Licence Committee - minutes

Thursday, 5 November 2015

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

Centre 0175 (University of Manchester) and centre 0067 (St Mary's Hospital) – application for research licence renewal, R0026

Committee members	Andy Greenfield (Chair) Anita Bharucha Kate Brian Margaret Gilmore	
Members of the Executive	Sam Hartley	Head of Governance and Licensing
Legal Adviser	Graham Miles	Blake Morgan

Declarations of interest:

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members

The following papers were considered by the committee:

- Research Inspection reports x2
- Executive summary
- Application forms x2
- Peer review
- Previous licensing minutes for the last three years
  - 10 January 2014 Interim inspection report
  - 19 November 2012 Renewal inspection report

1. Consideration of application

1.1. The committee noted that research project R0026 'In-vitro development and implantation of normal human pre-implantation embryos and comparison with uni- or poly-pronucleate pre-embryos' was first licenced in 1996. The current licence is due to expire on 31 December 2015. The committee also noted that although this research project was currently conducted across three centres, only two centres would be continuing the research. The renewal was therefore for centres 0175 (University of Manchester) and 0067 (St Mary's Hospital) only.

1.2. The committee noted that at the time of inspection, which took place on 7 July 2015, there were three areas of practice requiring improvement, relating to counselling, written information for patients, and record-keeping (with the latter area of practice relating only to centre 0067).

1.3. The committee had regard to its decision tree. The committee was satisfied that the application was submitted in the form required and contained the supporting information required by General Direction 0008. Furthermore, it was satisfied that the appropriate fees had been paid. The committee noted that the application was made by the Person Responsible (PR) for the research project.

1.4. The committee was satisfied that the PR possesses the required qualifications and experience and that the character of the PR is such as is required for supervision of the licensed activities. It was further satisfied that the PR will discharge his duties under section 17 of the Act. The committee noted that the inspectorate was satisfied that the PR had satisfactorily completed the PR entry programme.

1.5. The committee was satisfied that the premises to be licenced are suitable for the conduct of licensed activities as stated by the inspectorate.

1.6. The committee was satisfied that the renewed research licence would not apply to more than one research project and that the activities applied for, permitted under the Act, are creation of embryos; keeping embryos; use of embryos; and storage of embryos.

1.7. The committee found that the use of human embryos is necessary as knowledge from animal models now needs to be tested by experimentation in order to derive direct knowledge of human embryonic development. This can only occur using human embryos.

1.8. The committee was further satisfied that the activities to be licensed are necessary or desirable for the following purposes, specified in paragraphs 3A(1) and 3A(2) of Schedule 2 to the Act, for the following reasons:

- promoting advances in the treatment of infertility:

  The proposed research will examine normal and abnormal embryo development. This knowledge and understanding of human embryogenesis may assist in identifying embryos with improved or superior viability. This may lead to improvements in fertility treatment.

- increasing knowledge about the causes of miscarriage:

  Understanding early human embryo development and the regulation of cell fate and its effects on implantation may be relevant to understanding why embryos do not develop to term, i.e. miscarry.

- increasing knowledge about the development of embryos:

  Studies of the regulation of cell fate and pluripotency and mechanisms of implantation will contribute directly to our understanding of early human embryo development.

1.9. The committee was satisfied that the proposed research project does not involve the mixing of sperm with the egg of an animal.

1.10. The committee was satisfied that the research project had received the necessary level of research ethics.

1.11. The committee noted that the recommendation from the inspectorate was that the centre's research licence be renewed for a period for three years without any additional conditions.

2. Decision

2.1. The committee noted with some concern that three major non-compliances were identified at inspection, but that the PR had committed to addressing these. In relation to the provision of counselling, although noting the PR's commitment to addressing this non-compliance, the committee encouraged the PR to ensure that counselling and the taking of consent is not viewed purely as a paper exercise; the amendment of patient information sheets is a positive step in addressing this non-compliance but this should be reinforced by staff ensuring that patients donating frozen embryos and eggs are given a suitable opportunity to receive proper counselling.

2.2. The committee agreed to renew the research licence for project R0026 at centre 0067 and 0175 for a period of three years with no additional conditions.

