HFEA Licence Committee Meeting

7 November 2013

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

Minutes – Item 7

Centre 0037 (Glasgow Royal Infirmary) – Renewal of Treatment and Storage (with Embryo Testing) Licence

Members of the Committee: Sally Cheshire (lay) Chair Gemma Hobcraft (lay) Bishop Lee Rayfield (lay) (video) Debbie Barber (professional) Andy Greenfield (professional) Committee Secretary: Lauren Crawford	Legal Adviser: Graham Miles, Morgan Cole Observing: Sam Hartley, Head of Governance and Licensing, HFEA Juliet Tizzard, Interim Director of Strategy, HFEA

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

- Executive Summary concerning the additional licence condition on the centre's licence
- Report of renewal inspection on 5 September 2013.
- Renewal application form
- 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

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 Licence Committee previously considered an incident report at Centre 0037 in March 2013. Further to the incident an update report was considered in July and the Licence Committee further requested that the renewal report come before them rather than the ELP (Executive Licensing Panel).

2. At the meeting in March the Licence Committee added a condition to the centre's licence which states that 'no licensed activities other than 'storage of gametes and embryos' and 'distribution of gametes' may take place at the centre.

3. The Committee noted that the inspection of the centre took place in September 2013. The centre currently holds a Treatment and Storage (with embryo testing) licence which they wish to renew, although the condition prohibiting treatment will remain as the centre's licensed premises are still being renovated.

4. The Committee noted that the centre's treatment activities have been transferred to HFEA licensed centre 0115. The centre has not performed any treatment activity since November 2012.

5. The Committee noted that once the renovation of the premises is complete the centre will apply to have the licence condition removed to allow the transfer of treatment activity back to the centre.

6. The Committee also noted that the centre would like to amend the address on their new licence to reflect the premises where licensed treatments will be taking place. Currently the licence states the address is:

   Assisted Conception Services Unit, Walton Building, 84 Castle Street, Glasgow, Scotland G4 0SF

   Whereas the licence renewal application lists the centre's address as:

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

7. The Committee noted that the Walton Building is adjacent to the Queen Elizabeth building on the campus with inter-connections between the two, both being part of the Glasgow Royal Infirmary campus. The Walton building usually hosts the administrative function of the centre and was considered as 'home' but after the renovation all work will be carried out in the Queen Elizabeth building and therefore the licence should reflect this.

8. The Committee noted that once the renovation of the premises is complete the centre will apply to have the licence condition removed to allow the transfer of treatment activity back to the centre (from centre 0115).

9. The Committee noted that at the time of the inspection, the Inspectorate reported that there were a number of areas of practice that required improvement, including two areas of 'major' non-compliance and one 'other' areas of non-compliance or poor practice.

Major areas of non-compliance

- The PR should ensure the dewars are validated.
- The PR should take immediate corrective actions to ensure material is not stored without consent.

Other areas of non-compliance

- The PR should ensure that in future gamete/embryo providers are screened for HBsAg and anti-HBc before their material is stored.

10. The Committee noted that since the inspection the Person Responsible (PR) has committed to fully implement the recommendations within the prescribed timescales.

11. The Committee noted the Inspectorate's recommendation to grant the centre's licence for a four-year period with the additional condition and to change the centre's address.

12. The Committee noted receipt of an additional executive summary which proposes a slight change to the licence condition to include the distribution of gametes. This would mean that the condition would state that **'no licensed activities other than 'storage of gametes and embryos' and 'distribution of gametes and embryos' may take place at the centre**'.

<u>Discussion</u>

13. The Committee referred to its decision tree. It was satisfied that the appropriate application and fee had been submitted, and noted that the executive had received the supporting information required by General Direction 0008.

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14. The Committee noted that the proposed PR holds academic qualifications in the field of medicine. The proposed PR also has more than two years'

practical experience which is directly relevant to the activity to be authorised by the licence as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii). She has successfully completed the HFEA PR Entry Programme.

15. The Committee noted the PR is suitable and will discharge her duty under section 17 of the HF&E Act 1990 (as amended).

16. The Committee was satisfied that the licence application concerns treatment, storage or non-medical fertility services which relate to gametes or embryos intended for human application.

17. The Committee was satisfied that premises to be licensed are suitable for the conduct of licensed activities based on evidence provided within the report.

