HFEA Licence Committee Meeting

10 July 2014

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

Minutes – Item 7

Centre 0037 (Glasgow Royal Infirmary) – Variation of Licence to Remove Licence Condition, and to Vary Licensed Premises Inspection Report

Members of the Committee: Andy Greenfield (lay) (Chair) David Archard (lay) Debbie Barber (professional) Jane Dibblin (lay)	Legal Adviser: Tom Rider, Fieldfisher Committee Secretary: Lauren Crawford

Declarations of Interest: members of the Committee declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the Committee:

- Inspection report
- Application to vary the licence to account for changes to the premises.
- Plan showing the refurbished Assisted Conception Service area (plan 1)
- Plan showing enlargement of the laboratory/procedure room area within the ACS (plan 2)
- Application to vary the licence to remove an additional licence condition
- ELP minutes 14 June 2011: Interim Inspection.
- ELP minutes 19 October 2012: Interim Inspection.
- LC minutes 28 March 2013: Incident review report.
- LC minutes 11 July 2013: Incident review report; Executive follow up
- LC minutes 7 Nov 2013: Licence renewal

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree); and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted

- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Background

1. The Committee noted the Glasgow Royal Infirmary Assisted Conception Service is located in Glasgow and has held a licence with the HFEA since 1992. The centre normally offers a full range of fertility services and provided 1,110 cycles of treatment (excluding partner intrauterine insemination (IUI)) in the 12 months to 30 September 2012. In relation to its normal activity levels this is a large centre, however, treatment activity at the centre has been suspended since 8 November 2012 when the centre reported a Grade A incident related to low fertilisation rates.

2. In response to the incident, the centre invoked its contingency arrangement and transferred all treatment activity, and clinical and laboratory staff to support it, to the Glasgow Nuffield Hospital (centre 0115). An incident investigation found that renovation work on other floors of the building housing the centre may have adversely affected laboratory processes and treatment outcomes. On 28 March 2013, the Licence Committee (LC) that reviewed the incident report considered the centre's premises unsuitable for treatment activities and placed the following additional condition on the centre's licence: 'no licensed activities other than 'storage of gametes and embryos' and 'distribution of gametes' may take place at the centre.'

3. The centre was inspected in September 2013 in response to an application to renew the licence. Renovation work was ongoing at the time and the centre's patient treatment activities remained located at centre 0115. Consequently, the Person Responsible (PR) did not apply to remove the additional condition from the licence. The renewal inspection focussed on the licensed activities being undertaken by centre 0037 at that time, i.e. embryo and gamete storage and distribution to centre 0115 for use in treatment. The Licence Committee considered the report of the renewal inspection and approved the renewal of the centre's licence for four years with the additional condition still attached.

4. The PR applied on 27 March 2014 to vary the licence to have the additional condition removed and to change the licensed premises to account for substantial renovation work, which is now completed. The approval by the LC of these applications will enable licensed treatment activity to recommence at centre 0037. An inspection was undertaken to assess the suitability of the renovated premises and the proposed practices to be used for licensed activity at centre 0037. A review of the proposed practices was included because the renewal inspection report

considered by the LC in September 2013 stated: 'The Executive will perform a further inspection of centre 0037 to assess its suitability for treatment activity'.

Discussion

5. The Committee noted it was in receipt of an application to vary the centre's licence to remove the additional condition: 'no licensed activities other than 'storage of gametes and embryos' and 'distribution of gametes and embryos' may take place at the centre'.

6. The Committee noted that the centre was also inspected in order to assess the suitability of the renovated premises.

7. The Committee noted that at the time of submission of this report to the Licence Committee, recommendations remain to be implemented concerning two 'major' and one 'other' area of non-compliance. Improvements are required in order for the centre to reflect suitable practices, however, the PR has committed to implement these remaining recommendations within the required timescales.

8. The Committee noted that the PR has also committed to perform follow-up audits three months after activity commences to verify that actions taken to implement some of the recommendations have been successful.

9. The Committee noted that the new premises address will remain the same:

   Assisted Conception Services Unit
   Queen Elizabeth Building
   Alexandra Parade
   Glasgow
   G31 2ER

10. The Committee noted that the Executive recommends that the additional condition: "no licensed activities other than 'storage of gametes and embryos' and 'distribution of gametes and embryos' may take place at the centre'" be removed from the centre's licence.