2.3. The licensed activities are:

- creation of embryos
- keeping embryos
- use of embryos
- storage of embryos

2.4. The committee noted that the licence covering this project at centre 0033 would expire on 31 December 2015 without renewal. It noted that there is no application to renew the licence at centre 0033 and that the PR had informed the inspector that no research was being conducted at this centre and there were no samples in storage. Accordingly, the licence at centre 0033 will expire on 31 December 2015 and will not be renewed.

3. Chair's signature

3.1. I confirm this is a true and accurate record of the meeting.

Signature

Name

Andy Greenfield

Date

13 November 2015

Research Renewal Inspection Report

Purpose of this inspection report

The HFEA licenses and monitors establishments undertaking human embryo research. This is a report of an inspection, carried out to assess whether this centre complies with essential requirements when carrying out such research. Licences for individual research projects can be granted for up to three years and this report provides information on the centre's application for a renewal of its existing licence. The Authority's Licence Committee uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 7 July 2015

Purpose of inspection: Renewal of a licence to carry out research

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection, and communications received from the centre.

Inspectors: Vicki Lamb, Karen Conyers

Date of Licence Committee: 5 November 2015

Centre Details:

Project title	In-vitro development and implantation of normal human pre-implantation embryos and comparison with uni- or poly-pronucleate pre-embryos.
Centre names and numbers	St Mary's Hospital (0067)
Research project number	R0026
Centre address	Regional IVF and DI Unit, The Department of Reproductive Medicine St Mary's Hospital Whitworth Park Manchester, M13 0JH
Person Responsible (PR)	Daniel Brison
Licence Holder (LH)	Sue Kimber
Treatment centres donating to this research project	0007 Hewitt Fertility Centre 0008 Midland Fertility Services 0033 Manchester Fertility
Date licence issued	1 January 2013
Licence expiry date	31 December 2015
Additional conditions applied to this licence	None

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Section 1: Summary report

Brief description of the centre and its licensing history:

Centre 0067 is a treatment, storage and research centre. The current research project, entitled “In-vitro development and implantation of normal human pre-implantation embryos and comparison with uni- or poly-pronucleate pre-embryos” (R0026), was first licensed in June 1996.

The current licence is due to expire on 31 December 2015, having been renewed for three years by a Licence Committee on 19 November 2012. There are no additional conditions on the licence.

Summary for licensing decision:

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

Administrative requirements:

- the centre has submitted an appropriately completed application form
- the centre has submitted the supporting information required by General Direction 0008, including evidence of ethics approval and patient information and consent forms
- the application has designated an individual to act as the Person Responsible (PR)
- the proposed licence applies to one project of research
- the centre has submitted fees to the HFEA in accordance with requirements

Research activities applied for:

An application has been made for the following activities for the purpose of research:

- Creation of embryos in vitro
- Keeping embryos
- Use of embryos
- Storage of embryos

The current licence includes the purpose ‘creation of embryos in vitro’. The PR wishes to retain this purpose on the renewed licence in order to create embryos through chemical activation. The peer reviewer supports this.

The proposed research project does not involve the derivation of human embryonic stem cell lines for human application. Research licence conditions (RLC) R41-89 are therefore not applicable to this research project.

Purposes for which research activities may be licensed:

The research project is currently licensed for the following purposes:

- Promoting advances in the treatment of infertility;
- Increasing knowledge about the causes of miscarriage;
- Developing more effective techniques of contraception;
- Increasing knowledge about the development of embryos;

But, having considered the direction of the research, the PR now only wishes the project to be licensed for:

- Promoting advances in the treatment of infertility;
- Increasing knowledge about the causes of miscarriage;
- Increasing knowledge about the development of embryos.

The PR and peer reviewer consider that the research project will meet the purposes defined in Schedule 2 3A (1) and (2) to the HF&E Act 1990 (as amended) as follows:

- Promoting advances in the treatment of infertility

  The PR has stated: The aim of this project is to understand the way in which human embryos develop normally and abnormally in culture. In particular, we study the regulation of cell fate in embryos, in terms of survival, maintenance of pluripotency, and differentiation/cell lineage specification, and expression of molecules involved in embryo development, and the implantation process. We have a particular interest in how the in vitro environment and IVF manipulations impact on this, for example the way in which growth factors regulate cell fate, the influence of DNA damage in sperm on embryonic development, or the impact of cryopreservation on embryonic development, gene expression and implantation. This work has lead to an assessment of the role of growth factors in embryo culture medium, the influence of DNA damage in sperm on fertility treatment, and the possible role of oocyte activation in fertility treatment.