18. The Committee referred to 'Guidance on periods for which new or renewed licences can be granted'. The Committee took into account matters set out in paragraph 4.3 and noted paragraph 4.4 of the guidance which states [The Licence Committee] will normally only grant a renewal licence for treatments/ storage non-medical fertility services licence for a period of up to four years where the evidence before it reveals no concerns in the matters specified in paragraph 4.3.

Decision

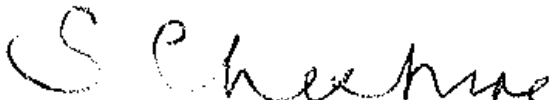
19. The Committee agreed to endorse the inspectorate's recommendation to renew the centre's licence for a period of four years with the revised additional condition which states that **'no licensed activities other than 'storage of gametes and embryos' and 'distribution of gametes and embryos' may take place at the centre.**'

20. The Committee agreed to change the centres premises address to:

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

21. The Committee expects that the recommendations within the report will be completed within the prescribed timeframes.

Signed: Date: 21/11/2013



Sally Cheshire (Chair)

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and this report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Licence Committee (LC) uses the renewal application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to it. This application will be considered by the LC, rather than the Executive Licensing Panel, as required by the LC on 11 July 2013 which considered a report regarding a Grade A incident at the centre.

Date of inspection: 5 September 2013
Inspectors: Dr Andrew Leonard
Purpose of inspection: Renewal of a licence to carry out 'Treatment (including embryo testing) and Storage'

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.

Date of Licence Committee: 7 November 2013

Centre name	Glasgow Royal Infirmary
Centre number	0037
Licence number	L/0037/13/f
Centre address	Currently: Assisted Conception Services Unit, Walton Building, 84 Castle Street, Glasgow, Scotland, G4 0SF, UK In the renewal application: Assisted Conception Services Unit, Queen Elizabeth Building, Alexandra Parade, Glasgow, G31 2ER
Person Responsible	Dr Helen Lyall
Licence Holder	Professor Scott Nelson
Date licence issued	01/01/2009
Licence expiry date	31/12/2013
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 is currently suspended while the premises are renovated, as discussed below.

The centre was last subjected to a renewal inspection on 14 May 2008 which resulted in a five year licence being approved, active from 1 January 2009. An interim inspection was last performed on 26 July 2012.

The centre reported a Grade A incident to the HFEA on 8 November 2012 related to low success rates. In response to the incident, the centre invoked its contingency arrangement and transferred all treatment activity to centre 0115 as well as clinical and laboratory staff to support patient treatment. An incident inspection report produced by the Executive found that renovation work on other floors of the building in which the centre's licensed activities are situated may have adversely affected treatment outcomes perhaps through an effect on air quality although this remains unproven. The LC on 28 March 2013 which reviewed the incident report considered these premises unsuitable for treatment activities and placed an 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.

As a result of the transfer of licensed treatment activities to centre 0115, centre 0037 elected to include the centre's premises in the extensive renovation work being undertaken throughout the host building. This renovation was to include the centre's cryostore, the physical state of which was considered non-compliant at the interim inspection in 2012.

Prior to this inspection, the PR advised the Executive that renovation work is still on-going at the centre and the centre's clinical and scientific staff are still treating their patients at centre 0115. Consequently, centre 0037 has not applied to have the additional condition removed from the licence and treatment activity is still not being undertaken at the centre. Gamete and embryo storage activities continue and stored material is distributed to centre 0115 for use in treatment, when required by the gamete providers or the persons to be treated. This renewal inspection therefore focussed on these activities. The PR has been advised that any licence issued as a result of the renewal application and this inspection, must contain the additional licence condition currently placed on the centre's licence.

When the renovation of the premises is completed, estimated January 2014, the PR will apply to have the additional condition removed from the licence to allow treatment activity to transfer back from centre 0115 to centre 0037. The Executive will perform a further inspection of centre 0037 to assess its suitability for treatment activity. A report of that inspection's findings will be provided to the LC which considers the application to remove the additional licence condition.

Current activities at the centre:

Type of treatment	Since 8 November 2012
In vitro fertilisation (IVF)	None
Intracytoplasmic sperm injection (ICSI)	None
Gamete intrafallopian transfer (GIFT)	None
Frozen embryo transfer (FET)	None
Donor insemination (DI)	None
Partner insemination	None

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓

Outcomes
No success rate or treatment outcome data is reported here because the centre ceased treatment activity on 8 November 2012.

