HFEA Executive Licensing Panel Meeting

29 November 2013

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

Minutes – Item 2

Centre 0201 – (Edinburgh Assisted Conception Unit) – Renewal Treatment (including embryo testing) & Storage Inspection Report

Members of the Panel:	**Committee Secretary:**
Juliet Tizzard – Interim Director of Strategy (Chair)	Dee Knoyle
Rachel Hopkins – Head of Human Resources	**Observing:**
Paula Robinson – Head of Business Planning	Sam Hartley – Head of Governance and Licensing

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

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 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)
- 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 Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel considered the papers, which included a completed application form, inspection report and licensing minutes for the past three years.

2. The Panel noted that this is a treatment and storage centre which provides a full range of licensed treatments, including embryo testing. The Panel noted that in relation to activity levels this is a medium-sized centre.

3. The Panel noted that the centre has been licensed by the HFEA since 1992 and is on a five-year licence due to expire on 28 February 2014.

4. The Panel noted that in the 12 months to 31 July 2013, the centre provided 493 cycles of fresh in vitro fertilisation (IVF) or intracytoplasmic sperm injection (ICSI) treatment and 253 cycles of frozen embryo transfer (FET) treatment.

5. The Panel noted that for IVF and ICSI, HFEA-held register data for the period 1 May 2012 to 30 April 2013 show the centre's clinical pregnancy rates are in line with national averages.

6. The Panel noted that in 2012, the centre reported six cycles of partner insemination with one pregnancy. This number of cycles is too low to report whether the success rate is significantly different from the national average.

7. Between 1 April 2010 and 31 March 2011, the centre's multiple live birth rate for all IVF, ICSI and FET cycles for all age groups was 16%. This represented performance that was not statistically different from the 20% maximum multiple live birth rate target for this period.

8. Between 1 April 2011 and 30 September 2012, the centre's multiple clinical pregnancy rates for all IVF, ICSI and FET cycles for all age groups was 15%. This represented performance that was not likely to be statistically different from the 15% maximum multiple live birth rate target for this period.

9. The Panel noted that at the time of the inspection on 3 and 4 September 2013, the Inspectorate observed four major and nine other areas of non-compliance. The Panel noted the PR's commitment to implement the outstanding recommendations within the set timescales.

10. The Panel noted the Inspectorate's recommendation that some improvement is required in order for the centre to reflect good practice and demonstrate the quality and safety of the service it provides.

11. The Panel noted the Inspectorate recommends the renewal of the centre's Treatment (including embryo testing) and Storage licence for a period of four years without additional conditions, subject to compliance with the recommendations made in this report being implemented within the prescribed timescales.

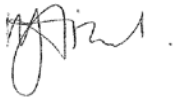
Decision

12. The Panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

13. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licenced activities, and that he has discharged his duty under section 17 of the HF&E Act 1990 (as amended).

14. The Panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

15. The Panel endorsed the Inspectorate's recommendation to renew the centre's Treatment (including embryo testing) and Storage licence for four years, without additional conditions, subject to compliance with the recommendations made in this renewal inspection report being implemented within the prescribed timescales.



Signed: Date: 13 December 2013

Juliet Tizzard (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 the 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 Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 03/04 September 2013

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.

Inspectors: Andrew Leonard (Lead); Douglas Gray (Scientific); Kathryn Mangold (Clinical); Chris Hall (Register); Sara Peacey (Register).

Date of ELP: 29 November 2013

Centre name	Edinburgh Assisted Conception Unit
Centre number	0201
Licence number	L/0201/6/d
Centre address	Edinburgh Fertility & Reproductive Endocrine Centre, Royal Infirmary of Edinburgh, 51, Little France Crescent, Edinburgh, Lothian, EH16 4SA
Person Responsible	Dr K J Thong
Licence Holder	Sandra Mair
Date licence issued	01/03/2009
Licence expiry date	28/02/2014
Additional conditions applied to this licence	None

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Section 1: Summary report

Brief description of the centre and its licensing history:

The Edinburgh Assisted Conception Unit (centre 0201) is also known as Edinburgh Fertility and Reproductive Endocrinology Centre (EFREC) and is located at the Royal Infirmary of Edinburgh. The centre has held a licence with the HFEA since 1992 and since 2002 at its current premises. The centre provides a full range of fertility services including embryo testing.

In the 12 months to 31 July 2013, the centre provided 493 cycles of fresh in vitro fertilisation (IVF) or intracytoplasmic sperm injection (ICSI) treatment and 253 cycles of frozen embryo transfer (FET) treatment. In relation to activity levels, this is a medium sized treatment and storage centre.

