to make embryos specifically for hES cell derivation. Although the success rate of these procedures may be lower than from normal embryos, we anticipate that many patients will be willing to give consent as the use of these eggs/embryos for research is preferable to then- being discarded. Information gained from these studies will then help to improve methods such as in vitro maturation, to be used hi clinical IVF treatment.

		R0026	R0170/0171
Research activities	Research on human embryos	✓	✓
	Storage of licensed material	✓	✓
	Creation of embryos for research	✓	✓
	Derivation of human embryonic stem cells		✓
	Cell nuclear replacement		

Changes/ improvements since last inspection

Centre 0033
The new premises for licensed treatment at Centre 0033 were initially inspected on 26 April 2006. On 24 May 2006 Licence Committee approved the request to perform licensed treatment on these premises pending a further visit by the HFEA Inspectors. This visit took place on 14 June 2006 and this visit was satisfactory. The Research Licence Committee, on 26 July 2006, agreed that research using human embryos could take place at the new premises.

Centre 0175
The new premises for Centre 0175 were inspected on 14 June 2006. On 26 July 2006, the Research Licence Committee agreed that research using human embryos could take place at the new premises.

There have been some staff changes in the research teams of both projects.

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

Licence R0026 was issued with one additional condition:

The creation of embryos explicitly for use in research must not be undertaken until the following have been submitted for consideration by a Licence committee of the Authority:

(i) local ethics committee approval,

(ii) further discussion as to why the creation of embryos specially for research is necessary or desirable for the proposed research project,

(iii) amended patient information and consent forms for potential egg donors

(iv) evidence of appropriate consent for the use of donor sperm for this purpose.

(v) evidence of the availability of appropriate counselling for donors

This condition has been complied with.

Licences R0170/0171 were issued without additional conditions.

Summary for Licence Committee

R0026
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.

The application for renewal of licence R0026 was considered by an external peer reviewer: the reviewer supports the renewal of the licence.

R0170/0171
Progress has been achieved in relation to the stated aims 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.

The licences at centres 0067 and 0175 have recently been varied to include the derivation of hES cells (0067, granted May 2006, and, following inspection in June 2006, Centre 0175), in addition to the Roslin Institute as in the original application and most recent renewal.

General
One issue was identified in the course of the inspection which warrants consideration:

- The centre should record the donation and use of both gametes and embryos to research projects.

The Persons Responsible for both projects should consider the recommendation of the inspection team in relation to this issue and implement any changes that are considered necessary.

The inspection team also support the renewal of licence R0026 and the continuance of research licences R0170/0171.

Proposed licence variations

R0026
The centres have applied to vary the licences to include the study of oocytes derived from cryopreserved ovarian tissue.

R0170/0171
The centre has applied to vary the licences to include a revised project title. The new title is: Derivation of human embryonic stem cell lines from embryos, *including those* created from clinically unused oocytes or abnormally fertilised embryos

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 R0026*

Principal investigator	Daniel Brison and Sue Kimber
Scientists	3
Laboratory technicians	
Support staff (receptionists, record managers, quality and risk managers etc)	Staff at centres 0033 and 0067

Staff R0170/0171*

Principal investigator	Daniel Brison and Sue Kimber
Scientists	3
Laboratory technicans	
Support staff (receptionists, record managers, quality and risk managers etc)	Staff from centres 0033 and 0067

*There is overlap between staff working on projects R0026 and R0170/0171.

Highlighted areas of firm compliance
The PRs of R0026 and R0170/0171 have extensive knowledge of the regulatory requirements of the HFEA. They both have extensive appropriate experience and publishing history. All new staff at centres 0033 and 0067 undergo an induction programme that includes the regulatory requirements of the HFEA. In addition all staff keep folders in which they record evidence of continuing professional development. The PhD students involved in licensed research at centres 0067 and 0175 are registered in the University of Manchester's graduate development programme which includes lectures on ethics. It is reported that both projects have ongoing funding. The centres' hold weekly clinical meeting and these include discussions regarding the licensed research projects every month to six weeks. In addition there is a meeting between all research staff every two weeks and a

teleconference between staff at centre 0067 and the Roslin Institute occurs monthly. The R0171 monthly Roslin telemeetings and the meetings of the NW ES cell centre in Manchester are formally minuted. The R0026 licence meetings are not minuted.
Issues for consideration
The centre should consider making a formal record of decisions made during the research meetings.
Executive recommendations for Licence Committee
None
Areas not covered in this inspection
None

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
- Storage facilities
- Safety of equipment

Highlighted areas of firm compliance
The creation and manipulation of viable embryos is carried out on licensed premises. Embryos are stored in designated secure areas with controlled access under the auspices of the licences of centres 0033, 0067 and 0175. The research laboratory at centre 0067 has two incubators and micromanipulation equipment as well as a class II laminar flow hood. The laboratory is locked at all times when not in use. The laboratories at centres 0033 and 0175 were not inspected as part of this visit has they had been inspected in June of this year.
Issues for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered in 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
- Ensuring patient consent is not breached
- Donor and patient records

Summary

Centre 0067 – All prospective patients attend a 'waiting list' meeting where they are introduced to the concept of donating gametes and embryos to research. Patients are also given the information sheets and consent forms relating to the specific research projects undertaken in the licensed centres in Manchester.