Summary for licensing decision

The centre's address is listed on the current licence as:

Assisted Conception Services Unit, Walton Building, 84 Castle Street, Glasgow, Scotland, G4 0SF

whereas the licence renewal application lists the centre's address as:

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

The Walton Building is adjacent to the Queen Elizabeth Building, with inter-connections between the two, both being part of the Glasgow Royal Infirmary campus. Historically, the centre's non-licensable outpatient activities, administration and offices were located in the Walton Building but all licensable activities occurred in the Queen Elizabeth Building. Thus the address on the current licence has been historically inaccurate and does not identify the premises where licensed activities occur, though it was considered by the centre as its 'home' address given that the administrative function and offices were located there. The LC is asked to note that the premises in the Queen Elizabeth building have always been the subject of HFEA inspections and floor plans for those premises have been previously submitted to the HFEA. The renewal application provides an address that more accurately reflects the premises that have always been licensed. This address will also be accurate in future as all the centre's licensable and non-licensable activities will be located within the Queen Elizabeth building when the renovation of the centre is completed.

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:

- the PR is suitable and has discharged her duty under Section 17 of the HF&E Act 1990 (as amended)
- the premises are suitable for the activities currently licensed
- the practices are suitable for the activities currently licensed
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, in application for renewal of their licence
- the centre has submitted an application fee to the HFEA in accordance with requirements

The LC is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including no critical, two major and one 'other' areas of non-compliance or poor practice which led to the following recommendations:

Critical areas of concern:

- **None**

Major areas of non compliance:

- The PR should ensure the dewars are validated.
- The PR should take immediate corrective actions to ensure material is not stored without consent.

'Other' areas of non-compliance or poor practice that require improvement:

- The PR should ensure that in future gamete/embryo providers are screened for HBsAg and anti-HBc before their material is stored.

The PR has given a commitment to fully implement all the recommendations above within the expected timescales.

Recommendation to the Licence Committee

Some improvement is required in order for the centre to reflect good practice and demonstrate the quality and safety of the service it provides.

The inspection team is satisfied that the current licensed activities carried out at the centre are necessary or desirable in order to provide licensed services.

The inspection team recommends the renewal of the centre's treatment (including embryo testing) and storage licence for a period of four years, subject to the centre's compliance with the recommendations made in this report within the prescribed timescales. The inspection team also recommends that the additional condition on the licence be continued should renewal be approved, albeit with some changes as discussed in the Executive Summary accompanying this report.

The inspection team also recommends that the address of the licensed premises be listed as Assisted Conception Services Unit, Queen Elizabeth Building, Alexandra Parade, Glasgow, G31 2ER, should renewal be approved. This will correct a historic inaccuracy and provide the correct address where licensed activities occur.

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

1. Protection of the patient, and children born following treatment

Witnessing and assuring patient and donor identification (Guidance Note 18)

What the centre does well.

Regarding the centre's current licensed activities, the centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate during these activities, are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better.

No issues were identified

Patient and donor selection criteria and laboratory tests

What the centre does well.

Screening of patients and / or donors (Guidance Notes 11 and 15)

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.

Regarding the centre's current licensed activities, the centre's procedures for screening patients and / or donors are broadly compliant with HFEA requirements with one exception discussed in detail below.

Payments for donors (Guidance Note 13)

No donors are currently recruited. The requirements of this section were therefore not inspected against.

Donor assisted conception (Guidance Note 20)

Donor gametes are not currently used in treatment at this centre. The requirements of this section were therefore not inspected against.

What the centre could do better.

Screening of patients and / or donors (Guidance Notes 11 and 15)

The providers of gametes and embryos have not been screened for antibodies against

hepatitis B core antigen (anti-HBc) before their material was stored (SLC T50a). Hepatitis B surface antigen (HBsAg) screening has however been performed in all cases. It is noted that no treatment activities have occurred at the centre since November 2012 so no gametes or embryos have been placed in storage since this date. The absence of anti-HBc screening has also already been recognised by centre staff. The HFEA will not usually expect centres to carry out screening for anti-HBc retrospectively or to see separate storage for the gametes or embryos of patients screened for HBV by different methods (Recommendation 3).

Good clinical practice

What the centre does well.

Multiple births (Guidance Note 7)
No treatment is currently provided at the centre so the requirements of this section were not inspected against.

Process validation (Guidance Note 15)
The centre's procedures and processes related to the current licensed activities have been fully validated to ensure they are effective and do not compromise the quality and safety of the gametes or embryos.

