HFEA Licence Committee Meeting

7 November 2013

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

Minutes – Item 2

Centre 0328 (GCRM Belfast) – Initial Treatment and Storage Inspection Report

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

- Initial inspection report
- Application form
- CV and references of the proposed Person Responsible
- CV of the proposed Licence Holder

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 that an initial application was received by the HFEA from GCRM Belfast in December 2012, for a treatment and storage (with embryo testing) licence. Further to this the proposed Person Responsible (PR) has now confirmed that the centre now only wish to apply for a Treatment and Storage Licence and will apply to vary the licence to include embryo testing at a later date.

2. The Committee noted that GCRM Belfast is located at:

   Edgewater House
   Edgewater Business Park
   Edgewater Road
   Belfast, Country Antrim
   Northern Ireland
   BT3 9QJ

3. The Committee noted that at the time of the inspection, the Inspectorate reported that there were no areas of practice that required improvement.

4. The Committee noted the Inspectorate's recommendation to grant the centre's licence for a two year period without additional conditions and to also appoint the proposed PR and Licence Holder (LH).

Discussion

5. 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.

6. The Committee noted that the proposed PR (Mr Peter McFaul) holds academic qualifications in the field of medicine and is registered with the General Medical Council (GMC). 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). He has successfully completed the HFEA PR Entry Programme.

7. The Committee was satisfied that the proposed PR is suitable and will discharge his duty under section 17 of the HF&E Act 1990 (as amended). Two references have been supplied along with this application.

8. The Committee was satisfied regarding the suitability of the proposed LH, Dr Ralph Roberts.

9. 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.

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

11. The Committee noted that at the time of the inspection, all clinical and laboratory equipment required has been purchased and is on site. The installation of key equipment is well underway and approximately 25% of key equipment had been validated at the time of inspection. At the time of writing, evidence has been provided that all critical equipment validation is now complete with the exception of two pieces of equipment.

12. The Committee noted that the report requests that '**The proposed PR is requested to provide a copy of the final validation documentation for the items of critical equipment that remain outstanding to the lead inspector before commencing licensed activity.**'

13. 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 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.

14. The Committee noted the Inspectorate's recommendation for a two year licence, without additional conditions, subject to the proposed PR providing evidence of validating the critical equipment that remains outstanding, to the Inspector.

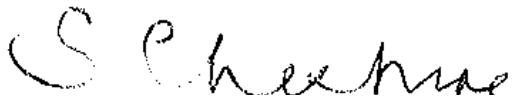
Decision

15. The Panel agreed to appoint Mr Peter McFaul as the Person Responsible for GCRM Belfast (Centre 0328) with immediate effect, in accordance with section 18A of the HFE Act 1990 (as amended).

16. The Panel agreed to appoint Dr Ralph Roberts as the Licence Holder for GCRM Belfast (Centre 0328) with immediate effect.

17. The Committee agreed to grant the centre's licence for a period of two years with no additional conditions, subject to the PR providing evidence of validating the new equipment.

Signed: Date: 21/11/2013



Sally Cheshire (Chair)

Initial Licence Inspection Report

Date of Inspection: 17 and 18 September 2013
Length of inspection: 12 hours

Inspection details:
The report covers the pre-inspection analysis, the visit, information received with the new licence application and following the inspection visit.

Date of Licence Committee: 7 November 2013

Purpose of the Inspection report
The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

The purpose of the inspection is to assess whether a new centre will have processes and procedures in place to ensure that they will comply with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC) to ensure that centres will provide a quality service for patients. The report summarises the findings of the inspection. It is primarily written for the Authority's Licence Committee which makes the decision about the centre's licence application

Centre details

Centre Name	GCRM Belfast
Centre Number	0328
Centre Address	Edgewater House, Edgewater Business Park, Edgewater Road, Belfast, County Antrim, Northern Ireland, BT3 9JQ
Person Responsible	Mr Peter McFaul
Licence Holder	Dr Ralph Roberts
Proposed date of licence issue	Following Licence Committee decision on 7 November 2013

Contents

Report to Licence Committee

Brief description of the centre:

The HFEA received a Treatment (including embryo testing) with Storage Licence application from the proposed Person Responsible (PR) on 10 December 2012. The application proposed that the centre be operational by April 2013, however delays in achieving planning permission and other material factors resulted in a revised schedule for licensing. Subject to approval by the Licence Committee, the centre aims to be operational in December 2013. The licence application is for a full range of activities including embryo testing. However the PR has provided written confirmation that an application to vary the licence to include embryo testing will now be made at a later date and that this application is for a Treatment with Storage Licence only.