Centre 0033 - Patients are given the information sheets and consent for both research projects during their initial clinical consultation.

Patients, from either centre 0033 or 0067, who express an interest in donating gametes and / or embryos to the stem cell project (R0170/0171) meet with either the postdoctoral scientist or the research nurse to discuss the implications of this project and to sign the consent forms.

A medical consultant gives patients information and obtains consent from patients who wish to donate gametes and / or embryos to the embryo development project. The licence authorising this project of research does not have conditions that require a separation between obtaining consent to treatment and consent to research.

Approximately 40% of patients consent to the donation of gametes and embryos for use in the R0171 licensed research project. The figure for R0026 is approximately 70%.

If patients consent to the donation of gametes and / or embryos to be used in licensed research a coloured sticker (green for project R0026 and yellow for project R0170/0171) is placed on the treatment cycle embryo tracking form. The transfer of gametes and / or embryos from clinical use to research is witnessed by two appropriate people and this includes checking that appropriate consent is in place.

Centrally held records reviewed in the course of the inspection contained necessary information to allow tracking of individual embryos.

All the fresh embryos donated to research are those that are unsuitable for use in treatment and do not meet the centre's criteria for freezing. 45% of patients who receive licensed treatment at centre 0067 have embryos frozen and more than 50% of patients receiving licensed treatment at centre 0033 have embryos cryopreserved for potential future use.

The decision of whether embryos are unsuitable for use in treatment or cryopreservation is

always made by a clinical embryologist not involved in research. Two of the embryologists at centre 0067 are involved, on a part time basis, in licensed research. However, they do not make decisions regarding the suitability of embryos for clinical use if they are going to be carrying out research on the embryos donated from these patients.
Issues for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered in 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
The centres have patient information and consent forms for both projects of research. The information sheet and consent forms for project that involves the derivation of human embryonic stem cell lines are based on the one developed by the national human embryonic stem cell co-ordinators group. Patient information and consents comply with all of the requirements outlined in standard licence conditions and the 6th Code of Practice (COP). New patient and consent forms have been developed for the donation and use of oocytes from cryopreserved ovarian tissue. These have been approved by COREC.
Summary of audit of patient records
Witnessing of the transfer of embryos to research was documented appropriately in all of the records reviewed. The transfer of embryos to research is witnessed, the operator and witness sign to confirm that the patients donating embryos have completed appropriate consents to research. Eleven sets of records from patients who donated embryos to either R0026 and / or R0170/0171 were reviewed. Consent forms in all sets of records were present and consistent with the use of the material in research. An error was identified in two sets of records: • The HFEA treatment record form recorded that the patients' eggs, not used in treatment, had been allowed to perish where they had been donated to research. These forms are completed electronically and the electronic form does not have a field that allows the operator to record that eggs have been used in research.
Issues for consideration
Eggs donated to research cannot be recorded on the current electronic treatment form.
Executive recommendations for Licence Committee
The centre should revise the electronic treatment form, or take other action, to ensure that gametes and embryos donated to research are recorded appropriately.
Areas not covered in by this inspection
None

5. Scientific practice R0026

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
During the period 01/02/2006 to 31/07/2006 the centre has received 17 immature oocytes, 52 failed to fertilise oocytes, 184 fresh embryos and 29 frozen embryos from centre 0067. All these eggs and embryos have been used in the project of research.
Project objectives
The objective of this project is to investigate both normal and abnormal human embryo development in culture, and the regulation by growth factors, using the techniques of fixing embryos for protein analysis by immunocytochemistry and apoptosis analysis using TUNEL, and lysing embryos for mRNA analysis of gene expression. The centres have continued to obtain data on expression of several genes involved in embryo and ES cell pluripotency and lineage specification. This information has increased the knowledge of cell fate regulation and early embryo development in general. **New project aim:** **Ovarian tissue cryopreservation and autografting to reverse chemotherapy and radiation induced infertility in women treated for cancer** This project is an extension of the work to create embryos from oocytes for research purposes. The Ovarian tissue project will be carried in collaboration with Professor J Radford (Christie Hospital) and Dr H Picton (University of Leeds). The clinical aim is to assess the genetic safety and developmental competence of oocytes derived from cryopreserved ovarian tissue (as a means to preserve fertility for female patients undergoing cancer therapies). The scientific aims of the work are to: 1. Xenograft cryopreserved human ovarian tissue into NOD-SCID mice in order to derive mature oocytes “in vivo”. This aim falls outside the HFEA remit, the centre’s programme to graft ovarian tissue into women for fertility treatment. 2. Activate or fertilise mature oocytes to form embryos at all developmental stages up to blastocyst. This work is to be done in Manchester only at Centres 0033 and 0067. 3. Analyse the developmental competence of oocytes and embryos at all stages, by : • Assessing gene expression, using standard protocols and target genes covered by project R0026 (Manchester only, centres 0067 and 0175)

