# Licence Committee - minutes

## Centre 0102 Guy's Hospital

## Renewal Research Licence – Research Project R0075

HFEA Level 2, 10 Spring Gardens, London SW1A 2BU

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| Committee members | Andy Greenfield (Chair)<br>Ruth Wilde<br>Kate Brian | |
| Members of the Executive | Richard Chamberlain<br>Dee Knoyle (Observer)<br>Catherine Burwood (Observer) | Committee Secretary<br>Committee Secretary<br>Senior Governance Manager |
| Legal Adviser | Graham Miles | Blake Morgan LLP |
| Specialist Adviser | | |
| Observers | | |

## Declarations of interest:

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

## The committee 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:

Renewal inspection report
Renewal Application
Publication
Peer Review
Previous licensing minutes

- 26 February 2016 – interim inspection report
- 7 May 2015

## 1. Consideration of application

**1.1.** The committee noted that the application for renewal of licence for the project entitled "Improving methods for preimplantation genetic diagnosis of inherited genetic disease" was received from the PR, Dr Dusko Ilic, of the Stem Cell and Embryology Research Laboratories, 11th Floor Tower Wing, Guy's Hospital, London SE1 9RT.

**1.2.** The committee noted the application was for a renewal of a licence to carry out research and the inspection report covers the performance of the centre since the last inspection in 2015 when it was renewed by the Licence Committee on 7 May 2015. The current licence was due to expire on 31 August 2018.

**1.3.** All documents required were supplied.

**1.4.** The committee noted that the research centre was renowned for its research, including that for making improvements in preimplantation genetic diagnosis (PGD), and that the application was strongly supported by the peer reviewer who confirmed that the research required the use of human embryos and had great scientific potential.

**1.5.** The committee noted the reasons for the previous licence being approved, given in the minutes of the previous application from the centre, which was approved by the Licence Committee on 7 May 2015.

**1.6.** The committee noted that the inspectors found only one major area of non-compliance, which was that the advice given to patients did not mention how patients could access counselling about the implications of their donation. It was noted that this requirement had now been added to an update of the patient information leaflet, which an inspector had seen.

**1.7.** The committee had regard to its decision tree. It noted the only area of non-compliance had been rectified since the visit by changes to the patient information leaflet.

## 2. Decision

**2.1.** The committee agreed to the renewal of the licence to carry out research at centre 0102 with no additional conditions, to run for a further three years until 31 August 2021. The following activities will apply to the licence:

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

**2.2.** The committee was 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 of the HF&E Act 1990 (as amended):

- Increasing knowledge about serious disease or other serious medical conditions

  Various assays, such as the detection of microRNAs released into culture medium, may be methods for detecting genetically abnormal embryos and result in increased knowledge of underlying cellular and molecular abnormalities.

- Increasing knowledge about the causes of any other congenital disease or congenital medical condition.

  The proposed research may result in improved understanding of serious genetic, including mitochondrial, disease and also understanding of the biopsy processes used in PGD.

- Promoting advances in the treatment of infertility.

  Some of the mutations causing genetic diseases identified by PGD in embryos will be modelled in stem cells derived from these; some of these mutations cause infertility e.g. Robertsonian translocations in males, cystic fibrosis in males, fragile X syndrome in women.

- Developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation.

  The aims of the current research are to improve methods for detection of genetic disorders in preimplantation embryos

- Increasing knowledge about the development of embryos

  In addition to leading to improved understanding of normal and abnormal embryo development in general, by comparing the genetic constitution of inner cell mass cells isolated for stem cell research with trophectoderm, from which it is separated, the researchers can directly compare the two types of tissues, and thus establish the validity of different genetic test methodologies (PGD and PGS) made at the blastocyst stage as well as improve understanding of the differentiation processes required to establish these cells.

**2.3.** The PR no longer wished the following activity to appear on the licence – “Increasing knowledge about the causes of miscarriage”.