The centre will provide treatment to self funded patients and is designed to provide a maximum of 600 in vitro fertilisation (IVF) or intracytoplasmic sperm injection (ICSI) treatment cycles and 50 partner / donor insemination treatments cycles per annum, the PR estimates the centre will provide approximately 200 to 300 treatment cycles in the first year and there will be a phased increase in activity.

The proposed PR has also made an application to be registered with the Regulation and Quality Improvement Authority (RQIA) for Northern Ireland and had their final registration inspection on 23 September 2013. The formal outcome of this inspection will be made known to the HFEA when it is available but early indication is that the RQIA see no apparent impediment to the registration of this centre.

GCRM Belfast is a stand alone facility located in a business park on the outskirts of Belfast city centre. The centre will operate as a sister clinic to GCRM Glasgow, HFEA licensed centre 0250. All IT systems, protocols and processess for both centres will be the same and staff will maintain close professsional links.

The premises are arranged over two floors. The ground floor houses a procedure room, three patient recovery rooms, embryology laboratory, andrology laboratory, cryo-preservation store and a room designated for semen production. The upper floor may be accessed by a lift or stairs. This floor houses a reception area, three consultations rooms, a seminar room, adminstration area and other offices. There is a designated ultrasound scanning room and phlebotomy room on this floor also.

The centre is fully accessible to wheelchair users.

Proposed activities of the Centre:

Type of treatment	Number of treatment cycles premises are designed to accommodate per annum
Partner/Donor insemination	50
IVF/ICSI/FET	600

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

Summary for licensing decision:

The proposed PR has submitted documentation to satisfy the requirements of General Direction 0008 - Information to be submitted to the Human Fertilisation and Embryology Authority as part of the licensing process. These documents have been reviewed by the inspection team and are considered to be comprehensive and compliant with Code of Practice (CoP) requirements.

The centre has submitted an application fee to the HFEA in accordance with Direction 0008.

In considering overall compliance, the inspection team considers that there is sufficient information drawn from documentation submitted by the centre prior to and after the inspection, and from observations and interviews conducted during the inspection visit to conclude that:

- The proposed PR satisfies the requirements of section 16 of the HF&E Act 1990 (as amended) necessary for a licence to be granted since:

    1. The proposed PR is the applicant for this Treatment with Storage Licence.
    2. The proposed PR holds academic qualifications in the field of medicine and is registered with the General Medical Council (GMC). The proposed PR also has more than two years' practical experience which is directly relevant to the activities to be authorised by the licence.
    3. The proposed PR has satisfactorily completed the PR entry programme (certificate number: T/1228/81).
    4. Two referees have attested to the suitability of the character of the applicant for the post of PR. The proposed PR is also currently PR for HFEA licenced centre 0077.

- The proposed PR is suitable and is expected to discharge his duty under section 17 of the HF&E Act 1990 (as amended).

- The initial Treatment and Storage licence application details the appointment of a Licence Holder. The proposed Licence Holder's CV has been submitted. The proposed Licence Holder was present on inspection and confirmed his acceptance of this role.

- The premises and equipment are suitable:

  At inspection, the premises appeared appropriate for the proposed licensable activities and should provide a safe, clean and private environment for patients and donors, their gametes and embryos, and for centre staff. Final handover of the building is complete and all building occupancy certification is in place. Essential fire and health and safety assessments have been successfully completed. The centre's internal and external security measures are now fully commissioned and operational. The building is decorated and furnished.

  All clinical and laboratory equipment required has been purchased and is on site. The installation of key equipment is well underway and approximately 25% of key equipment had been validated at the time of inspection. At the time of writing, evidence has been provided that all critical equipment validation is now complete with the exception of two pieces of equipment. It is recommended that:

  1. **The proposed PR should provide a copy of the final validation documentation for the items of critical equipment that remain outstanding to the lead inspector before commencing licensed activity.**

  Final air quality testing was conducted on 4 October 2013. Air quality achieved was at least grade C in the critical processing areas and grade D in the laboratory background air which meets the requirements of standard licence condition SLC T20.