  The peer reviewer agrees and has stated: The proposed research will examine normal and abnormal embryo development in relation to (i) gene expression, in particular in relation to the regulation of cell fate and lineage allocation; (ii) different cryopreservation procedures; (iii) DNA damage in sperm used to achieve fertilization; (iv) exposure to certain environmental factors. All these may yield information increasing knowledge and understanding of human embryogenesis that may lead to improvements in fertility treatment.

- Increasing knowledge about the causes of miscarriage

  The PR has stated: Understanding early human embryo development and the regulation of cell fate and pluripotency and implantation may be relevant to understanding why embryos do not develop to term, i.e. miscarry.

  The peer reviewer agrees and has stated: Embryos that are developing abnormally may still implant and lead to pregnancy. Such pregnancies may fail after implantation and result in miscarriage. Through greater understanding of normal and abnormal development, and how abnormalities may arise and possibly be prevented, the incidence of such abnormalities following fertility treatment, and of resulting miscarriages, may be reduced.

- Increasing knowledge about the development of embryos

The PR has stated: Understanding early human embryo development and the regulation of cell fate and pluripotency and implantation may be relevant to understanding why embryos do not develop.

The peer reviewer agrees and has stated: The proposed research will examine normal and abnormal embryo development in relation to (i) gene expression, in particular in relation to the regulation of cell fate and lineage allocation; (ii) different cryopreservation procedures; (iii) DNA damage in sperm used to achieve fertilization; (iv) exposure to certain environmental factors. All these may yield information increasing knowledge and understanding of human embryogenesis that may lead to improvements in fertility treatment.

Prohibited research activities:
The activities to be licensed are not prohibited by the HF&E Act 1990 (as amended) including those activities specifically prohibited by Sections 3, 3ZA, 4 or 4A, or by Schedule 2, paragraph 3 of the Act.

Use of embryos:
The peer reviewer states that the use of human embryos is necessary for this research project because: The proposed research will apply knowledge and techniques that have been derived from and refined using animal models to the human embryo; it is appropriate that this knowledge and technology is now to be applied to human embryos.

PR considerations:
The PR is suitable and has discharged their duty under Section 17 of the HF&E Act 1990 (as amended).

Premises:
The premises are suitable.

Recommendation:

The Licence Committee is asked to note the areas of practice that require improvement. The PR has agreed to comply with the following recommendations within the time-frames set out in this inspection report.

Major areas of non-compliance:

- The PR should ensure that patients donating fresh or frozen embryos are offered the opportunity to receive counselling about the implications of their donation.
- The PR should review the written patient information and ensure that all the requirements of standard licence conditions are included.
- The PR should review the processes for keeping records of embryos donated to research and the research project to which they have been donated.

The inspection team recommends the renewal of the centre's licence for a period of three years without additional conditions, subject to the recommendations made in this report being implemented within the prescribed timescales.

The inspection team recommends that the licence issued should include the following activities that the centre has applied for:

- Creation of embryos in vitro
- Keeping embryos
- Use of embryos
- Storage of embryos

For the following purposes:

- Promoting advances in the treatment of infertility
- Increasing knowledge about the causes of miscarriage
- Increasing knowledge about the development of embryos

Section 2: Summary of the research project

This section summarises information submitted in the research licence application and from the Peer Reviewer.

Lay summary of the research project:

We plan to continue our current project to understand early human embryo development by studying sperm, eggs and embryos donated by IVF patients at our participating centres. For this we use some eggs and embryos which have been frozen in IVF procedures. We analyse culture the embryos up to day 8 after fertilisation, well before the limit of 14 days post-fertilisation. We are looking at the effect of freezing on how the embryos develop using molecules which tell us about their health and normality and their ability to implant in the wall of the womb and develop. We are looking at how the different cells in the embryo differ from one another and how naturally occurring molecules added to the culture medium affect the components that the embryos make, and their ability to implant. These studies will help us to be able to identify what the normal time course of molecular changes are in early human development and what goes wrong. This work will ultimately benefit IVF treatments by increasing our understanding of human embryo development and implantation.