The centre has varied the licensed premises to enlarge the laboratory since the last licence renewal. The current licence (L/0201/6D) lists the Licence Holder (LH) as Dr Stewart Irvine. This is an administrative error within the HFEA as the LH on the previous version of the licence (L/0201/6C) was listed as Sandra Mair and no application to change the LH was made by the PR. Sandra Mair is the LH listed in the renewal application.

Activities of the centre:

Type of treatment	Treatment cycles between 01 August 2012 and 31 July 2013*
In Vitro Fertilisation (IVF)	285
Intracytoplasmic sperm injection (ICSI)	208
Gamete intrafallopian transfer (GIFT)	0
Frozen embryo transfer (FET)	253
Donor insemination (DI)	0
Egg share provider (sharer)	0
Egg share recipient	0
Egg donation (non egg share)	5
Insemination with partner sperm	6 in Jan – Dec 2012

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓
Research (if applicable)	No

Outcomes [1]

For IVF and ICSI, HFEA held register data for the period 1 May 2012 – 30 April 2013 show the centre's clinical pregnancy rates are in line with national averages.

In 2012, the centre reported six cycles of partner insemination with one pregnancy. This number of cycles is too low to report whether the success rate is significantly different from the national average.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.

Between 1 April 2010 and 31 March 2011, the centre's multiple live birth rate for all IVF, ICSI and FET cycles for all age groups was 16%: this represented performance that was not statistically different from the 20% multiple live birth rate target for this period.

Between 1 April 2011 and 30 September 2012, the centre's multiple clinical pregnancy rates for all IVF, ICSI and FET cycles for all age groups was 15%; this represented performance that was not statistically likely to be different from the 15% multiple live birth rate target for this period. The centre is commended by the inspection team for its performance in this regard.

[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. The HFEA considers differences in a centre's success rates and multiple pregnancy rates from the national averages are only statistically significant if they occur at a significance level of $P \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the multiple live birth rate (MLBR) target to a multiple clinical pregnancy rate (MCPR) target. The 2011/12 MLBR target of 15% is calculated as equivalent to a 19% MCPR.

Summary for licensing decision

Taking into account the essential requirements of 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 PR is suitable and has discharged his duty under Section 17 of the HF&E Act 1990 (as amended)
- the premises are suitable
- the practices are suitable
- 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 ELP 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, four major and nine 'other' areas of non-compliance or poor practice which have resulted in the following recommendations:

Critical areas of concern:

- **None**

Major areas of non compliance:

- The PR should develop induction, training and competence assessment in several areas discussed below.
- The PR should ensure the processes for cryopreservation of sperm, thawing of sperm and thawing of embryos are fully validated.
- The PR should ensure gametes and embryos are not stored without valid consent.
- The PR should ensure the all critical equipment including the cryostorage dewars, Gilson pipettes, dry shipper and refrigerator are fully validated.

'Other' areas of poor practice that require improvement:

- The PR should ensure that the witnessing standard operating procedure (SOP) is revised to accurately document witnessing practices and that all witnessing checks are documented in the patient records.
- The PR should complete a risk assessment for the medical gas cylinder store and take any necessary corrective actions to ensure the safety of staff.
- The PR should ensure that information provided to patients regarding the use of embryos in training is amended so that it includes information concerning whether the results of the use of their embryos in training will be fed back to them. The PR should also audit the centre's website against the requirements of Chair's Letter 11(02) and should implement corrective actions to correct non-compliance.
- The PR should take action to ensure that all traceability data is recorded in the records about anything coming into contact with gametes or embryos.
- The PR should ensure SOPs are documented for all administrative processes which may impact on licensed activity within the centre. The PR should also ensure that patient information provision is audited against CoP requirements.
- The PR should ensure the document control procedure is reviewed to verify that it is suitable.
- The PR should ensure that the returned drugs drawer is locked when unattended.

- The PR should take appropriate actions to ensure that all HFEA invoices are paid within the 28 day deadline.
- The PR should take appropriate actions to ensure that the centre submits accurate information to the Register regarding consent to disclosure to researchers.

The PR has given a commitment to fully implement all the recommendations listed above within the required timeframes.

Recommendation to the ELP

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 however satisfied that activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

The inspection team recommends the renewal of the centre's treatment (including embryo testing) and storage licence for a period of four years without additional conditions, subject to compliance with the recommendations made in this report being implemented within the prescribed timescales

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.

Procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate, ensure that patients receive treatment using the correct gametes or embryos. The centre's procedures for double checking are broadly compliant with HFEA requirements.

What the centre could do better.