- Assessing gene expression using loss of imprinting arrays, work to be done in Leeds under HFEA licence R0104 at HFEA Centre 0052.
- Assessing karyotype, work to be done in Leeds under licence R0104 at HFEA Centre 0052.

This work has COREC approval.

Lay summary of research undertaken

We have gathered extensive information on the types of genes which are switched on in early embryos, by analysing messenger RNA and proteins produced by these genes. We have focussed in the past on molecules involved in cell adhesion, cell-cell communication, and the regulation of cell death (apoptosis). More recently we have looked at genes that regulate cell fate, particularly the decision to remain pluripotent (i.e. remain capable of forming all tissues in the body) or differentiate. We are expanding these studies to look at many more genes simultaneously, using gene chip technology, as it is likely that genes work together in particular pathways to regulate embryo development. We continue to compare normal embryos to abnormal ones, to try to understand the molecular basis for the abnormalities. As part of this we are creating embryos for research purposes, for example from oocytes which did not fertilise in an IVF cycle and would normally have been discarded. We are now applying to have our licence extended to include in this work oocytes which come from ovarian tissue frozen for women who are having sterilising treatments for cancer. This study is important to understand whether ovarian tissue freezing is safe and effective as a method of fertility preservation, and to learn more about early embryo development.

Peer reviewers comments

The application to renew the research licence for this project was subject to external peer review. The reviewer recommended that the application be accepted without any changes.

Issues for consideration

None

Executive recommendations for Licence Committee

The Executive recommends that the licences be varied to include the creation and use of embryos from cryopreserved ovarian tissue.

Areas not covered in this inspection

None

6. Scientific practice R0170/R0171

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
In the 12 month period from 01/07/2005 to 30/06/2006 centre 0067 received and used 23 immature eggs, 115 failed to fertilised eggs and 32 fresh embryos. A total of 76 embryos have also been created for use in this project. 113 of the 115 failed to fertilise oocytes, and 5 of the 23 immature oocytes (118 oocytes in total) were activated or inseminated with sperm. 76 of these formed embryos with 1 or more pronuclei and were therefore considered embryos. All of these were used in the project, for the aim of gene expression analyses. However none during the time period in question were sent to the Roslin Institute for stem cell derivation as the laboratory was undergoing refurbishment to GMP standards.
Project objectives and results
The overall objective of this project is to derive new human embryonic stem (hES) cell lines from fertilised embryos that may be suitable for therapeutic use in the future. In order to achieve this aim the centres use embryos that have been donated to the project as well as embryos created specially for research purposes which have been created by either the insemination of in vitro matured eggs or by parthenogenetic activation. In the past 12 months the centres have undertaken work to establish protocols for performing in vitro maturation on immature oocytes as well as optimising techniques for activating failed to fertilised oocytes using either parthenogenesis or insemination by intracytoplasmic sperm injection (ICSI). 23 immature oocytes (GV or MII) have been grown in one of three different culture media (one is commercially available while the other two are made in-house containing a variety of growth factors and hormones) for up to 48 hours. 5 eggs reached the MII stage i.e. a polar body was observed. These five MII eggs then underwent parthenogenetic activation. To date, three embryos have been created and one developed to the blastocyst stage following parthenogenetic activation. During the past 12 months the centres have parthenogenetically activated 97 eggs, of which 63 developed into embryos (i.e. where 1 or more pronuclei have been observed). Therefore, the development of parthenogenetic activation methods to recover failed to fertilised oocytes resulted in an activation rate of 63%.

To date, 7 blastocysts have been created from parthenogenetically activated embryos that would have been suitable for hES cell derivation. However, as the derivation laboratory of Dr Paul DeSousa was undergoing refurbishment to GMP standards, these blastocysts were not shipped to Edinburgh, instead these embryos, and the other embryos that failed to reach the blastocyst stage, were analysed for various markers to investigate normalcy in these embryos. These blastocysts were shown to express Oct-4 and Sox-2, both markers of pluripotency in human embryos.