- The proposed practices and processes appear to be suitable:

  The centre has documented standard operating procedures (SOPs) for the proposed licensed activities and activities carried out in connection with the provision of licensed treatment. All critical processes have been validated.

  All current staff provided evidence that they are suitably qualified and experienced to carry out their designated roles and the PR demonstrated appropriate plans to ensure that staff receive proper induction and that their competence to perform their designated roles will be assessed.

  The centre has documented quality indicators (QIs) and will establish monitoring and audit programmes which will allow the PR to identify whether processes are being effectively implemented and that practices are suitable.

Recommendation to the Licence Committee:

The inspection team considers that overall; there is sufficient information available to recommend:

- A Treatment and Storage Licence is granted for a period of two years without additional conditions. The proposed Person Responsible is to provide evidence of compliance with 1. above prior to licensed activity commencing.

- The appointment of the proposed Person Responsible.

- The appointment of the proposed Licence Holder.

Details of Inspection findings

1. Protection of patients and children born following treatment

Focus
The purpose of the inspection was to assess whether the centre:

- conducts all licensed activities with skill and care and in an appropriate environment, in line with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring
- takes into account the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth
- ensures that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose
- reports all adverse incidents (including serious adverse events and reactions) to the HFEA, investigates all adverse incidents and shares lessons learned.

▶ **Witnessing and assuring patient and donor identification** (Guidance Note 18)
What the proposed centre does well. The centre's proposed procedures for double checking the identification of gametes and embryos, and the patient or donor to whom they relate are compliant with HFEA requirements. The centre has an SOP (SLC T33(b)) for witnessing to ensure that no mismatches of gametes or embryos or identification errors occur (SLC T71). The centre has an electronic witnessing system in place for which staff training and competence assessment frameworks were seen. Centre staff will also be trained and assessed for competence in manual witnessing procedures (SLC T15(a)).
What the proposed centre could do better. Nothing noted.

▶ **Patient selection criteria and laboratory tests** • Procuring, processing and transporting gametes and embryos (Guidance Note 15) • Counselling (Guidance Note 3)
What the proposed centre does well. **Procuring, processing and transporting gametes and embryos** SOPs are in place for the procuring, processing and transporting gametes and embryos

(SLC T33b). Prior to the processing of gametes or embryos intended for use in treatment or storage, the centre will screen patients in accordance with SLC T50 under a third party agreement (TPA). The laboratory to be used for screening is accredited with Clinical Pathology Accreditation (UK) Ltd (CPA) (SLC T51).

The centre does not intend to seek CPA accreditation for diagnostic semen analysis, but was able to demonstrate that they will be working to an equivalent standard which includes having a robust quality management system (QMS) and participation in the UK National External Quality Assessment Service (NEQAS) for reproductive science (SLC T21).

If sperm is produced at home, the centre will record this in the gametes provider's records (SLC T68). The centre will not provide sperm for home insemination.

Counselling
Counselling will be offered to those providing consent as required by Schedule 3 and 3ZA of the HF&E Act 1990 (as amended).

The centre will offer counselling to all patients and donors prior to consent to treatment or donation being sought. An SOP is in place for counselling (SLC T33b).

When surrogacy is planned, counselling will be offered to all parties in the arrangement.

Where required there is provision in place for more specialist counselling to be made available.

QIs have been established and audits of the service are planned (SLC T35 and T36).

What the proposed centre could do better.
Nothing noted.

Donor recruitment, assessment and screening (Guidance Note 11)
Payments for Donors (Guidance Note 13)
Donor assisted conception (Guidance Note 20)

What the proposed centre does well.
Donor recruitment, assessment and screening
There is an SOP for the recruitment, assessment and screening of donors (SLC T33(b)). Discussions with staff and documentation reviewed showed that donors will be selected on the basis of their age, health and medical information and following a medical examination conducted by a trained healthcare professional (SLC T52(a)). Potential donors will be screened in accordance with SLC T52(b,e,g and h). Blood samples will be obtained from donors within the timeframe specified by the Authority and the laboratory testing will be conducted by a CPA (UK) laboratory under a TPA with the centre (SLC T52). There are documented procedures in place to identify when additional screening may be required (T52(g and h)).