The witnessing SOP does not specify the performance of witnessed checks of identifiers, which are said by staff to occur when a labelled sperm pot is provided to a patient couple for home production of sperm or when the sperm pot is received back from the patient couple (SLC T33b; Recommendation 5). The witnessing record sheet held in each patient record has space for these checks to be documented, suggesting it is the centre's practice to perform them, however review by an inspector of a patient record documenting a recent home sperm production, showed that these witnessed checks (i.e. when the labelled sperm pot was provided to the patient couple and when it was received back from them) had not been documented (SLC T71; Recommendation 5). Review of witnessing record sheets also indicated that the time of witness checks at oocyte stripping during ICSI is not documented (SLC T71; Recommendation 5).

Patient and donor selection criteria and laboratory tests

What the centre does well.

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

The centre's procedures for screening patients and / or donors are 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.

Payments for donors (Guidance note 13)

Payments to donors are fully in line with the requirements of the HFEA. 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)
People born as a result of donation are entitled to request and receive their donor's name and last known address, once they reach the age of 18. Therefore it is important that centres use donated gametes or embryos from identifiable donors. The centre is fully compliant with the requirements of the HFEA to ensure the donor conceived will be able to receive this information.

What the centre could do better.
Nothing noted on this inspection

Good clinical practice

What the centre does well.

Multiple births (Guidance note 7)
The single biggest risk of fertility treatment is a multiple pregnancy.

The centre's performance since 2010 has complied with HFEA multiple birth rate targets suggesting that the centre has been proactive and effective in developing their multiple births minimisation strategy.

Process Validation (Guidance note 15)
The centre has partially validated critical processing procedures to ensure that these procedures are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA requirements, with one minor exception, ensuring it has the ability -
(a) to identify and locate gametes and embryos during any step from procurement to use for human application or disposal,
(b) identify the donor and 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 broadly compliant with HFEA requirements. The centre uses its quality management system to ensure optimum outcomes and improve the quality and safety of the treatment and services provided.

Third party agreements (Guidance note 24)
The centre has agreements in place which cover the:
(a) procurement, testing or processing of gametes or embryos on behalf of the licensed centre, and the
(b) supply of any goods or services (including distribution services) to the licensed centre 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. Nearly all have been validated, with some exceptions 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 licensed activities in an appropriate environment, in line with good clinical practice, with minor exceptions discussed below. All diagnostic testing is carried out in suitably accredited laboratories.

Adverse incidents (Guidance note 27)
The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre has investigated all of the adverse incidents that have occurred and shares the lessons learned in order to continuously improve the services it offers.

What the centre could do better.

Process Validation (Guidance note 15)
The centre has not validated the following critical procurement and processing procedures: cryopreservation of sperm; thawing of sperm; thawing of embryos (SLC T72; Recommendation 2).

Traceability (Guidance note 19)
In one record reviewed on inspection, traceability data regarding the ICSI rig was not documented, contrary to the centre's standard practice (SLC T99; Recommendation 8).

Quality management system (Guidance note 23)
SOPs to direct all the administrative procedures within the centre are not present, for example the use and maintenance of patient records on the database used by the centre (SLC T33(b); Recommendation 9)

Patient information provision has not been audited against CoP requirements in the last two years (SLC T36; Recommendation 9).

Equipment and materials (Guidance note 26)
The following critical equipment has not been validated: Cryostorage dewars; Gilson pipettes; dry shipper; refrigerator (SLC T24; Recommendation 4).

Premises (Guidance note 25)
Access to the medical gas cylinder store was restricted by decommissioned cylinders and cryostorage dewars, such that the inspection team questioned the safety of staff accessing the store, and thus whether the PR was ensuring that licensed activities are carried out on suitable premises (SLC T17; Recommendation 6).

The drawer in which drugs returned by patients to the centre are stored was not locked and was in an unlocked room. This was contrary to the centre's normal practice and was considered to reflect unsuitable practice (SLC T2; Recommendation 11).

Staff engaged in licensed activity

What the centre does well.

Person Responsible (Guidance note 1)
The PR has a key role to play in implementing the requirements of the HF&E Act 1990 (as amended) and is the person under whose supervision the licensed activities are authorised. The PR has the primary (legal) responsibility under Section 17 of the HF&E Act 1990 (as amended) to secure:

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

The PR has academic qualifications in the field of medicine and has more than two years 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/1098/7).

Staff (Guidance Note 2)
The centre has suitably qualified and competent staff to carry out all of the licensed activities and associated services, with some exceptions discussed below.

What the centre could do better.

Staff (Guidance note 2)
The centre does not have a documented induction training procedure for some staff, notably those in the centre's administration team. In addition, some staff (e.g. anaesthetists; administrators) have commenced work without completing an induction and training programme (SLC T15; Recommendation 1).