## Chair’s signature

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

**Signature**

**Name** Andy Greenfield

**Date** 1 August 2018

# 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:** 29 March 2018

**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:** Dr Vicki Lamb

**Date of Licence Committee:** 12 July 2018

## Centre Details:

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|---|---|
| **Project title** | Improving methods for preimplantation genetic diagnosis of inherited genetic disease and predicting embryo quality |
| **Centre name** | Guys Hospital |
| **Centre number** | 0102 |
| **Research project number** | R0075 |
| **Centre address** | Stem Cell and Embryology Research Laboratories<br>11th Floor, Tower Wing<br>Guy's Hospital<br>London<br>SE1 9RT |
| **Person Responsible (PR)** | Dr Dusko Ilic |
| **Licence Holder (LH)** | Mr Yakoub Khalaf |
| **Treatment centres donating to this research project** | 0102 Guys Hospital |
| **Date licence issued** | 1 September 2015 |
| **Licence expiry date** | 31 August 2018 |
| **Additional conditions applied to this licence** | None |

# Contents

## Section 1: Summary report

### Brief description of the centre and its licensing history:

Centre 0102 is a treatment, storage and research centre. The research project, entitled 'Improving methods for preimplantation genetic diagnosis of inherited genetic disease and predicting embryo quality' (R0075), was first licensed in July 1994.

The current licence is due to expire on 31 August 2018, having been renewed for three years by a Licence Committee on 7 May 2015, following a desk-based assessment. There are no additional conditions on the licence. The research premises were last inspected on 10 December 2015.

### 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. Evidence of ethics approval and patient information and consent forms were reviewed during the inspection
- 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 proposed research project does not involve the derivation of human embryonic stem cell lines for human application. Research licence conditions R41-89 are therefore not applicable to this research project.

Purposes for which research activities may be licensed:

The activities specified above are required for the following purposes, as defined in Schedule 2 3A (1) and (2) of the HF&E Act 1990 (as amended):

- Increasing knowledge about serious disease or other serious medical conditions

  This activity is currently on the research licence and, although the PR had not indicated he wished this to be on the renewed licence, the peer reviewer considers that this activity is relevant to the current research. This was discussed with the PR during the inspection and he is happy for this activity to appear on the renewed licence.

- Increasing knowledge about the causes of any other congenital disease or congenital medical condition

  This activity is currently on the research licence. The PR has stated: '*Work includes understanding more about serious genetic and mitochondrial diseases, and also understanding about the biopsy processes used in PGD.*'

- Promoting advances in the treatment of infertility

  This activity is currently on the research licence. The PR has stated: *'Some of the genetic diseases from which we will derive stem cells from PGD embryos unsuitable for transfer involve infertility as a result specifically of the genetic condition - e.g. Robertsonian translocation in males, cystic fibrosis in males, fragile X syndrome in women.'* The peer reviewer did not consider that the research is likely to contribute to this purpose.

- Developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation

  This activity is currently on the research licence and, although the PR had not indicated he wished this to be on the renewed licence, the peer reviewer considers that this activity is relevant to the current research. The peer reviewer has supported this by stating: '*The aims of the current research were to improve methods of detecting genetic disorders in preimplantation embryos.'*
  This was discussed with the PR during the inspection and he is happy for this activity to appear on the renewed licence.

- Increasing knowledge about the development of embryos

  This activity is currently on the research licence. The PR has stated: *'By comparing the genetic constitution of inner cell masses isolated for stem cell research with trophectoderm from which it is separated, we can examine the constituency of findings between the two types of tissues, and thus establish the validity of genetic tests (PGD and PGS) made at the blastocyst stage.'*
  The peer reviewer has supported this by stating: '*The aims of current research were to increase understanding of human embryo development.'*

The PR no longer wishes the following activity to appear on the licence:

- Increasing knowledge about the causes of miscarriage

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 use of human embryos is considered necessary. This is based on the application and comments by the peer reviewer: *'As the research questions specifically apply to human embryological problems and the aims of preimplantation genetic testing it is self-evident that the use of human embryos is required'.*
The renewal application proposes the use of 50 frozen and 50 created embryos each year for the next three years.

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 that at the time of the inspection there was one major area of non-compliance which has now been addressed by the PR:

Major area of non-compliance:

- The PR should ensure that patients donating embryos are offered the opportunity to receive counselling about the implications of their donation.