Decision

11. The Committee was satisfied, based on evidence within the inspection report, that the centre's premises are now suitable and agreed to vary its licence by removing the additional condition from the centre's licence and approving the renovated premises.

Signed: Date: 23/07/2014

Andy Greenfield (Chair)

Inspection Report

Purpose of the inspection and this report

This is a report of an inspection performed in response to applications made by the Person Responsible (PR) to vary the licence:

- to remove an additional condition ('no licensed activities other than 'storage of gametes and embryos' and 'distribution of gametes' may take place at the centre') and thus to allow treatment activities to be resumed at the centre;
- to change the licensed premises to account for substantial redesign and renovation work at the existing premises.

The purpose of this report is to document evidence obtained during the inspection regarding the suitability of the premises and the proposed practices for licensed activity. The report is provided to the Licence Committee (LC) to assist it in deciding whether to vary the licence in response to the applications made by the PR, under the powers provided by the HF&E Act 1990 (as amended), Section 18A 2.

Date of inspection: 15 and 16 May 2014

The centre has applied to add the following activities:

None; however if the additional condition is removed from the licence in response to the centre's application, it will allow the centre to perform all licensed treatment activities. The centre's activities are currently limited by the additional condition to gamete and embryo storage and distribution.

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

Inspectors: Andrew Leonard; Susan Jolliffe; Kathryn Mangold

Date of Licence Committee: 10 July 2014

Centre name	Glasgow Royal Infirmary
Centre number	0037
Licence number	L/0037/14/a
Centre address	Assisted Conception Services Unit, Queen Elizabeth Building, Alexandra Parade, Glasgow, G31 2ER
Person Responsible	Dr Helen Lyall
Licence Holder	Prof Scott Nelson
Date licence issued	1 January 2014
Licence expiry date	31 December 2017
Additional conditions applied to this licence	No licensed activities other than 'storage of gametes and embryos' and 'distribution of gametes' may take place at the Centre

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Glasgow Royal Infirmary Assisted Conception Service is located in Glasgow and has held a licence with the HFEA since 1992. The centre normally offers a full range of fertility services and provided 1110 cycles of treatment (excluding partner intrauterine insemination (IUI)) in the 12 months to 30 September 2012. In relation to its normal activity levels this is a large centre, however treatment activity at the centre has been suspended since 8 November 2012 when the centre reported a Grade A incident related to low fertilisation rates.

In response to the incident, the centre invoked its contingency arrangement and transferred all treatment activity, and clinical and laboratory staff to support it, to the Glasgow Nuffield Hospital (centre 0115). An incident investigation found that renovation work on other floors of the building housing the centre may have adversely affected laboratory processes and treatment outcomes. The LC on 28 March 2013 which reviewed the incident report considered the centre's premises unsuitable for treatment activities and placed the following additional condition on the centre's licence: 'no licensed activities other than 'storage of gametes and embryos' and 'distribution of gametes' may take place at the centre.'

Following the incident, centre 0037 elected to include the centre's premises in the renovation work being undertaken throughout the building. This renovation included the provision of a new cryostore adjacent to the existing cryostore, the physical state of the latter having been considered non-compliant at the interim inspection in 2012.

The centre was inspected in September 2013 in response to an application to renew the licence. Renovation work was on-going at the time and the centre's patient treatment activities remained located at centre 0115. Consequently, the PR did not apply to remove the additional condition from the licence. The renewal inspection focussed on the licensed activities being undertaken by centre 0037 at that time, i.e. embryo and gamete storage and distribution to centre 0115 for use in treatment. The Licence Committee considered the report of the renewal inspection and approved the renewal of the centre's licence for four years with the additional condition still attached.

The PR applied on 27 March 2014 to vary the licence to have the additional condition removed and to change the licensed premises to account for substantial renovation work, which is now completed. The approval by the LC of these applications will enable licensed treatment activity to re-commence at centre 0037. The aim of this inspection was to assess the suitability of the renovated premises and the proposed practices to be used for licensed activity at centre 0037. A review of the proposed practices was included because the renewal inspection report considered by the LC in September 2013 stated: 'The Executive will perform a further inspection of centre 0037 to assess its suitability for treatment activity'.

Pregnancy outcomes[1]

The centre has been inactive since November 2012, therefore no current pregnancy outcome data is available. The PR reported that pregnancy outcomes achieved by the centre's staff while treating patients at centre 0115 have been monitored and have not been outside of the quality objectives set by the centre's management.