Objectives of the research:

We aim to continue our current licence aims to include:
1) studies of gene expression in order to understand normal and abnormal embryonic development and in particular the regulation of cell fate and lineage allocation, including analysis of individual embryonic cells, and genes involved in implantation. We will also include in this analysis of genes involved in the implantation process.
2) the impact of cryopreservation, including vitrification, on oocyte and embryo development.
3) the impact of sperm DNA damage on embryonic development, including the influence of the environment e.g. lifestyle factors and environmental exposures to compounds such as bisphenol-A and nicotine (advanced glycosylation end products; known as AGEs) on sperm parameters and DNA integrity.
4) the impact of the environment on oocyte and embryonic development, including growth factors, and AGEs, and the extracellular matrix molecular hyaluronate.
In some studies human embryos may be created by chemical activation. These studies are important and have proved very revealing in the past (Sneddon et al., 2011) as a model of abnormal human embryo development.

Summary of the research undertaken to date:

Our studies of sperm, eggs and embryos donated by IVF patients at our participating centres has provided insights into early human embryo development. We have found that sperm carry marks of damage to their DNA, some of which may be associated with the man’s lifestyle, exposure to chemicals, occupation and eating habits, and may also be related to embryo development and the outcome of the IVF treatment cycle. We have also shown that freezing of oocytes using vitrification causes changes to the genes involved in oocyte health, with the type of culture medium used being the most important influence. Our studies of genes in embryonic development have revealed new genes and pathways which might be important in regulating embryo development and implantation into the wall of the womb. We have also measured this directly in the laboratory as the ability of the

embryo to respond to molecules found naturally in the environment and to attach to cells and form an outgrowth. This work will ultimately benefit IVF treatments by increasing our understanding of human embryo development and implantation.

Donation and use of embryos:

In the period from 1 January 2014 to 31 December 2014, the project has used 60 fresh and 63 frozen embryos. The PR estimates that a maximum of 200 frozen and 400 fresh embryos will be used in each year of the renewed licence. The estimated increase in embryo usage in the project is due to extra funding that has become available and a consequent increase in staff working on the project.

Section 3: Details of the inspection findings

Principle:

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

What we inspected against:

Research Licence Conditions (RLC) R23, R24, R26, R27, R28, R29, CoP Guidance Note 22.

What the centre does well.

Observations during the inspection provided assurance that the special status of the human embryo is respected:

- processes, documented in standard operating procedures (SOPs), are in place to ensure that no embryo obtained for the purposes of any research project is kept or used for any purpose other than the purposes of that research project (RLC R23). Staff training and their close supervision ensure procedures are adhered to, preventing the use of donated embryos in unlicensed activities.
- recruitment practices ensure that no money or other benefit is given to those donating embryos to research unless authorised by directions (RLC R24).
- each embryo used in the research project is uniquely labelled (RLC R26)
- documented procedures have been established, implemented and complied with to ensure that clinical and research roles are separated (RLC R27).
- procedures ensure that embryos do not develop after 14 days or the primitive streak has appeared (if earlier) (RLC R28). The culture and manipulation of each embryo is recorded in the laboratory records, which are regularly reviewed.

What they could do better.

Nothing noted.

Principle:

5. Provide prospective and current patients and donors with sufficient, accessible and up-to-date information in order to allow them to make informed decisions.

6. Ensure that patients and donors have provided all relevant consents, before any licensed activity is undertaken.

What we inspected against:

Information, counselling and consent; CoP Guidance Note 22, RLC R18, R19, R20, R21, R22. Consent for storage; CoP Guidance Note 22, RLC R31, R32, R33, R34, R35, R36, R37, R38, R39.

What the centre does well.

Provision of information and counselling to those consenting to donate to research

Prior to giving consent, those donating to research should be provided with relevant information, and given a suitable opportunity to receive counselling about the implications of their donation. Observations and discussion during the inspection provided assurance that:

- information is provided to patients by trained personnel in a manner and using terms that are easily understood (RLC R21). The competence of staff at the recruiting centres to provide information in this way, and to seek consent, has been assessed.
- a designated individual, who is not directly involved in the patient's treatment, is available to discuss with the patient the project of research and the possibility of donating material to the project (RLC R22). Contact details for this designated individual are provided in the patient information.

Consent for storage

Stored gametes and embryos are obtained only from centres to which a HFEA licence or third party agreement applies (RLC R31, R32, R33).

No gametes or embryos are kept in storage for longer than the statutory storage period (RLC R35, R36, R38 and R39), or the period specified in a patients' consent if less than the statutory storage period. This was assessed by reviewing the centres record of stored gametes and embryos. A bring-forward system is maintained, ensuring gametes and embryos are stored only within the statutory storage period or the patients' consent.