Traceability (Guidance Note 19)
Regarding the centre's current licensed activities, traceability procedures are compliant with HFEA requirements and ensure the centre has the ability -
(a) to identify and locate gametes and embryos at all stages of storage and distribution,
(b) to identify the donor and intended recipient of particular gametes or embryos,
(c) to identify any person who has carried out any activity in relation to particular gametes or embryos, and
(d) to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

Quality management system (Guidance Note 23)
The centre has a quality management system in place that is compliant with HFEA requirements. The centre uses its quality management system to monitor and improve the centre's current licensed activities.

Third party agreements (Guidance Note 24)
The centre has third party agreements in place which cover the supply of goods and services (including distribution services) which may affect the quality or safety of gametes or embryos.

Equipment and materials (Guidance Note 26)
All equipment and materials used in the currently licensed activities are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff. All have been validated with one exception discussed below. Equipment is subject to appropriate monitoring of critical parameters with suitable alerts, alarms and corrective actions.

Premises (Guidance Note 25)
The centre conducts all of the currently licensed activities in an appropriate environment in line with good clinical practice.

The centre's premises in the Queen Elizabeth Building are being subjected to major renovation work while licensed treatment activities are suspended. The centre's cryostore and office, where current licensed activities are undertaken, sit within this area but arrangements are in place to ensure the continued safety and security of the stored gametes and embryos, the confidential records and staff on site.

The cryostore requires renovation, as noted by the interim inspection in July 2012, however it has been risk assessed and appropriate risk control measures have been implemented to satisfy the requirements of that inspection. The PR explained on this inspection that the cryostore renovation plan had to coordinate with the centre's renovation plan, which itself had to fit within the building's renovation plan. This has led to the renovation of the cryostore planned after the inspection in July 2012, being delayed by the decision in November 2012 to fully renovate all the centre's premises. The renovation of the centre is expected to be completed by January 2014.

All diagnostic testing is carried out in a suitable accredited laboratory.

Adverse incidents (Guidance Note 27)
The centre has procedures in place to report adverse incidents related to the current licensed activities. Incidents related to treatment activities provided by the centre's staff operating at centre 0115 are reported by that centre. The centre has in the past investigated all adverse incidents and shared the lessons learned in order to continuously improve the services it provides.

What the centre could do better.

Equipment and materials (Guidance Note 26)
The centre has not validated cryopreservation dewars in which gametes and embryos are stored (SLC T24) (Recommendation 1).

Staff engaged in licensed activity

What the centre does well.

Person Responsible (Guidance Note 1)
The PR has a key role 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 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 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 (T/1023/7).

Staff (Guidance Note 2)
The centre has suitably qualified and competent staff to carry out the current licensed activities.

What the centre could do better.
No issues were identified

Welfare of the child (Guidance Note 8)

What the centre does well.
No treatment activity is currently provided at the centre so the requirements of this section were not inspected against.

What the centre could do better.
Not relevant

Embryo testing

- Preimplantation genetic screening (Guidance Note 9)
- Embryo testing and sex selection (Guidance Note 10)

What the centre does well.
No treatment activity is currently provided at the centre so the requirements of this section were not inspected against.

What the centre could do better.
Not relevant

2. The experience of patients

Patient feedback

What the centre does well.

No treatment activity is currently provided at centre 0037. Patients referred to centre 0037 are treated by that centre's clinicians at centre 0115. Patient feedback could therefore not be sought during the inspection visit to centre 0037.

Thirty six patients have provided feedback directly to the HFEA in the time since the last interim inspection in July 2012. Feedback was positive in nearly all cases and indicated that the suspension of treatment services in November 2012 and the transfer of patients to centre 0115 were facilitated with only limited disruption to patient care.

What the centre could do better.

No issues were identified

Treating patients fairly

What the centre does well.

Gamete sharing arrangements (Guidance Note 12)

No treatment activity is currently provided at the centre so the requirements of this section were not inspected against.

Surrogacy (Guidance Note 14)

No treatment activity is currently provided at the centre so the requirements of this section were not inspected against.

Complaints (Guidance Note 28)

No treatment activity is currently provided at the centre so the requirements of this section were not inspected against. Patients using the material stored at centre 0037 are treated with it at centre 0115; any complaints regarding their treatment are addressed at that centre.

Treating patients fairly (Guidance note 29)

No treatment activity is currently provided at the centre so the requirements of this section were not inspected against.

Confidentiality and privacy (Guidance note 30)

Regarding the centre's current licensed activities, the centre's procedures and premises are compliant with HFEA requirements and ensure the confidentiality of patient identifying information is maintained.