Multiple births[2]

The centre has been inactive since November 2012, therefore no multiple pregnancy or birth outcome data is available.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

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:

- the applications to vary the licence have been submitted by the Person Responsible (PR) in the form required;
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged her duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the applications contain the supporting information required by General Direction 0008, plans of the premises being provided with the committee papers while compliant equipment validation is discussed in this inspection report;
- no fee is invoiced by the HFEA for licence variation applications such as these;

The Licence Committee is asked to note that at the time of the report being provided to the PR, there were three major and four 'other' areas of non-compliance which required improvement and led to recommendations being made by the inspection team.

At the time this report is submitted to the Licence Committee, the following recommendations have been implemented:

Major areas of non compliance:

2. The PR should ensure that blood tests for screening purposes are taken from patients and donors within the timeframes specified by the Authority.

'Other' areas that requires improvement:

4. The PR should ensure written information is provided to persons considering the donation of their embryos for use in training.
5. The PR should ensure that corrective actions are taken to control access through the main entrance door.
7. The PR should ensure that the controlled drugs book is completed appropriately in all cases.

The PR has given a commitment to fully implementing the following recommendations:

Major areas of non compliance:

1. A full audit of all dewar contents and storage consent forms against the storage records, should be performed. Corrective actions to obtain consent to storage or to discard should be documented, with timescales for implementation, for all samples found to not have valid consent. These plans should be provided to the HFEA.
3. The PR should ensure that suitable staffing resources are available to support the counselling service.

'Other' areas that requires improvement:

6. The PR should ensure corrective actions are taken to control the risks to patient privacy identified in this report.

The PR has also committed to perform follow up audits three months after activity commences to verify that actions taken to implement recommendations 2 and 7 have succeeded.

Recommendation to the Licence Committee

At the time of submission of this report to the Licence Committee, recommendations remain to be implemented concerning two major and one 'other' area of non-compliance. Improvements are required in order for the centre to reflect suitable practices however the PR has committed to implement these remaining recommendations within the required timescales.

The centre's inspector will continue to monitor the centre's performance.

The inspection team recommends the Licence Committee approves the licence variation applications made by the centre to:

- vary the licence to have the additional condition removed
- vary the licence to change the licensed premises to account for substantial renovation work recently completed at the centre

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

At this inspection, the centre was not carrying out licensed treatment activities due to the additional condition on the licence, so evidence for compliance could not be obtained from observation of on-going activity. Instead, evidence was sought in several places:

- In the activities undertaken to prepare the centre to resume treating patients;
- In recent audits of processes involved in treatments performed by the centre's staff using the centre's procedures while at the centre's temporary clinical facilities at centre 0115;
- Through discussions with staff about proposed processes and procedures to be used at the centre.

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)
The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

Manual witnessing is used at the centre for the current storage and distribution activities and will also be used when full treatment activity resumes. All relevant staff are trained and competent to perform manual witnessing. An electronic witnessing system is also being installed and will be used once it has been fully validated and staff trained in its use. The centre has documented plans for this validation and staff training.

What the centre could do better
Nothing identified at this inspection.

Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
The centre's procedures for screening donors are compliant with HFEA requirements. It is

important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Payments for donors (Guidance note 13; General Direction 0001)
The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect of any supply of gametes or embryos. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

Donor assisted conception (Guidance note 20)
A donor-conceived person is entitled to know details of their donor and any donor-conceived genetic siblings they may have. Parents of a donor-conceived child are able to access information about their child's donor (and any donor-conceived genetic siblings) from the HFEA or the clinic where they received treatment. Therefore it is important that centres use donated gametes or embryos from identifiable donors.

The centre's procedures are compliant with HFEA requirements ensuring the donor conceived and their parents are able to receive the information they require.

What the centre could do better
Nothing identified at this inspection.

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are broadly suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account to ensure patients and staff are in safe surroundings that prevent harm.

The centre has no satellite or transport facilities. The premises of laboratories which conduct tests, on the centre's behalf, that impact on the quality and safety of gametes and/or embryos are considered suitable on the basis of their accreditation status.

The centre is compliant with HFEA requirements to process gametes and/or embryos in an environment of appropriate air quality. The inspection team note the centre's attention to detail regarding the design, installation and validation of the air cleaning equipment installed in the refurbished centre. The PR also provided, on request, a document which rationalised the centre's approach to minimising the possibility of air quality impacting on the quality of the centre's services.