What they could do better.

While patients donating fresh embryos are offered counselling, those donating frozen embryos to research are not given a suitable opportunity to receive proper counselling about the implications of their donation (RLC R18) (see recommendation 1).

The written patient information does not include all required elements; prior to giving consent patients are not told whether any information will be fed back to them (RLC R19) (see recommendation 2).

Principle:

8. Ensure that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose.

What we inspected against:

Premises and facilities; RLC R10.

What the centre does well.

Premises and facilities

The premises and facilities are secure, clean, well maintained and are suitable for carrying out the licensed activities (RLC R10).

What they could do better.

Nothing noted.

Principle:

10. Maintain proper and accurate records and information about all licensed activities

What we inspected against:

Information and record keeping; RLC R13, R14, R15, R16, R17, General Direction 0002.

What the centre does well.

Embryo storage and usage records are in a form that prevents the removal of data (RLC R16).

Since the last inspection, the centre has submitted the annual research information and data sheet to the HFEA within the required timeframes (RLC R14 & General Direction 0002).

What they could do better.

During a review of embryo donation and storage logs at centre 0067, the inspection team found one case where embryo fate had not been recorded in the relevant log. As a result, the use of those embryos was not clear, although their fate was eventually established. Whilst the fate of the embryos was ultimately determined, the inspection team were seriously concerned that this lack of clarity demonstrated a lack of control over the logs and potentially over the correct usage, and recording of usage, of embryos by the researchers (RLC R13) (see recommendation 3).

Principle:

11. Report all adverse incidents (including serious adverse events and reactions) to the HFEA, investigate all complaints properly, and share lessons learned appropriately

What we inspected against:

Incidents; RLC R40.

What the centre does well.

Processes are in place to detect, report to the HFEA and investigate adverse incidents (RLC R40).

What they could do better.

Nothing noted.

Principle:

12. Ensure that all licensed research by the centre meets ethical standards, and is done only where there is both a clear scientific justification and no viable alternative to the use of embryos.

What we inspected against:

HF&E Act 1990 (as amended), Schedule 2 (3(5) and 3A).

What the centre does well.

The research project has been approved by the NRES Committee South Central - Berkshire B Ethics Committee. Evidence was provided by the PR that this approval remains active and covers the research activity described in the licence application.

The research project does not include any activities that have been prohibited by the HF&E Act 1990 (as amended).

A peer review was obtained for this renewal application and it is supportive of the licence renewal. Justifications that the activities to be licensed are necessary or desirable to meet the statutory purposes, have been provided by the PR and the peer reviewer, as discussed in detail in the 'Summary for Licensing Decision'. The PR and peer reviewer have also provided reasons why the use of human embryos is necessary.

What they could do better.

Nothing noted.

Principle:

13. Conduct all licensed activities with regard for the regulatory framework governing treatment and research involving gametes or embryos within the UK, including:

- maintaining up-to-date awareness and understanding of legal obligations;
- responding promptly to requests for information and documents;
- co-operating fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare.

What we inspected against:

Licensing; RLC R1, R2, R3, R5, R6. The Person Responsible; HF&E Act 1990 (as amended) Section 16 & 17, RLC R8, R9.

What the centre does well.

Licensing

Inspection of the licensed premises indicated that all licensed research activities are performed only on the premises specified on the licence and under the supervision of the PR (RLC R1, R2).

The Person Responsible

The PR has a key role to play in implementing the requirements of the HF&E Act 1990 (as amended) and is the person under whose supervision the licensed activities are authorised. The PR has the primary legal responsibility under Section 17 of the HF&E Act 1990 (as amended) to secure:

- that suitable practices are used in undertaking the licensed activities;
- that other persons working under the licence are suitable and;
- that the conditions of the licence are complied with.

The PR has academic qualifications in the field of biological sciences and has more than

two years of practical experience which is directly relevant to the activity to be authorised by the licence (HF&E Act 1990 (as amended), Section 16 (2) (c)). The PR has successfully completed the HFEA PR Entry Programme (PREP number R/1020/7). The inspection team considered that the PR has fulfilled his responsibilities under Section 17 of the HF&E Act 1990 (as amended).
What they could do better. Nothing noted

Section 4: Monitoring of the centre's performance

Following an interim inspection in 2013, a recommendation for improvement was made in relation to one 'other' area of non-compliance.