What the centre could do better.

No issues were identified

Information (Guidance Note 4)

What the centre does well.

No treatment activity is currently provided at the centre so the requirements of this section were not inspected against beyond noting that patients are provided with appropriate information by letter when their gametes and/or embryos are approaching the expiry date of their storage consent.

What the centre could do better.

No issues were identified

Consent (Guidance Note 5)

What the centre does well.

No treatment activity is currently provided at the centre so the requirements of this section were not inspected against, beyond noting that patients are provided with appropriate information by letter when their gametes and/or embryos are approaching the expiry date of their storage consent.

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

No treatment is currently provided so these requirements were not inspected against.

What the centre could do better.

No issues were identified

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well.

The centre has no treatment activity at present. Within the centre's currently licensed activities, the centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended) and ensure that the centre has respect for the special status of the embryo.

- Licensed activities only take place on licensed premises.
- 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.

No issues were identified

Storage of gametes and embryos (Guidance Note 17)

What the centre does well.

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.

The centre's procedures for storing gametes and embryos are broadly compliant with HFEA requirements, with one exception discussed below. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre generally stores gametes and embryos in accordance with the consent of the gamete providers.

What the centre could do better.

Discussions with the Laboratory Manager and review of storage records indicated that on the day of the inspection, the centre was storing the gametes of 20 patients and the embryos of 26 patients beyond the consented storage period (Schedule 3, 8.1, HF&E Act 1990 (as amended)). The notification of registered delivery to patients of letters concerning storage consent, is obtained from the Royal Mail website using the unique code attached to each letter. Notifications are generally reviewed weekly, because they only remain on the Royal Mail website for a short time. Notifications when found on the website, are documented in the patient record. Due to staff changes, this system lapsed for a short period and the notification of registered delivery of consent expiry letters to the 46 patients whose samples are now beyond their consented storage period, was not logged before the notifications were deleted from the Royal Mail website. The centre's procedures dictate that in the absence of the notification of registered delivery, the PR cannot sanction disposal of a sample when its storage consent expires, because the delivery of the warning letter to the patient cannot be confirmed. To correct this situation, further letters have already been dispatched to the patients and will be acted upon within the timeframes discussed within the centre's bring-forward procedures. The inspector

considered that this reflected a temporary breakdown in the bring-forward system which has now been corrected, rather than a systemic failure due to poor design of the system (Recommendation 2).

Distribution and / or receipt of gametes and embryos (Guidance Note 15)

What the centre does well.

The centre's procedures for distributing and/or receiving gametes and embryos are compliant with HFEA requirements. This ensures that all gametes/embryos sent to other licensed centres within or outside the UK are appropriately labelled and relevant information is sent to the other centre to ensure the continued quality and safety of the gametes and embryos. The centre only accepts gametes and embryos from other centres if they are appropriately labelled and have enough information with them to permit them to be stored or used in a way that does not comprise their quality and safety.

What the centre could do better.

No issues were identified

Use of embryos for training staff (Guidance Note 22)

What the centre does well.

No treatment activity is currently provided at the centre so the requirements of this section were not inspected against because the use of embryos in staff training has been suspended.

What the centre could do better.

No issues were identified

4. Information management

Record keeping and submitting information to the HFEA

What the centre does well.

Record keeping and document control (Guidance Note 31)
Regarding the centre's current licensed activities, the centre's procedures for keeping records are compliant with HFEA requirements.

Obligations and reporting requirements (Guidance Note 32)
No treatment is currently provided at centre 0037 so a HFEA Register team did not attend this inspection. The centre's procedures for submitting information about the current licensed activities (e.g. gamete and embryo movements) to the Authority are compliant with HFEA requirements

It was considered more useful for a HFEA Register team to attend any inspection resulting from the centre applying in the future to remove the additional licence condition so that treatment activities can resume.

What the centre could do better.
No issues were identified

Section 3: Monitoring of the centre's performance

Following the interim inspection in July 2012, recommendations for improvement were made in relation to one area of critical non-compliance, three areas of major non-compliance and no 'other' areas of non-compliance.

The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales or had become irrelevant due to the suspension of treatment activities on 8 November 2012 and the subsequent renovation of the centre.