Laboratory staff could not provide evidence of having received training in traceability procedures or of having had an assessment of their competence in this area of practice (SLC T15; Recommendation 1).

Staff involved in data submission to the HFEA provided no evidence of the completion of training in data submission processes (SLC T15; Recommendation 1).

Welfare of the child (Guidance note 8)

What the centre does well.
The centre's procedures for taking into account the welfare of the child are compliant with HFEA requirements. The centre 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.

What the centre could do better.
Nothing noted on this inspection

Embryo testing

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

What the centre does well.

The centre's procedures for performing embryo testing are compliant with HFEA requirements ensuring 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.

The centre ensures that people seeking embryo testing are given written information, are given every opportunity to discuss the implications of their treatment and have access to clinical geneticists, genetic counsellors and infertility counsellors where required.

What the centre could do better.

Nothing noted on this inspection

2. The experience of patients

Patient feedback

What the centre does well.

During the inspection visit the inspectors did not speak to any patients regarding their experiences at the centre as none volunteered to be interviewed. A further 54 patients have provided feedback directly to the HFEA since September 2011. Feedback was positive with 35 of the individuals providing written feedback to the HFEA commenting that they had compliments about the care that they received.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- 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 noted on this inspection

Treating patients fairly

What the centre does well.

Gamete sharing arrangements (Guidance note 12)

The centre does not currently offer treatment involving gamete sharing therefore the requirements of this guidance note were not reviewed on inspection.

Surrogacy (Guidance note 14)

The centre does not currently offer treatment involving surrogacy arrangements therefore the requirements of this guidance note were not reviewed on inspection.

Complaints (Guidance note 28)

The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. The centre actively seeks patient feedback and uses it and any complaints as an opportunity to learn and improve the services.

Treating patients fairly (Guidance note 29)

The centre treats prospective and current patients and donors fairly and ensures that all licensed activities are conducted in a non-discriminatory way.

Confidentiality and privacy (Guidance note 30)

The centre's procedures are broadly compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors.

What the centre could do better

Confidentiality and privacy (Guidance note 30):
All staff are supposed to sign a confidentiality agreement before commencing work at the centre, however they do this without being advised about the confidentiality requirements of HF&E Act 1990 (as amended), Section 33A, reviewing the centre's confidentiality SOP or receiving any other training regarding confidentiality (SLC T15). Furthermore some staff have not signed the confidentiality agreement (Recommendation 1).

Information

What the centre does well.
The centre's procedures for providing information to patients and / or donors are 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.

Provision of a costed treatment plan (Guidance note 4)
The centre provides a treatment plan and treatment price list to all self-funding patients. This ensures that patients know the full cost of their proposed treatment before deciding on whether to proceed or not.

What the centre could do better

Information to be provided prior to providing consent (Guidance note 4)
The centre's website was considered non-compliant with the requirements of Chair's Letter 11(02), e.g. the success rates quoted do not include live birth rates and are not from within the last three years (Recommendation 7). The centre staff explained that the website is being updated.

Prior to consenting for the use of their embryos in training, patients are not provided with information regarding whether any results from the use of their embryos in training will be fed back to them (SLC T97d; Recommendation 7).

Consent

What the centre does well.
The centre's procedures for obtaining treatment consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Disclosure of information, held on the HFEA Register, for use in research
The Register started operating in August 1991 and is a rich source of information about assisted reproductive technologies (ART), its outcomes and the factors that contribute to the birth of a baby following treatment. This information can be used by researchers and, in certain circumstances, linked to other health registers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment. Whereas the HFEA is permitted to disclose non-identifying information to researchers it can only provide identifying information with the consent of patients. Therefore, it is important that

patients are asked to give their consent and that their wishes are accurately recorded and passed on to the HFEA. The centre's procedures for doing this do not reliably ensure that the HFEA holds an accurate record of the patients' consent, so that it only releases their identifying information to researchers with their consent.

What the centre could do better.

In the ten sets of patient records reviewed, two discrepancies were found between completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register. This suggests that the centre's procedures may not ensure that the HFEA holds an accurate record of the patients' consent to disclosure to researchers (Chair's Letter CH(10)05 and guidance; General Direction 0007; recommendation 13).

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 ensures 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.
- 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 noted on this inspection

Storage of gametes and embryos

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 partially compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Samples within the centre's established gamete and embryo store are stored with valid documented storage consent under an effective bring-forward system, however some exceptions are discussed below related to recent changes in storage at the centre.

What the centre could do better.