The inspection team note that the redesign and refurbishment of premises for centre 0037 has allowed the centre to coalesce all licensed treatment and storage and associated activities, into one location on the ground floor of the Queen Elizabeth Building, Glasgow Royal Infirmary. The centre premises comprise a clinical treatment corridor (with a six bay recovery area, two procedure rooms, laboratory facilities for embryology, andrology and cryostorage and office space for staff) and a reception and waiting area for patients. A corridor for outpatient activities has been added to the centre's premises adjacent to the reception area, with rooms for consultations, examinations and scanning. All the premises have been refurbished to a high specification appropriate for the licensed activities to be performed.

The location of the licensed premises has not changed however the Executive considered that the re-design and refurbishment of the premises were significant enough to warrant focused inspection and a variation of the licence.

Laboratory accreditation(Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are already compliant with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

Medicines management
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are broadly compliant with guidance.

Pre-operative assessment and the surgical pathway
The centre has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

Multiple births (Guidance note 7; General Direction 0003)
The single biggest risk of fertility treatment is a multiple pregnancy. The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements which seek to reduce this risk. A summary log of cases in which multiple embryos have

been transferred is maintained and regular audits and evaluations of the progress and effectiveness of the strategy have been performed.

Procurement of gametes and embryos (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to:

- document the justification for the use of the patient's gametes (or embryos created with their gametes) in treatment, based on the patient's medical history and therapeutic indications;
- document when sperm is procured at home in the gamete provider's records.

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes and embryos sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- The container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if the gametes and embryos are appropriately labelled and have enough accompanying information to permit them to be stored or used in treatment in a way that does not compromise quality and safety.

Imports and exports (Guidance note 16; General Direction 0006)
The centre's procedures for imports and exports of gametes and embryos are compliant with HFEA requirements.

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA traceability requirements. These requirements ensure that the centre has the ability to:

- identify and locate gametes and embryos during any step from procurement to use for human application or disposal,
- identify the donor and recipient of particular gametes or embryos,
- identify any person who has carried out any activity in relation to particular gametes or embryos, and
- identify and locate all relevant data relating to products and materials coming into contact with gametes or embryos which could affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS that is compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's third party agreements are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has no transport or satellite centres.

Equipment and materials (Guidance note 26)
The centre uses, and will use, equipment and materials that are compliant with HFEA requirements. All the equipment and materials to be used in licensed activity are designated for the purpose and appropriately maintained in order to minimise any hazard to patients and/or staff. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions. The centre is compliant with HFEA requirements to validate critical equipment before using it in gamete and embryo processing or patient treatment.

Process validation (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to validate critical processes. Validation ensures that the processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre has investigated all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve their services.

What the centre could do better

Safety and suitability of premises and facilities
At the time of the inspection the entrance doors to the centre were not secure because they have not yet been fitted with swipe card locks, door bells, CCTV camera and the reception desk activated remote opening system, as is planned (SLC T17).

Medicines management
The controlled drugs book recording the unit's use of drugs while providing treatment activity at centre 0115 was reviewed. In some cases it had not been completed to show the NHS number (SLC T2).

Staff engaged in licensed activity

Person Responsible (PR)

Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has complied with the requirements of the HF&E Act 1990 (as amended).

The PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (PREP

number T/1023/7).

Staff (Guidance note 2)
The centre is broadly compliant with HFEA requirements regarding staffing. The centre has suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services, except in one area discussed below. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities, respectively.

What the centre could do better

Staff
The inspection team were satisfied, in general, that activity is likely to be matched to staffing resources however concerns were raised regarding delays in providing counselling appointments of up to 6 weeks. The counsellor is also only available for 24.5 hours per week and no second counsellor is formally available to cover holiday and sickness. Counselling provision has not been included in the workforce planning and activity assessment (SLC T12).

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures for taking into account the welfare of the child are compliant with HFEA requirements. This is important to ensure that the centre takes into account the welfare of any child who may be born as a result of the licensed treatment, and of any other child who may be affected by that birth before treatment is provided.

Safeguarding
The centre's procedures are compliant with safeguarding requirements. This ensures that the centre's patients and staff are protected from harm where possible.