The inspection team considers that, overall, there is sufficient information and evidence available to recommend the renewal of the centre's licence for a period of three years without additional conditions.

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:

- Increasing knowledge about serious disease or other serious medical conditions
- Increasing knowledge about the causes of any other congenital disease or congenital medical condition
- Promoting advances in the treatment of infertility
- Developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation
- 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:

The researchers' work is aimed at both developing new approaches to diagnostic testing of preimplantation embryos, and increasing knowledge of the biology and genetics of early embryo development, with a view to understanding the basis of successful pregnancies and improving the chances of healthy offspring for couples undergoing preimplantation genetic diagnosis (PGD) and IVF procedures. They intend to work over the next three years, further developing this approach. Their aims will be: a) Improve the chances of healthy offspring by introducing and developing better strategies and protocols for embryo culture and testing b) Explore new avenues in modelling early human development to understand biology and genetics of human embryos.

### Objectives of the research:

The researchers wish to continue to improve their PGD and IVF programmes by introducing and developing better strategies and protocols for embryo culture and testing. They also wish to understand more about the biology and genetics of early human embryos. For the last few years they have explored embryo twinning. The blastomere separation technique of embryo splitting seems to be unsuitable for either clinical or research purposes. However, embryo bisection, a preferable method of cloning in veterinary medicine, has not yet been tested on human embryos. The researchers would like to investigate this approach in more detail.

### Summary of the research undertaken to date:

The researchers have addressed their aims in the following ways:
1) Embryo splitting is a strategy to increase the number of embryos available for research Embryo splitting provides the opportunity to obtain genetically identical embryos, a feature that is necessary for comparative research. Human embryo splitting has been previously reported. The results were, however, inconsistent. There are two technical approaches to embryo twinning: a) blastomere separation, and b) embryo bisection. They investigated whether the quality of the human embryos generated by twinning in vitro using blastomere separation is comparable to the quality of the embryos created by fertilisation. The morphokinetic data suggested that the human preimplantation development is subjected to a strict temporal control. Due to a 'developmental clock', the size of twin embryos was proportionate to the number of cells used for their creation. Furthermore, the first fate decision was somewhat delayed; the inner cell mass (ICM) became distinguishable later in the twin than in the normal blastocysts obtained through fertilisation. If an ICM was present at all, it was small and of poor quality. The majority of the cells in the twin embryos expressed ICM and trophectoderm markers simultaneously. Taken together, our data suggested that human twin embryos created in vitro by blastomere separation are unsuitable not only for clinical use but also for research purposes.
2) Investigating molecular mechanisms of natural twinning using high-resolution RNA sequencing. Discordant growth is a common complication of monochorionic/diamniotic pregnancies. In approximately 50% of cases the cause is unknown. The researchers studied the transcriptomes of two morphologically distinct ICMs within a single blastocyst using high-resolution RNA sequencing. The data indicated that the two ICM were at different stages of development; one was in the earliest stages of lineage commitment, while the other had already differentiated into epiblast and primitive endoderm. They