A store of sperm samples from oncology patients has very recently come under the control of the Laboratory Manager. She needs to audit the samples and their consent forms to confirm their storage consent status however she thought it possible that some of the sperm samples were being stored beyond the consented storage period (HF&E Act 1990 (amended), Schedule 3, 8.1; Recommendation 3).

Distribution and / or receipt of gametes and embryos

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 the gametes and embryos are appropriately labelled and has enough information to permit the gametes and embryos be stored or used in a way that does not compromise their quality and safety.

What the centre could do better.
Nothing noted on this inspection

Use of embryos for training staff (Guidance note 22)

What the centre does well.
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.

The centre uses embryos to train staff in the following activities:

- Embryo biopsy
- Blastocyst biopsy
- Cryopreservation and thawing techniques

All of these activities have been authorised by the Authority.

What the centre could do better.
Nothing noted on this inspection

4. Information management

Record keeping and submitting information to the HFEA

What the centre does well.

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are 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. Document control procedures were considered broadly compliant, with some exceptions discussed below.

Obligations and reporting requirements (Guidance note 32)
The HFEA has a legal responsibility to maintain a register containing information about all licensed activities including information on donors and on any children conceived as a result of their donation. In order to maintain this Register, centres are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

The centre's procedures for submitting information, about licensed activities, to the Authority are compliant with HFEA requirements and ensure the HFEA can supply accurate information to a donor-conceived person and their parents.

What the centre could do better.

Record keeping and document control (Guidance note 31)
Three patient information sheets were seen to have not been subjected to review within the timescale set by the centre and were 'out of date' given the document control details on them. Uncontrolled training documents were also present in the administration section. These observations suggest the centre's document control procedures need to be reviewed (SLC T34; Recommendation 10).

Section 3: Monitoring of the centre's performance

Following the interim inspection in September 2012, no recommendations for improvement were made in relation to critical or major areas of non-compliance, however four recommendations were made in response to 'other' areas of practice that required improvement.

The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales.

Risk based assessment tool (RBAT) alerts

In the last twelve months, the centre has been issued with several performance alerts concerning:

- January 2013: Clinical pregnancy rates following ICSI in patients aged under 38. Centre staff informed the HFEA that they were aware of a decline in fertilisation rates in patients aged under 38 following ICSI when the alert was issued. A detailed investigation was performed, a report of which was provided to the HFEA: no specific issues were found that required corrective action. The centre has continued to monitor their ICSI success rates and have noted that results in this area are now improving. They have concluded that the alert represents a brief dip in success rates which has now corrected and no further action is required. The inspection team were minded to agree and note that the centre's quality indicator monitoring will detect similar issues in the future and that the centre investigated this alert effectively.

- December 2012, January 2013, May 2013, June 2013 and October 2013: Risk tool alerts related to the late payment of invoices (>60 days after their issue). Chair's Letter CH(10)02 requires payment of HFEA invoices within 28 days (Recommendation 12).

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. Staff The centre does not have a documented induction training procedure for all staff, notably those in the administration team. In addition, some staff (e.g. anaesthetists; administrators) have commenced work without completing induction training (SLC T15).	The PR should ensure that a suitable induction training plan is established and documented for all staff, and it is completed by all staff starting work at the centre. The actions taken to implement this recommendation should be advised to the HFEA by 3 December 2013. The completion of induction training should be audited and corrective actions should be taken where staff have not completed it. The report of this audit and the corrective actions proposed should be provided to the HFEA by 3 March 2013.	The documentation regarding induction/training/competency for admin & clerical staff is being updated and will be more comprehensive. Arrangements are being made for all admin & clerical staff to repeat the induction process using the new documentation. This process will be completed and audited by 3rd March 2014. Other staff (e.g.anaesthetists) working on an ad hoc basis, will have a generic induction document.	14 November 2013: The PR has indicated that appropriate actions are being taken to implement these recommendations within the required timescales. Evidence of their successful implementation will be followed up with the PR through the on-going monitoring system.

Laboratory staff could not provide evidence of having received training in traceability procedures or of having had an assessment of their competence in this area of practice (SLC T15).	The PR should ensure that laboratory staff are provided with training regarding traceability procedures and that this training is documented. This recommendation should be implemented by 3 March 2014 and the actions taken advised to the HFEA.	There is a standard operating (SOP) procedure on the Traceability of gametes, embryos, patients, staff carrying out procedures, equipment, consumables, reagents and any item which can effect the safety or quality of gametes and embryos. All embryologists read and sign off this SOP annually so are conversant with these procedures. There is also a documented induction procedure with regards to tracebility with associated training records. We also carry out an annual audit of tracebility in laboratory procedures which would highlight any ongoing trend in performance problems of any one individual. However, there is currently no ongoing competency assessment for traceability. Therefore this will be built into the annual competency-re-assessment programme for the forthcoming year.	
Staff involved in data submission to the HFEA provided no evidence of the completion of training in data submission	The PR should ensure that staff involved in data submission to the HFEA are provided with appropriate training and that this is documented. This recommendation should be implemented by 3 March 2014	A comprehensive induction and training programme was carried out for this member of staff. New documentation has been created and the induction process will be repeated and signed off.	