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			

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) Equipment validation The centre has not validated the cryo-preservation dewars in which gametes and embryos are stored (SLC T24).	The PR should ensure the dewars are validated and that validation evidence is documented and provided to the HFEA. This recommendation should be implemented by 5 December 2013	As part of the refurbishment programme in GRI, we have designed our new cryostore to accommodate large vapour phase auto fill storage dewars in addition to purchasing new liquid phase dewars. On receipt and Installation/ Operational Qualification (IOQ) of this new equipment, we will reconfigure our current storage and transfer samples from our existing dewars into the new, validated storage equipment. Regarding our existing dewars, our laboratory manager will prepare a validation document to be submitted to the HFEA by 30 November 2013. This will detail serial numbers, inspection of the standard of the dewars, whether there is evidence of any damage and whether	23 October 2013: The PR's response indicates that the recommendation will be implemented within the required timescale. Implementation within the specified timescale will be monitored by the Executive.

		they are deemed to be fit for purpose, audit of depth and temperature readings.	
2) Storage consent On the day of the inspection, the centre was storing the gametes of 20 patients and the embryos of 26 patients beyond the consented storage period (Schedule 3, 8.1, HF&E Act 1990 (as amended); SLC T79).	The PR should take immediate corrective actions to ensure material is not stored without consent. By the time this report is considered by a Licensing Committee (7 November 2013), the PR should provide the HFEA with an update on the number of patients for whom gametes and/or embryos remain in store beyond the consented storage period. For these samples, planned corrective actions should be documented with timescale for implementation. The PR should thereafter provide monthly updates to the HFEA on the progress in implementing the proposed actions until no samples are stored without consent. The PR should also report as an incident to the HFEA the storage of these 46 samples beyond their consented storage periods.	All patients have been contacted by recorded delivery letter. The letter defines the status of the material in storage, including the date of consented expiry and requests a response by 30 November 2013 otherwise samples will be discarded. This date was selected to give the administrative staff sufficient time to post the letters and the patients sufficient time to respond. The status of recorded delivery and any potential responses will be monitored and collated on a regular basis by a member of ACS staff. In the event of a response requesting disposal of the sample, this will take place with immediate effect. On the 30th November, a final report will be collated outlining the outcome of each letter. On the 1st December, patients who have not responded will have stored material discarded. Any patients who wish material to remain in storage and are eligible to do so, will	23 October 2013: The PR's response and communications with the Laboratory Manager on 18 October 2013 indicate that this recommendation is being implemented. Currently all the samples beyond their consented storage period remain in storage, but appropriate actions are being implemented within a reasonable timescale to rectify this non-compliance. Implementation will be monitored by the Executive through the on-going monitoring system.

	An appropriate incident investigation should be performed and reported to the HFEA within timescales to be determined by the HFEA Clinical Governance team.	have extended storage consent organised. At the beginning of December, the laboratory manager will provide a report on the outcome. If there are any samples remaining in storage beyond the consented storage period she will outline the status. It is anticipated that some patients may possibly fall under the category of 'information not available yet' when cross checking recorded delivery status. If this transpires, a follow up report will be provided.	

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
3) Screening of patients and / or donors The providers of gametes and embryos have not been screened for antibodies against hepatitis B core antigen (anti-HBc) before their material is stored (SLC T50a). Hepatitis B surface antigen (HBsAg) screening has however been performed in all cases.	The PR should ensure that in future gamete/embryo providers are screened for HBsAg and anti-HBc before their material is stored. The HFEA should be advised of the measures taken to implement this recommendation by the time this report is considered by a LC. The PR should also ensure a quality indicator for patient screening is developed and monitored. This recommendation should be implemented by the time that licensed treatment activity resumes and the HFEA advised of the actions taken.	Patients have always been tested for HBsAg at centre 0037 but antiHBc testing was not performed. Immediately after the relocation of our treatment activities to centre 0115 on 9 November 2012, we started testing for antiHBc as well as HBsAg. This change has been documented in our treatment SOPs. We will transfer this screening practice back to centre 0037 when licensed treatment activities resume there after the refurbishment. We do not plan to perform retrospective testing for antiHBc of patients with samples in storage or to segregate the storage of samples from patients who have been tested for hepatitis B in different ways, since HFEA guidance does not require it.	23 October 2013: The PR's response indicates that anti-HBc screening will be performed at centre 0037 when treatment activity recommences. The PR is reminded that a quality indicator for patient screening should be developed by the time licensed treatment activity resumes at centre 0037 and the HFEA advised of the actions taken. Implementation will be reviewed through the on-going monitoring system.

Reponse from the Person Responsible to this inspection report