Sperm and embryos provided for donation will routinely be quarantined for a minimum of 180 days prior to repeat testing of the donor. Additionally, nucleic acid amplification (NAT) testing will be available if required (SLC T53(c)).

Appropriate TPAs were seen to be in place where donor sperm is to be provided by external organisations.

Payment of donors
The centre's proposed procedures for the payment of monetary compensation to donors are compliant with Directions 0001. Where treatment or services are to be provided to egg or sperm sharers, the centre's procedures for providing that benefit are also compliant with Directions 0001.

Donor assisted conception
Staff were able to describe and demonstrate the procedures in place to ensure that, if requested, any donor may be provided with information regarding the number of children born as a result of their donation(s) and the sex and year of birth of each child born (HF&E Act 1990 (as amended) 31ZD(3)).

What the proposed centre could do better.
Nothing noted.

Good clinical practice

- Quality management system (Guidance Note 23)
- Traceability (Guidance Note 19)
- Validation (Guidance Note 15)
- Equipment and materials (Guidance Note 26)
- Premises – suitability of the premises and air quality (Guidance Note 25)
- Adverse incidents (Guidance Notes 27)
- Third party agreements (Guidance Note 24)
- Intracytoplasmic sperm injection (ICSI) (Guidance Note 21)

What the proposed centre does well.

Quality management system (QMS)
A comprehensive QMS is in place (SLC T32), including a quality manual, QIs, SOPs and associated documents (SLC T33 and T35). A skeleton audit schedule is in place (SLC T36). Dependant on the level of licensed activity and treatment outcomes, the centre will conduct initial audits of critical procedures and processes within six to 12 months of the centre first providing licensed treatment services.

SOPs are in place for activities included in the licence application, and those activities that do not require a licence (SLC T33(b)). Where relevant, SOPs detail the specifications for critical materials and reagents to be used (SLC T31).

There will be an annual review of the QMS (HF&E Act 1990 (as amended), Schedule 3A

(10)).

Traceability
There is an SOP to ensure traceability of gametes and embryos and also materials and equipment coming into contact with them (SLC T22, T99 and T102). With the exception of tubes used during egg collection, all other containers for gametes and embryos will be appropriately labelled using the patient's full name, date of birth and hospital number (SLC T101). The Laboratory Director has risk assessed the practice of not labelling tubes used to transfer follicular fluid during egg collection and will implement a documented 'clean down' practice between patients to remove the risk of misidentification of oocytes during this procedure. A copy of the risk assessment and actions taken to remove the risk of misidentification of oocytes has been provided to the lead inspector. The measures described to remove the risk of misidentification of oocytes appear to be satisfactory.

An SOP is in place to ensure data required for traceability is stored for the necessary period of time (SLC T103). Traceability data will be stored electronically. The Laboratory Director described the process by which this data will be 'backed up' by a reciprocal arrangement with their sister clinic centre 0250 GCRM Glasgow.

Validation
The centre's staff described how they will be using established protocols for critical procurement and processing procedures validated by their sister centre 0250 GCRM Glasgow. The validation approach used by centre 0250 includes a retrospective analysis of this centre's own data and benchmarking with other comparable centres and was considered to be compliant with SLC T72 at their renewal inspection in 2010.
An on-going review of process validation will be performed as the centre gathers its own data.

Equipment and materials
Activities will be carried out using equipment designated for the purpose (SLC T23). Service agreements are in place for equipment (SLC T26). Equipment will be regularly inspected and maintained. At the time of inspection approximately 30% of all critical equipment had been validated (SLC T24). The records of commissioning and validation of equipment as available were reviewed during the inspection.

There are documented procedures for the operation of all critical equipment and these outline what to do if the equipment malfunctions or fails (SLC T27). Equipment will be monitored and fitted with alarms with auto dial-out facility where appropriate (SLC T24). Equipment with a critical measuring function will be appropriately calibrated (SLC T24).

Sterile equipment and devices will be used for the procurement and processing of gametes and embryos (SLC T28). Wherever possible, CE marked consumables will be used (SLC T30).