processes (SLC T15). All staff are supposed to sign a confidentiality agreement however they do this without being advised about the confidentiality requirements of HF&E Act 1990 (as amended), Section 33A, reviewing the centre's confidentiality SOP or receiving any other training regarding confidentiality (SLC T15). Furthermore some staff have not signed the confidentiality agreement	and the actions taken advised to the HFEA. The PR should ensure that all staff are provided effective training regarding confidentiality (including the requirements of the HF&E Act 1990 (as amended)) and sign the centre's confidentiality agreement. This recommendation should be implemented by 3 March 2014 and the actions taken advised to the HFEA.	New documentation is being created regarding the confidentiality declaration. This will include an information document advising the requirements of the HFEA, confidentiality and other local 'rules'. The confidentiality protocol will be reviewed and updated as necessary. It will be reinforced to all staff that the confidentiality declaration must be signed before any staff commence work in the centre.	
2. Process Validation The centre has not validated the following critical procurement and	The PR should ensure the processes for cryopreservation of sperm, thawing of sperm and thawing of embryos are fully	These validations will be carried out and incorporated into the over arching Process Validation document	14 November 2013: The PR has indicated that actions are being taken to implement this recommendation within the

processing procedures: cryopreservation of sperm; thawing of sperm; thawing of embryos (SLC T72).	validated. It is expected that validation will be prioritised on the basis of risk associated with the procedure and that these validations will be complete by 3 March 2014. On completion, the HFEA will ask for a sample of validation documents to be submitted for review.		required timescale. The completion of these process validation documents will be followed up with the PR through the on-going monitoring system.
3. Storage Consent On the day of the inspection it was likely that the centre was storing the gametes of an unknown number of sperm providers beyond the consented storage period (HF&E Act 1990 (amended), Schedule 3, 8.1).	The PR should ensure gametes and embryos are not stored without valid consent being in place. The PR should provide the HFEA with an update on the number of patients for whom sperm remains in store beyond the consented storage period and a plan to correct this non-compliance with timescales for implementation. This report should be provided as quickly as possible however given the number of samples which need to be reviewed (>1600) a final deadline of 3 March 2014 is reasonable. The PR should provide monthly updates to the HFEA on progress	This area has recently been returned to local management and there had been a few problems with the "bring forward" system for reviewing samples close to storage consent expiry. This system has now been overhauled and brought into line with the "bring forward" system in embryology. Samples are now brought forward for contact 6-8 months ahead of consent expiry rather than the previous 2 months. This should allow enough time for the often onerous task of tracing patients who may have moved away from their previous address. We have also requested additional administrative support in order that more regular contact can be made with patients who have samples in	24 October 2013: An email from the Laboratory Manger indicates a provisional audit of a sample of storage consents has been performed and that only a small proportion (1-4%) of the >1600 samples are likely to be stored without valid consent. A full physical audit of the samples is progressing after which all storage consents will be reviewed. 14 November 2013: The PR has indicated that appropriate actions are being taken to implement this recommendation. The completion of these corrective actions by 3 March 2013,

	in implementing the proposed actions. 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 where legal challenge is possible.	long term storage. Audit of consents is carried out on an annual basis. The previous audit, carried out in 2012 had indicated "some minor inconsistencies in consents mostly attributable to long term storage from oncology patients at the Western General Hospital". After the HFEA inspection, another small sample audit of sperm storage notes has taken place (50 cases) including original referral, consents, storage records and any attempted contacts during the period of storage. These indicated a high level of compliance with HFEA guidelines for storage consent, but several samples from patients who had been "lost to contact" had been extended after their initial 10 years storage period to storage until their 55th birthday, on the basis of their indicating they wished the "maximum" storage period on the original consent. Most of these had been extended without a formal medical practitioners statement as they had been lost to contact. Otherwise the consents were in	including the physical and consent audits of the sperm samples, will be followed up with the PR through the on-going monitoring system.