The centre has created 13 embryos by injecting 17 failed to fertilise oocytes with donor sperm. None of these reached the blastocyst stage in culture but have been used fro genetic analysis.

No hES cell lines have been derived from the project as yet. This is due to the refurbishment programme at Dr Paul DeSousa's laboratory in Edinburgh. This has recently been completed and shipment of embryos to Edinburgh begun in August 2006.

Attempts to derive hES cell lines from embryos is also about to begin in Manchester, at Centres 0067 and 0175 (both licensed for this purpose), and in due course the North West Embryonic Stem Cell Centre (as yet unlicenced, pending inspection).

Lay summary of research undertaken

Immature eggs and eggs which have failed to fertilise are not suitable for clinical IVF treatment and are normally discarded. In this project, these eggs have been used to establish and optimise methods for the recovery of clinically unusable oocytes by in vitro maturation and/or parthenogenic activation or fertilisation, in order to generate viable embryos for human embryonic stem cell derivation.

Our results have shown that maturation of immature eggs can be achieved in the laboratory using culture fluid supplemented with various factors which encourage growth. We are studying the expression of various gene patterns in eggs matured in the laboratory and comparing them to normal healthy eggs. At the moment, eggs matured in this way cannot be used for clinical treatment as not enough is known about the normalcy of these eggs but results from this project will increase this knowledge leading to the use of immature eggs for IVF treatment in the future.

Parthenogenic activation involves an egg being artificially stimulated by chemicals in order to trigger embryo development. Alternatively, eggs which have failed to fertilise may be re-inseminated using donor sperm. Eggs which have failed to fertilise after standard IVF treatment are being treated by both of these methods in the laboratory. Eggs which successfully fertilise after such treatment are cultured in the incubator for up to 7 days and carefully monitored. The normality of such embryos is established by analysing DNA prepared from the embryos for expression of genes which may act as markers of normal development.

The eventual aim of the project is to derive human embryonic stem cell lines from embryos generated using these methods. Any such stem cell lines will be derived in a purpose built facility and will undergo a variety of tests to establish the normality of the cell lines before they will be submitted to the UK Stem Cell Bank.

Issues for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered in this inspection
Peer review – not required

Report compiled by:

Name……Chris O'Toole…….

Designation……HFEA Head of Research Regulation…….

Date…29 September 2006……

Appendix A: Centre Staff interviewed

Daniel Brison, Person Responsible R0026 (Centres 0033 and 0067) R0170/0171 (Centres 0033, 0067 and 0175
Sue Kimber, Person Responsible R0026 (Centre 0175) and Nominal Licensee R0170/071 (Centre 0175)

Four other members of the team took part in meetings with the inspection team.

Appendix B: Licence history for previous 3 years

R0026

Status	Licence	Type	Active From	Expires
Active	R0026/12/a	Research Project	01/02/2004	31/01/2007
Expired	R0026/11/a	Research Project	16/01/2001	31/01/2004

R0026/12/a was issued with one condition:

- The creation of embryos explicitly for use in research must not be undertaken until the following have been submitted for consideration by a Licence committee of the Authority:

  (i) local ethics committee approval,

  (ii) further discussion as to why the creation of embryos specially for research is necessary or desirable for the proposed research project,

  (iii) amended patient information and consent forms for potential egg donors

  (iv) evidence of appropriate consent for the use of donor sperm for this purpose.

  (v) evidence of the availability of appropriate counselling for donors

R0026/11/a was issued with one condition:

- If the inner cell mass or any cells derived from it are removed from the intact embryo, they must be fixed or lysed immediately

R0170/0171

Status	Licence	Type	Active From	Expires
Active	R0170/1/b R0171/1/b	Research Project	01/06/2006	31/12/2009
Replaced by new version	R0170/1/a R0171/1/a	Research Project	01/01/2006	31/12/2009
Expired	R0156/2/a	Research Project	27/10/2004	31/10/2005

R0156 was replaced by R0170/0171 for administrative purposes.

R0170/0171 were issued without any additional conditions.

R0156/2/a was issued with one additional condition:

- Once 200 embryos have been created as part of the project, the Person Responsible must contact the Authority to communicate that fact, to update the Authority about the results of the research and to demonstrate whether the creation of more embryos is necessary. In addition the Authority would like to be told how many blastocysts have been derived from the embryos used.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO INSPECTION REPORT

Centre Numbers: 0033, 0067 and 0175

Name of PRs: Daniel Brison and Sue Kimber

Date of Inspection: 19 September 2006

Date of Response: 20 October 2006

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

We will start minuting meetings for project R0026 when the new CRUK postdoc starts (Jan 2007). Our new ACUsys database will in the future allow us to record the fate of oocytes used for research. This is due to arrive Jan 2007.

Name: Daniel Brison, Sue Kimber

Date: 20 October 2006

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).