What the centre could do better
Nothing identified at this inspection.

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9); Embryo testing and sex selection (Guidance note 10)
These requirements were not reviewed at this inspection because the centre's procedures for performing embryo testing were reviewed at the time of the last renewal inspection in September 2013 and were found to be compliant with HFEA requirements. This ensures that:

- no embryo is transferred to a woman where that embryo or material removed from it, or the gametes that produced it, has been subject to genetic testing unless expressly authorised by the HFEA
- no information derived from tests conducted has been used to select embryos of a particular sex for social reasons
- no embryo is tested unless it meets the statutory tests i.e. that the embryos is at a significant risk of having a series genetic condition
- people seeking embryo testing are given written information, opportunities to discuss the implications of their treatment and access to clinical geneticists, genetic counsellors and infertility counsellors where required.

What the centre could do better
Nothing identified at this inspection.

2. The experience of patients

Patient feedback

What the centre does well

The centre is not yet seeing patients for licensed treatment on the refurbished premises so no patients were available to speak to about their experiences. Forty-four patients have provided feedback directly to the HFEA since 15 November 2012 about their experiences undergoing pre-treatment assessment at centre 0037 (which is not licensable) and treatment at centre 0115. Feedback was generally positive, with 27 of the individuals providing written feedback commenting that they had compliments about the care that they received.

On the basis of this feedback it was possible to assess that the centre:

- has managed the transfer of the treatment service to centre 0115 in a manner which has had relatively low impact on patients
- has respect for the privacy and confidentiality of patients;
- generally gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg [and sperm] sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)

The centre's counselling procedures are broadly compliant with HFEA requirements; one concern in this area is discussed in 'staffing'. This is important to ensure that counselling support is offered and provided to patients and donors before they provide consent to treatment, storage or legal parenthood.

Egg [and sperm] sharing arrangements (Guidance note 12; General Direction 0001)
The centre will not perform sperm and egg sharing arrangements when treatment activity resumes.

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are, and will be, compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are, and will be, broadly compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

What the centre could do better

Confidentiality and privacy (Guidance note 30)
The inspection team had minor concerns regarding patient privacy and dignity (SLC T17) specifically:

- There is no lock on the door between the two procedure rooms which may compromise patient privacy during a procedure.
- Signs on the doors to the men's production rooms and the pre-procedure room do not show when the rooms are occupied.

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's procedures for providing information to patients and/or donors are, and will be, broadly compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better

Information
The centre does not have written patient information concerning the use of embryos in training, which provides all the information required by CoP guidance 22.10 (SLC T97).

Consent and Disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are, and will be, compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

The centre completed an audit of consenting to legal parenthood, as required by Chief Executive's letter CH(14)01. A report of the audit was provided to the centre's inspector within the required timescale which indicated that the centre had no non-conformances in this area of practice.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre's procedures for taking consent to disclosure to researchers are, and will be, compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases the patients' identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

What the centre could do better
Nothing identified at this inspection.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended). This will ensure that the centre has respect for the special status of the embryo when conducting licensed activities.

- licensed activities only take place on licensed premises;
- only permitted embryos are used in the provision of treatment services;
- embryos are not selected for use in treatment for social reasons;
- embryos are not created by embryo splitting;
- embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman and
- embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

What the centre could do better

Nothing identified at this inspection.

Screening of patients
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)

The centre's procedures for screening patients are broadly compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Storage of gametes and embryos (Guidance note 17)

The centre's procedures for storing gametes and embryos are broadly compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety, and are stored only in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

What the centre could do better

Screening of patients

Current procedures dictate that blood tests for screening patients must be performed within two years of the first or subsequent treatments. Thus tests for screening patients will not be performed within the timeframes specified by the Authority, i.e. three months before the first treatment and two years for subsequent treatments (SLC T51b).

Storage of gametes and embryos
On the day of the inspection, the centre was storing the gametes of 31 patients and the embryos of 11 patients beyond the consented storage period (HF&E Act 1990 (as amended), Schedule 3, 8.1; SLC T79). This matter is discussed further in 'Monitoring of the centre's performance'.

Use of embryos for training staff (Guidance note 22)

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre's procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

What the centre could do better
Nothing identified at this inspection.

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are, and will be, compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32 ; General Direction 0005)
The centre's procedures for submitting information about licensed activities to the Authority were not assessed at this inspection because the centre currently performed no licensed treatment activity.