The PR provided information and evidence that the recommendation was fully implemented within the agreed timescale.

Section 5: Areas of practice that require the attention of the Person Responsible

The section sets out matters which the inspection team considers may constitute areas of non-compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Act, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical areas of non-compliance

A critical area of non-compliance is an area of practice which poses a significant direct risk of causing harm to a patient, donor or to an embryo. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

Major areas of non-compliance

A major area of non-compliance is a non-critical area of non-compliance:

- which poses an indirect risk to the safety of a patient, donor or to an embryo through the procurement, use, storage or distribution of gametes and embryos, which do not comply with the centre's licence;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several "other" area of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. While patients donating fresh embryos are offered counselling, those donating frozen embryos to research are not given a suitable opportunity to receive proper counselling about the implications of their donation (RLC R18).	The PR should ensure that patients donating fresh or frozen embryos are offered the opportunity to receive counselling about the implications of their donation. The PR should inform the inspector of the actions taken to ensure counselling is offered to this patient cohort by the time this report is considered by the Licence Committee.	We have amended our patient information sheet to include this, as advised.	This response and additional correspondence between the PR and the inspector demonstrates that patients will now be offered counselling. No further action.
2. The written patient information does not include all required elements; prior to giving consent patients are not told whether any information will be fed back to them (RLC R19).	The PR should review the written patient information and ensure that all the requirements of standard licence conditions are included. The PR should provide the inspector with a copy of the updated patient information by 7 December 2015. In the time before the written	We have amended our patient information sheet as advised and submitted this for ethical approval.	The PR has confirmed that the patient information has been reviewed to reflect the current aims of the research project. In separate correspondence the PR has agreed to submit a copy of the patient information by 7 December. Until the revised patient

	patient information is finalised, the PR should ensure that patients are given verbal information that covers all the requirements of standard licence conditions and confirm that this is being done by the time this report is presented to a Licence Committee.		information has ethical approval, patients are being given this information verbally. Further action required.
3. During a review of embryo donation and storage logs at centre 0067, the inspection team found one case where embryo fate had not been recorded in the relevant log. As a result, the use of those embryos was not clear, although their fate was eventually established. Whilst the fate of the embryos was ultimately determined, the inspection team were seriously concerned that this lack of clarity demonstrated a lack of control over the logs and potentially over the correct usage, and recording of usage, of embryos by the researchers (RLC R13)	The PR should review the processes for keeping records of embryos donated to research and the research project to which they have been donated. A summary report of this review, including any corrective actions to be taken and the timescale for their implementation, should be provided to the inspector by 7 October 2015. Three months after implementation of any corrective actions the PR should audit the records of embryos donated to research for all the embryos donated to this project since the implementation of the corrective actions. A summary report of this audit should be provided to the inspector by 7 March 2016.	We have reviewed this process immediately following the inspection and advised the inspector of our findings. In short, as PR I believe that the existing longstanding system was fully in compliance with the CoP and allowed me as PR to fulfill my legal obligation to trace the fate of all embryos donated to research. However the system relied on tracking an anonymised code number for each embryo from databases held at centres 0067 or 0175 through to the researcher's individual records. As these records are legally under the control of the PR this system was sound and allowed the necessary separation between researcher and identifying patient information. However our review meeting	The PR provided a summary report of the review of the logs within the required timescale, and provided a brief synopsis of that review here. An audit of the system is due by 7 March 2016. Further action required.

		concluded that with our expansion in research activities, the system was no longer fit for purpose and was (1) cumbersome, (2) made our routine audits more cumbersome than necessary, and (3) also made external inspection more difficult. As a result we have proposed a modified system whereby all users of research embryos will, in addition to their own individual research records, maintain an integrated electronic database held at the University of Manchester on a secure shared server. This database will be updated by each researcher as they use embryos, as a condition of continued use. This database will be regularly audited against the donation database held at centres 0067 and 0175.	

‘Other’ areas of practice that require improvement

‘Other’ areas of practice that require improvement is any area of practice, which cannot be classified as either a critical or major area of non-compliance, but which indicates a departure from good practice.

Area of practice and reference	Action required and timescale	PR Response	Executive Review
None			

Additional information from the Person Responsible
We would like to thank the inspection team for a useful and positive inspection with suggestions for improvements in practice which we are very happy to take on.