identified IGF1-mediated signalling as a likely molecular mechanism to play a key role in ICM growth and to be the major driver behind these differences.
3) Use of microRNAs (miRNAs) secreted into spent embryo culture medium as a biomarker for non-invasive embryo quality selection. MiRNAs are a group of small non-coding RNAs that are involved in regulating a range of developmental and physiological processes. Dysregulation of miRNA levels is observed in multiple diseases. Early studies showed that by analysing the expression profile of miRNAs in the tissue sample of a diseased person, it was possible to classify the disease into a specific subtype. Recently, it has been found that most cells release miRNAs in the extracellular environment. Since miRNAs are highly stable in circulation, they have generated intense interest as clinical biomarkers. In a collaboration effort with a Centre for Reproductive Medicine GENERA from Italy, we profiled with high reproducibility miRNAs secreted from human blastocysts in culture media, and explored this approach for non-invasive embryo selection.
4) Extending in vitro culture of human embryos post blastocyst stage. Due to experimental constraints it is nearly impossible to dissect molecular mechanisms of embryo development post-implantation and address the issues arising. We got involved in a collaboration with Magdalena Zernicka-Goetz's group from Cambridge in their attempts to establish an in vitro system to culture human embryos through implantation stages. Although, this is done in the absence of maternal tissues, still we can learn about reorganisation of embryonic lineages and organizing properties of human embryos.
5) Mitochondria maturation and segregation in early development. The researchers are investigating mitochondria maturation in preimplantation embryos. Oocyte and early embryonic mitochondria are typically spherical elements, 1µm in diameter with few, truncated cristae surrounding a matrix of high-electron density. From this structurally 'primitive' state, mitochondria undergo stage-specific structural transformations during the preimplantation period in which they elongate and develop an extensive array of cristae that completely traverse a matrix of progressively lower electron density. In the human, it is not until the early blastocyst stage that structural transformation takes place. It is thought that in early embryos initial ATP production and metabolism is through glycolysis and TCA. Only when mitochondria mature enough to get cristae, the metabolism switches to oxidative phosphorylation. Not only the morphology of mitochondria changes during development, their number also is differs depending on stage and cell type. One of the critical events in human development involving mitochondria is a segregation of mitochondrial DNA heteroplasmy in primordial germ cells. We got involved in a collaboration with Patrick Chinnery's group from Cambridge that is working on this and to be able to follow mitochondrial segregation during early development and formation of germ cells, we determined the number of mitochondria/cell in ICM.

## Donation and use of embryos:

The work last year concentrated on developing and improving methodologies for culturing and testing early embryos. This work involved the use of 397 frozen embryos. No fresh embryos were used. They analysed morphokinetics and developmental competence from either early (2-5 blastomeres) or late (6-10 blastomeres) cleavage stages.

## Peer review comments:

The peer reviewer's overall assess was: *'The research so far carried out has contributed to knowledge in the areas specified; this is evident from the progress reported here and from published work.*

*'This is an experienced team of researchers with considerable back up in terms of laboratory resources and supply of materials in the form of embryos that are donated for research so they have a good chance of achieving their aims.'*

## 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 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:

- necessary information is provided to patients prior to giving their consent (RLC R19 and R20).
- 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 centre 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 embryos are obtained only from centres to which a HFEA licence or third party agreement applies (RLC R32 and R33).

No embryos are kept in storage for longer than the statutory storage period (RLC 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 centre's records of stored embryos. A bring-forward system is maintained, ensuring embryos are stored only within the statutory storage period or the patients' consent.

What they could do better.

Patients donating frozen embryos to research are given information and provide their consent by post. The patient information provided to them does not mention that they can access counselling about the implications of their donation (RLC R18) (see recommendation 1).

**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.

A review of embryo storage and use records indicate that proper records are maintained (RLC R13 and R15). These 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.
Nothing noted.

**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 St Thomas's Hospital 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 and the proposed number of embryos to be used is justified.

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 suitable qualifications and experience for the activity authorised by the licence (HF&E Act 1990 (as amended), Section 16 (2)(ca)). The PR has successfully completed the HFEA PR Entry Programme (PREP number R/1184/8). The inspection team

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| considered that the PR has fulfilled his responsibilities under Section 17 of the HF&E Act 1990 (as amended). |
| What they could do better.<br>Nothing noted. |

## Section 4: Monitoring of the centre's performance

Following an interim inspection in 2015, no recommendations for improvement were made.

## 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" areas 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. The patient information does not mention that patients can access counselling about the implications of their donation (RLC R18). | The PR should ensure that patients donating embryos are offered the opportunity to receive counselling about the implications of their donation. | Our literature for the patients states that counselling is available to patients before, during and after this treatment. Technically, this availability | The PR has updated the patient information to include the offer of counselling. The patient information leaflet has been provided to the inspector. |

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| | The PR should inform the inspector of the actions taken to ensure counselling is offered to patients by the time this report is considered by the Licence Committee. | should cover any aspect of treatment/ storage and fate of embryos that patients need to have support with.<br>Following your suggestion, we specifically mentioned counselling contact in updated version of patient information sheet. | No further action. |

### ‘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 |
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