Premises – suitability of the premises and air quality
The inspection team considered the premises to be suitable (SLC T17). The main entrance has secure access controlled from the reception area and is montiored by closed circuit television. All areas in which patient records and gametes/embryos may be kept are secure and are controlled by personnel specific swipe card access. A documented

contingencey agreement is in place with a neighbouring HFEA Treatment with Storage licensed centre for the continuation of service and/or storage of gametes and embryos in the event of force majeure.

There is an uninterrupted power supply that will provide power to critical equipment in case of unexpected power failure.

Initial air quality testing in the areas where processing of gametes and embryos will take place reported at least Grade C air quality, with a background of at least Grade D (SLC T20). Air quality testing will be repeated in both the critical work areas and surrounding environment when the laboratories are fully commissioned and a final deep clean is conducted prior to treatment commencing. Cleaning records will be held for these areas (SLC T26).

Adverse incidents
Centre staff are aware of the requirements for reporting and investigating adverse incidents and an SOP for this is in place (SLC T118 and T119).

Third party agreements
Third party agreements (TPAs) are in place with all suppliers that provide goods or services that influence the quality and safety of gametes and embryos (SLC T111) and a list is maintained of all TPAs (SLC T115). Five TPAs from this list were audited for compliance against regulatory requirements, and were considered compliant with SLC T113, T114 and T116.

Satellite IVF services
The application form indicates that GCRM Belfast will act as the primary licenced centre for satellite IVF services at NIFS, Northwest Independent Hospital, Ballykelly. A satellite agreement is in place in accordance with Directions 0010.

ICSI
The centre has an SOP (SLC T33(b)) and quality indicators (SLC T35) relevant to ICSI. Laboratory staff who will perform ICSI will be appropriately trained and will have had their competence assessed (SLC T15).

What the proposed centre could do better.
Validation of critical equipment
At inspection the validation of all critical equipment was incomplete. Since this date the centre has provided evidence of excellent progress with the final validation of equipment. At the time of writing the validation for two pieces of equipment remains outstanding.

Multiple Births (Guidance Note 7)

What the proposed centre does well.

The centre has a multiple births minimisation strategy that is compliant with Directions 0003. Patient information reviewed informs patients of the risks of multiple pregnancies and staff confirmed that this information will also be provided verbally in consultation and that this will

then be recorded in the patient record.
What the proposed centre could do better Nothing noted.

Staff engaged in licensed activity

- Person Responsible (Guidance Note 1)
- Staff (Guidance Note 2)

What the proposed centre does well.

Person Responsible
The PR holds 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 (HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii)).

The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1228/81) and is also the PR for HFEA licensed centre 0077 Regional Fertility Centre, Belfast.

Staff
Based on discussions at the time of inspection, the proposed staff numbers are likely to be sufficient for the projected initial activity levels. (SLC T12).

Staff appointed to work at the centre are appropriately registered with their relevant professional and/or statutory bodies (SLC T14 and T16). There are documented induction and training procedures for all staff and these were provided to the inspection team (SLC T15). Arrangements for competence assessments are in place and processes have been established for all staff to participate in continuing professional development. Where key members of the clinical and embryology team have been away from clinical practice during the commissioning of the new centre, arrangements are in place for those staff members to have a short 'refresher' placement with the centre's sister unit, centre 0250 for assessment of their continued competence to perform their clinical and laboratory roles.

What the proposed centre could do better.
Nothing noted.

Welfare of the Child (Guidance Note 8)

What the proposed centre does well.

Account will be taken of the welfare of any child who may be born as a result of treatment and of any other child who may be affected by the birth, before treatment is provided (SLC T56). The centre has an SOP for conducting welfare of the child assessments and appropriate QIs have been developed. Welfare of the child assessment forms part of the audit schedule (SLC T36).

What the proposed centre could do better. Nothing noted.

Embryo Testing – *only applicable to centres licensed to carry out preimplantation genetic diagnosis and screening)* • Preimplantation genetic screening (Guidance Note 9) • Embryo testing and sex selection (Guidance Note 10)
What the proposed centre does well. These guidance notes were not inspected against as the PR has withdrawn an application for embryo testing to be included in this licence.
What the proposed centre could do better.