		order. A full consent audit will be carried out during 2013 and 2014, following completion of the physical audit which is currently underway.	
4. Equipment Validation The following critical equipment has not been validated: Cryostorage dewars; Gilson pipettes; dry shipper; refrigerator (SLC T24)	The PR should ensure that all critical equipment including the cryostorage dewars, Gilson pipettes, dry shipper and refrigerator are fully validated. It is expected that validation will be prioritised on the basis of risk associated with the equipment and that these validations will be complete by 3 March 2014. On completion, the HFEA will ask for a sample of validation documents to be submitted for review.	These validations have already started and will be completed by the date indicated on the inspection report. However, we would also like clarification of which 'fridge needs to be validated, there are many 'fridges in the unit.	14 November 2013: The PR has indicated that actions are being taken to implement this recommendation within the required timescale. The issue regarding the 'fridges to be validated has been discussed with the PR. The completion of these equipment validation documents will be followed up with the PR through 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
5. Witnessing The witnessing SOP does not document the centre's normal practice to perform witnessed checks of identifiers when a labelled sperm pot is provided to a patient couple for home production of sperm or when the sperm pot is received back from the patient couple (SLC T33b). The documentation of these checks was also missing from a patient record which documented a recent home production (SLC T71). The time of witness checks at oocyte stripping during ICSI was not documented in the records (SLC T71).	The PR should ensure the witnessing SOP is revised to accurately document witnessing practice at the centre and that it includes witnessing checks at all critical points of the clinical and laboratory process. The revised SOP should be provided to the HFEA by 3 December 2013 The PR should take immediate action to ensure that all witnessing checks are documented in the patient records. The HFEA should be advised of the measures taken to ensure that this happens by 3 December 2013.	The laboratory witnessing protocol will be revised accordingly and the forms involved in these two procedures will be revised according to the HFEA recommendations.	14 November 2013: The PR has indicated that actions are being taken to implement this recommendation within the required timescale. The revision of the witnessing SOPs and of the forms used to record the relevant witnessed checks will be followed up with the PR through the on-going monitoring system.
6. Premises Access to the medical gas cylinder store was restricted	The PR should complete a risk assessment for the medical	Some equipment has already been removed from the gas	14 November 2013: The PR has indicated that actions

by decommissioned cylinders and cryostorage dewars, such that the inspection team questioned the safety of staff accessing the store (CoP Guidance 25.7).	gas cylinder store and take any necessary corrective actions indicated by the risk assessment to ensure the safety of staff within the store. The PR should provide the risk assessment and evidence of the completion of any corrective actions, to the HFEA by 3 December 2013.	store, making access much easier, but there are still a few issues to address. A risk assessment will be carried out and any remaining problems addressed through the Health and Safety committee.	are being taken to implement this recommendation within the required timescale. Further actions are still required: The completion of the risk assessment for the gas cylinder store and the implementation of risk control measures (due 3 December 2013) will be followed up with the PR through the on-going monitoring system.
7. Patient Information Prior to consenting for the use of their embryos in training, patients are not provided with information regarding whether any results from the use of their embryos in training will be fed back to them (SLC T97d). The centre's website was	The PR should ensure that information provided to patients regarding the use of embryos in training, is amended so that it includes information concerning whether the results of the use of their embryos in training will be fed back to them. This recommendation should be implemented by 3 December 2013 The PR should audit the	The consent and information form will be amended to make it clear that no information will be fed back following use of material in training This audit will be implemented	14 November 2013: The PR has indicated that actions are being taken to implement these recommendations within the required timescales. Their completion will be followed up with the PR through the on-going monitoring system.

considered non-compliant with the requirements of Chair's Letter 11(02).	centre's website against the requirements of Chair's Letter 11(02) and should implement corrective actions to correct non-compliance. The audit report, including proposed corrective actions, should be provided to the HFEA. This recommendation should be implemented by 3 March 2014.	and corrective actions carried out within the timescale.	
8. Traceability In one record reviewed on inspection, traceability data regarding the ICSI rig was not documented, contrary to the centre's standard practice (SLC T99).	The PR should take action to ensure that traceability data is recorded in the records about anything coming into contact with gametes or embryos or used during their processing (such as the ICSI rig), which may affect their quality and safety. The HFEA should be advised of the corrective actions taken by 3 December 2013.	As indicated earlier in the report, there is a laboratory SOP on traceability and all embryologists are familiar with the requirements of the code of practice in this area. This ommission will be discussed with the embryologists at an embryology meeting and the need to complete all the relevant boxes on the paperwork when carrying out licenced processes will be stressed. A traceability audit is now due to be carried out and this will be done and any further infringements identified will be passed back to the embryology team. Compliance with traceability processes will be included in the	14 November 2013: The PR has indicated that actions have been taken to implement this recommendation and the centre's planned audit will determine their success and trigger further corrective actions if necessary. No further actions are required by the inspection team