What the centre could do better
Nothing identified at this inspection.

Section 3: Monitoring of the centre's performance

Following the renewal inspection in September 2013, recommendations for improvement were made in relation to two major and one 'other' area(s) of non-compliance.

The PR provided information and evidence that all of the recommendations were fully implemented within timescales agreed with the centre's inspector. This included the development of an action plan to address the storage of 46 gamete and embryo samples for which the consents to storage had expired. This action plan was implemented and on 25 April 2014 the Laboratory Manager advised that only eight of the samples remained in store without consent. In three cases, the gamete providers were scheduled to attend the centre to sign storage consent forms, and in five cases the gamete providers had needed to be sent further letters because no record had been retained by the post office of the delivery of the letter. Reasonable progress was though being made to address the non-compliance.

On the day before this inspection, the PR reported that further samples, totalling 32 sperm samples and 11 embryo samples, were in storage even though the storage consents had expired. This was discussed on inspection and it became clear that the storage consent forms had probably not been audited for some time, because storage audits in the past had reviewed the stored samples against the storage records without checking the storage consent form. The lead scientist, who is newly appointed, stated that as laboratory staff return to the centre, a key task is to perform a thorough audit of the storage dewar contents against the storage records and the storage consent forms held in patient records. Action plans have also been developed and progressed to contact the gamete providers in the 43 cases of storage with expired consent forms, to discuss the options available and to collect consent to extended storage if possible and necessary.

On-going monitoring of centre success rates

Centre 0037 has been inactive since November 2012 so has not been subject to review of success rates through the HFEA risk tool or been sent any alert emails.

Areas of practice requiring action

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 Acts, 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 area of non compliance

A critical area of non-compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. 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 noted			

Major area 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, embryo or to a child who may be born as a result of treatment services
- 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. On the day of the inspection, the centre was storing the gametes of 32 patients and the embryos of 11 patients beyond the consented storage period (Schedule 3, 8.1, HF&E Act 1990 (as amended); SLC T79). The inspection team notes that these are legacy issues and not due to flaws in current practice. The inspection team also notes that attempts to contact the gamete providers have already commenced.	The inspection team recommends that the PR commences as soon as possible with her plans for a full audit of all dewar contents and storage consent forms, against the storage records. This audit should be completed by 15 November 2014. The action plans should be provided to the HFEA. The PR should provide the centre's inspector with monthly updates regarding the progress of the audit and the implementation of corrective actions. The inspection team expect that by 15 November 2014 a final report should be delivered by the PR to the HFEA and that no samples should remain in storage without	The full and complete audit of all cryostorage contents and patient casenotes will start as soon as we resume activity on the GRI site. Due to the extent of the audit the embryology team feel this will take up to 1 year to complete. They propose that they provide monthly updates to the HFEA up to 15 November 2014 and following this date up to the completion of the audit. The Centre is also undertaking a major review of the process pathway for the recall system.	5 June 2014: The inspector notes that this matter has been reported as an incident to the HFEA. 19 June 2014: The inspector notes that attempts to contact the gamete providers are continuing so that consent to storage or discard can be obtained for the samples known to be held in store without valid consent. The inspector has reviewed the PR's response and an action plan sent by the Laboratory Manager to the HFEA Clinical Governance Inspector. Both indicate that

	valid storage consent. The PR is reminded of guidance issued by the HFEA in CH(03)02 (http://www.hfea.gov.uk/2721.html) in relation to the timely disposal of cryopreserved material where there is consent to do so and actions should there be a possibility of legal challenge to the disposal of cryopreserved material.	.	corrective actions to prevent recurrence (i.e. full audit of the stored material and the storage consent forms; review of the 'recall' system) will commence as soon as activity resumes. The inspector accepts that immediate action cannot be taken since staff are either at centre 0115 providing treatment, or are at centre 0037 preparing to provide treatment. The inspector also accepts the opinion that the audit may take up to one year, however work on it should commence as soon as is possible. Further actions are still required.
2. Current procedures dictate that blood tests for screening of patients and donors will not be obtained within the timeframes specified by the Authority (SLC T51b and T53b).	The PR should ensure that blood tests for screening purposes are taken from patients and donors within the timeframes specified by the Authority. This recommendation should be implemented by 3 July 2014 and evidence of this provided to the centre's inspector.	The audit will be performed within the required time-scale.	13 June 2014: The PR provided a revised SOP for patient screening which was compliant with HFEA requirements. No further actions are required beyond the PR performing an audit of patient screening records