2. Patient Experience

Focus

The purpose of the inspection visit was to assess whether the centre:

- treats prospective and current patients and donors fairly, and ensures that all licensed activities are conducted in a non-discriminatory way
- has respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions
- ensures that patients and donors have provided all relevant consents before carrying out any licensed activity

Treating patients fairly

- Treating patients fairly (Guidance Note 29)
- Confidentiality and privacy (Guidance Note 30)
- Complaints (Guidance Note 28)
- Provision of costed treatment plans (Guidance Note 4)
- Egg sharing arrangements (Guidance Note 12)
- Surrogacy (Guidance Note 14)

What the proposed centre does well.

Treating patients fairly
Following a review of the centre's policies and procedures and discussions with staff, the inspection team considers that all patients and donors will be treated fairly.

Complaints
There is a complaints policy in place, and a log of complaints will be maintained (CoP Guidance Note 28).

Provision of costed treatment plans
Based on a description provided during inspection, the process for issuing individualised costed treatment plans is likely to be compliant with Guidance Note 4.3. The proposed information to be provided to patients regarding treatment costs appears to be clear.

Egg sharing arrangements
The centre intends to facilitate both egg and sperm sharing. Information provided to potential gamete sharers was reviewed and appears comprehensive and clear. Where treatment as a benefit in kind is to be provided to egg sharers, this will be provided within the donation cycle unless it is considered not to be in the best interest of the egg sharer clinically. (Directions 0001)

Surrogacy
The centre has an SOP that requires that gamete providers in surrogacy arrangements will be screened and registered as donors (SLC T52 and T53), and that sperm will be quarantined for a minimum of 180 days prior to repeat testing or nuclei acid testing (NAT) will be performed(SLC T53(c)) Patient information is available on parental rights and

obligations in surrogacy arrangements. Centre staff are aware of potential changes to donor registration requirements and legal parenthood provisions relative to surrogacy effective from October 2013.

What the proposed centre could do better.
Nothing noted.

Information

- Information to be provided prior to consent (Guidance Note 4)
- Information about storage of embryos (including cooling off periods)
- Information about Intracytoplasmic sperm injection (Guidance Note 21)
- Information about legal parenthood (Guidance Note 6)

What the proposed centre does well.

There is an SOP for providing information to patients and donors (SLC T33(b)). A comprehensive suite of patient / donor information has been provided to the HFEA in accordance with Directions 0008. The patient / donor information provided has been audited by the inspection team against SLCs T58, T63 and the relevant guidance notes, including those for consent, storage of gametes and embryos, ICSI and legal parenthood and are considered to be compliant.

The centre's website is currently still under development and therefore could not be assessed for compliance with Chair's Letter CH (11)02.

What the proposed centre could do better.
Nothing noted.

Consent

- Consent to treatment, storage, donation, training and disclosure of information (Guidance Note 5)
- Consent to legal parenthood (Guidance Note 6)

What the proposed centre does well.

The centre will seek valid consent before gametes or embryos are used in treatment or storage or donated (SLC T57). Consents will be held in the patient's record, a copy of which will also be held electronically (SLC T46(f)). There is an SOP for seeking consent (SLC T33(b)), QI's have been established (SLC T35) and an audit is planned (SLC T36). The identity of the person providing consent will be verified. (CoP Guidance Note 5.10). There is an SOP in place to direct action where consent is withdrawn. This SOP also guides the 'cooling-off' period in the event that gamete providers are in dispute regarding the continued storage of embryos created with their gametes (CoP Guidance Note 5H).

Consent to legal parenthood will be obtained where required. Staff asked, were able to describe the requirements regarding legal parenthood. As part of the withdrawal of consent SOP there are mechanisms in place to ensure that where a patient or second parent withdraws consent, the second parent or patient will be informed and in the case of

the patient this will be before treatment takes place (SLC T64 and T65). Staff described the process for informing a women in the situation that the second parent has withdrawn their consent to be treated as the parent of any child born both verbally and in writing prior to being treated (SLC T64).
What the proposed centre could do better. Nothing noted.