		competency assessments going forward which will hopefully help to reduce any further problems in this area.	
9. Quality Management System SOPs to direct all the administrative procedures within the centre are not present, for example the use and maintenance of patient records on the database used by the centre (SLC T33(b)). Patient information provision has not been audited against CoP requirements in the last two years (SLC T36).	The PR should ensure SOPs are documented for all administrative processes which may impact on licensed activity within the centre. A report stating the SOPs to be developed and their completion dates should be provided to the HFEA by 3 March 2014 The PR should ensure that patient information provision is audited against CoP requirements. A summary report of the audit results and actions taken should be provided to the HFEA by 3 March 2014	Protocols are being created/updated for all administrative procedures. This process has commenced and is ongoing. Interim protocols are being created regarding the application of admin processes on the centre's database . These will be updated as the work on the new database progresses. The patient information provision against CoP is being addressed and the report and actions will be forwarded by 3rd March 2014.	14 November 2013: The PR has indicated that actions are being taken to implement this recommendation within the required timescale. Further actions are still required: Reports stating the SOPs to be developed and their completion dates, and of the audit of the centre's patient information provision (both due 3 March 2014) will be followed up with the PR through the on-going monitoring system.
10. Document Control Three patient information sheets had not been	The PR should ensure issues related to document control	The three documents concerned had been issued timeously for	14 November 2013: The PR has taken appropriate

subjected to annual review and were 'out of date' given the document control details on them. Uncontrolled training documents were also present. These observations suggest the centre's document control procedures are not robust and need revision (SLC T34).	are addressed and that the document control procedure is reviewed, including the range of documents throughout the centre to which it applies, to verify that it is fit for purpose. This recommendation should be implemented by 3 March 2014 and the actions taken advised to the HFEA.	review. They were followed up per the review process 'outstanding documents' and brought to the attention of the PR. These has now been rectified. The 'uncontrolled' documents were created by admin staff who did not understand the document control system. This has been addressed with the line manager through the non-conformance process. This procedure will be reviewed and made more comprehensive.	actions to correct this non-compliance. Further actions are still required: A report of the review of the fitness of the document control system and any actions taken to address concerns (due 3 March 2014) will be followed up with the PR through the on-going monitoring system.
11. Clinical Practices The drawer in which drugs returned by patients to the centre are stored was not locked and was in an unlocked room. This was contrary to the centre's normal practice and was considered to reflect unsuitable practice (SLC T2).	The PR should ensure that the returned drugs drawer is locked when nursing staff are not present. The actions taken to implement this recommendation should be advised to the HFEA by 3 December 2013. The PR should also audit the success of the actions taken in the three months after 3 December 2013 and report the	The policy within NHS Lothian, is that all drug cupboards/drawers must be locked at all times when not in use. The keys to all drug cupboards/drawers must be in the posession of either an NMC registered member of nursing staff or theatre ODP. This was reported as non conformance and will be discussed at the Nursing meeting	14 November 2013: The PR has taken appropriate actions to correct this non-compliance. Further actions are still required and the completion of the audit by 3 March 2014 will be followed up with the PR through the on-going monitoring system.

	audit findings to the HFEA by 3 March 2014.	to reduce the risk of this occuring again.	
12. Payment of fees The PR has not ensured payment of all invoices from the HFEA within 28 days, non-compliant with SLC T9d.	The PR should take appropriate actions to ensure that all HFEA invoices are paid within the 28 day deadline. This action should be completed by 3 March 2014.	The PR has worked with the Finance team in the Trust to comply with this.	14 November 2013: The PR has taken appropriate actions to correct this non-compliance. The success of these actions will be followed up with the PR through the on-going monitoring system.
13. Consent to disclosure to researchers Two discrepancies were found between completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register. (Chair's Letter CH(10)05 and guidance; General Direction 0007).	The PR should take actions to ensure that the centre submits accurate information to the Register regarding consent to disclosure to researchers. This should include actions to: • Correct the submissions that have been identified as being incorrect; • Review processes to ensure that the disclosure consent information supplied to the Authority accurately reflects that documented in completed disclosure consent forms. A report of	The PR will discuss the issues with the staff involved and take appropriate action(s). A report of review will be provided to HFEA by 3 March 2014.	14 November 2013: The PR has indicated that this recommendation will be implemented within the required timescale. Further actions are still required and the results of the review (due 3 March 2013) and completion of the audit (due 3 September 2014) will be followed up with the PR through the on-going monitoring system.

	the review, indicating any changes made, should be provided to the HFEA by 3 March 2013; • Conducting an audit six months after implementing any changes to confirm that they are having the desired effect. A report of the audit should be provided to the HFEA by 3 September 2014.		

Reponse from the Person Responsible to this inspection report