	Three months after activity recommences at centre 0037, records of patient screening should be audited to ensure good practice in this area is being observed. A report of this audit should be provided to the centre's inspector.		three months after activity recommences, to ensure the revised practice is followed. A report of this audit should be provided to the centre's inspector.
3. Delays in providing counselling of up to 6 weeks have occurred and the counsellor is only available for 24.5 hours per week and no second counsellor is formally available to cover holiday and sickness. Counselling provision has also not been included in the workforce planning and activity assessment (SLC T12).	The PR should ensure that suitable counselling resources are available. The PR should review the workload and availability of the counsellor against the proposed activity level and document the review in a workforce-activity assessment, as has been done for clinical, nursing and laboratory staffing. This recommendation should be implemented by 15 August 2014 and the HFEA advised of the actions taken.	The workforce-activity risk assessment is underway for the counselling service. The recommended time-scale is noted.	19 June 2014: The PR's response indicates that the recommendation is being implemented. Further actions are required and will be reviewed as part of the on-going monitoring system.

Other areas of practice that requires improvement

Areas of practice that requires 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 statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
4. The centre does not have written patient information concerning the use of embryos in training, which provides all the information required by CoP guidance 22.10 (SLC T97).	The PR should ensure written information is developed which provides all required information to persons considering the donation of their embryos for use in training. This recommendation should be implemented by 3 July 2014 and evidence of this provided to the centre's inspector.	This was sent to the HFEA on 19th June 2014.	19 June 2014: The centre provided an information sheet regarding the use of embryos in training. The inspector considered the information to be compliant with CoP requirements and to satisfy the recommendation. No further actions are required.
5. On the day of inspection, the main entrance doors to the centre were not secure because the plans to fit them with swipe card locks, door bells, CCTV camera and the reception desk activated remote opening system, have not yet been completed.	The PR should ensure that corrective actions are taken to control access through the main entrance door. The PR should advise the centre's inspector of the actions taken by 3 July 2014.	It is anticipated this work will be complete by Friday 20th June 2014.	5 June 2014: The inspector was provided with evidence that plans for this work had been approved by the Hospital Trust and quotes for the work have been sought. The communication made clear that the work would be completed as soon as possible. 20 June 2014: The PR provided evidence to the

			inspector that the main entrance door security system had been installed and was operational. No further actions are required.
6. The inspection team had two minor concerns regarding the ability of the premises to maintain patient privacy (SLC T17) specifically: • There is no lock on the door between the two procedure rooms which may lead to compromise in patient privacy during a procedure. • Signs on the doors to the men's production rooms and the pre-procedure room do not show when the rooms are occupied.	The PR should ensure that the premises protect patient privacy. Corrective actions to control the risks to patient privacy identified here should be completed before patients use these areas. The PR should advise the centre's inspector of the actions taken by 3 July 2014.	The signage for the doors has been received.	5 June 2014: The inspector was provided with evidence that an instruction to fit the lock between the procedure rooms has been issued. The PR should advise the HFEA when the work is completed. 13 June 2014: The inspector was provided with evidence that an instruction to fit the signs to the men's production rooms has been issued. The PR should advise the HFEA when the work is completed.
7. The controlled drugs book currently used by the unit while providing treatment at centre 0115, was not in all cases of controlled drugs use completed to show the NHS number.	The PR should ensure that the controlled drugs book is completed appropriately in all cases. An audit of the controlled drugs book for accuracy and against the centre's SOP for medicines	The audit will be performed within the required time-scale.	11 June 2014: An audit of the controlled drugs book was provided. The corrective action was to advise relevant clinical staff regarding the controlled drugs administration procedure.

	management should be completed. The results of the audit and any actions which arise from it should be shared with the lead inspector by 3 July 2014. Three months after activity recommences at centre 0037, the controlled drugs book should be re-audited against the centre's SOP for medicines management to ensure good practice in this area is being observed. A report of this audit should be provided to the centre's inspector.		No further actions are required beyond the PR performing an audit of the controlled drugs book three months after activity recommences, to ensure the correct practice is being followed. A report of this audit should be provided to the centre's inspector.

Reponses from the Person Responsible to this inspection report