3. Protection of gametes and embryos

Focus

The purpose of the inspection was to assess whether the centre has respect for the special status of the embryo when conducting licensed activities

Legal Requirements [Human Fertilisation and Embryology Act 1990 (as amended)]

- 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
- Embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies
- Embryos which are or have been stored are not given to a person, other than in the course of providing treatment services, unless that person is a person to whom a licence applies
- No money or other benefit is given or received in respect of the supply of gametes or embryos unless authorised by the Authority

What the centre does well.

The centre will be conducting the activities essential to the provision of licensed activities at the licensed premises only (SLC T1).

Only permitted embryos will be used in the provision of treatment services. Embryos will not be selected for use in treatment for social reasons and will not be created by embryo splitting. Centre staff are aware that embryos must only be created where there is a specific reason to do so and the clinician responsible for the patient will document the justification of the use of gametes and embryos based on the patient's medical history and therapeutic indications (SLC T49).

From discussions with staff and a review of the SOP in place, monetary compensations made to donors will be restricted to the limits prescribed in Direction 0001 version 3.

Where gametes are provided by overseas donors there are TPA's in place with the relevant donor organisations to ensure that all donors have only been compensated within the limits set in Directions 0001.

What the centre could do better.
Nothing noted.

Storage of gametes and embryos

- Storage of gametes and embryos (Guidance Note 17)

What the centre does well.

SOPs (SLC T33(b)) and QIs (SLC T35) are in place for procedures for storing gametes and embryos. These procedures have been validated using published studies and by adopting previously validated, established procedures in place at the centre's sister clinic GCRM Glasgow, centre 0250 (SLC T24).

Patients and donors will be appropriately screened before their gametes or embryos are stored (SLC T50 or T52 as appropriate). Screening tests will be carried out in a laboratory accredited by Clinical Pathology Accreditation (CPA) UK Ltd (SLC T51) under a TPA.

There is a process in place to manage the 'cooling off' period if required and staff demonstrated their understanding of this (CoP Guidance Note 5.35).

From discussions with staff and observations made, the inspection team conclude that the cryo-preservation storage facilities for gametes and embryos are designated for the purpose and appear to be adequate for the volume and types of activities proposed (CoP 17.2). Access to this area is limited to authorised personnel only. The cryopreservation dewars are fitted with local audio and visual alarms within the centre which are linked to an auto-dial system which will alert designated staff to a problem or malfunction out of hours. (CoP Guidance 17.5)

Staff were able to describe and demonstrate how they will operate a 'bring forward' system to ensure that sufficient notice is given of the end of the consented storage period to those storing gametes or embryos.

What the centre could do better.
Nothing noted.

Distribution and / or receipt of gametes and embryos

- Distribution of gametes and embryos (Guidance Note 15)
  Export of gametes and embryos (Guidance Note 16)
- Receipt of gametes and embryos (Guidance Note 15)
- Import of gametes and embryos (Guidance Note 16)

What the proposed centre does well.

SOPs are in place (SLC T33(b)) that detail the responsibilities and requirements for the distribution, receipt, and recall of gametes and embryos (SLC T105, T106, T107, T108, T109 and T110).

A courier will be used for transport of gametes or embryos and there is a TPA in place that ensures required transport conditions are maintained during distribution (CoP Guidance Note 15B; T11).

There are SOPs in place to direct the import or export of gametes and embryos which are compliant with Directions 0005 and 0006.

What the proposed centre could do better.
Nothing noted.

Use of embryos for training staff (Guidance Note 22)

What the proposed centre does well.
The centre's licence application states that embryos will be used for training staff in the following techniques:
Cryo preservation / thaw techniques
Vitrification (eggs and embryos)
Assisted hatching
Embryo handling.

The licence application also states that embryos will be used for training in embryo and blastocyst biopsy. The proposed PR and Laboratory Director confirmed on inspection that embryos will not be used for training in these techniques until such time as the centre is preparing to apply to vary the licence to conduct embryo biopsy, at which point SOPs, patient information will be provided to the HFEA.

There are procedures in place to ensure that no embryos are used for training purposes unless both gamete providers have consented to the use of their embryos, created with their gametes, for the purpose of training (SLC T94) and to ensure that there is no actual or perceived conflict of interest between the use of embryos in training and the use of embryos in the provision of treatment services (SLC T95). Consent to use of eggs or embryos is sought in principle prior to egg collection by trained staff separate from those conducting or participating in training in embryological techniques.

All gamete providers will be given information regarding the nature of the training for which their eggs or embryos would be used and whether information regarding the use of their eggs / embryos will be fed back to them. Gametes providers are also informed that their consent may be varied or withdrawn at any point until the embryos are used in training (SLC T97).

What the proposed centre could do better. Nothing noted.

4. Good governance and record keeping

Focus

The purpose of the inspection was to assess whether the centre:

- maintains accurate records and information about all licensed activities
- conducts all licensed activities with regard for the regulatory framework governing treatment involving gametes and embryos within the UK, including
    - maintaining up-to-date awareness and understanding of legal obligations
    - responding promptly to requests for information and documents from the HFEA
    - co-operates fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare

Record keeping • Record keeping and document control (Guidance Note 31)
What the proposed centre does well. Documents reviewed on inspection were controlled, with version numbers and review dates (SLC T34). The content of patient records as required by SLC T46 was discussed with the PR who confirmed that the required elements will be retained in the initial 'hard copy' patient record which will then be transferred to the electronic records management system. Paper and electronic records are protected from unauthorised access and amendment (SLC T47). These measures include password protection on the computers and the electronic records management system which is electronically 'backed up' each night as part of a reciprocal arrangement with centre 0250 GCRM Glasgow. The data systems are secure and not accessible to unauthorised personnel. Records will be held for a minimum of 30 years, and there is the facility to hold records for longer where circumstances require (SLC T48, T103 and T104).
What the proposed centre could do better. Nothing noted.

Legal requirements [Human Fertilisation and Embryology Authority 1990 (as amended)] • Obligations and reporting requirements of centres (Guidance Note 32)
What the proposed centre does well. There is an SOP for submitting data to the HFEA (SLC T33(b)). Staff confirmed that they are familiar with submitting data to the HFEA and the PR is satisfied with the competence of staff (SLC T15(a)). QIs have been established (SLC T35) and will be monitored as part of the audit schedule (SLC T36) Staff were aware of the requirements of General Directions 0005.
What the proposed centre could do better. Nothing noted.

Disclosure of information

- Confidentiality and privacy (Guidance Note 30)
- Disclosure of information, held on the HFEA Register, for use in research

What the proposed centre does well.

The inspection team considered that there is good provision for maintaining the confidentiality and privacy of patients and donors. The centre has a range of SOPs in place to ensure that all information is kept confidential and only disclosed in circumstances permitted by law (SLC T43). Access to identifying information and electronic patient records is restricted to authorised personnel records and ensures traceability whilst preventing unauthorised disclosure of information (SLC T44).

Access to areas where confidential identifying information can be seen or obtained will be restricted by swipe card and authorised by the PR (HF&E Act 1990 (as amended) section 33A(1)).

Patients and their partners will be identified by reference to their validated photographic identification, a copy of which will be retained in the patient's record (CoP Guidance Note 5.10).

Staff asked were able to accurately describe how and when patients, their partners and donors will be informed about and asked to document their consent decision regarding the disclosure of information held on the HFEA Register, for use in research, and how this information will then be provided to the HFEA.

What the proposed centre could do better.
Nothing noted.

Areas of proposed practice that require the attention of the proposed Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of potential non compliance. Each area 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. 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	Proposed PR Response	Executive Review
.None		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	Proposed PR Response	Executive Review
1. At inspection the validation of all critical equipment was incomplete. Since this date the centre has provided evidence of excellent progress with the final validation of equipment. At the time of writing the validation for two pieces of equipment remains outstanding.	The proposed PR should provide a copy of the final validation documentation for the items of critical equipment that remains outstanding to the lead inspector before commencing licensed activity.	The two items outstanding have both been returned to the supllier due to non conformances during the validation process. We are awaiting delivery of the replacment items and these should arrive in early Nov 13. As soon as these items are on site they will be validated and the required evidence forwarded directly to yourselves.	The Executive is satisfied with the proposed PR’s response and awaits confirmation of final validation of this equipment.

‘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	Proposed PR Response	Executive Review
None		none	

Additional information from the Person Responsible