Interim Inspection Report

Date of Inspection: 20 July 2010
Length of inspection: 6 hours
Inspectors: Andy Leonard
Ellie Suthers

Inspection details:
The report covers the pre-inspection analysis, the visit and information received between 19 August 2008 and 20 July 2010.

Date of Executive Licensing Panel: 7 October 2010

Purpose of the Inspection report
The purpose of the inspection is to assess whether centres are complying with the HF&E Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice, 8th Edition (CoP) to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence interim inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Authority's Licence Committee/ Executive Licensing Panel which make the decision about the continuation of the centre's licence.

Centre details

Centre Name	Edinburgh Assisted Conception Unit
Centre Number	0201
Licence Number	L0201/6/c
Centre Address	Edinburgh Fertility and Reproductive Endocrinology Centre, Edinburgh Royal Infirmary, Little France Crescent, Lothian, Edinburgh, EH164SA
Telephone Number	0131 242 2446
Person Responsible	Dr K J Thong
Licence Holder	Ms Sandra Mair
Date Licence issued	1 March 2009
Licence expiry date	28 February 2014
Additional conditions applied to this licence	None

Contents

Report to Licence Committee / Executive Licensing Panel

Recommendation to the Executive Licensing Panel:

The inspectorate considers that, overall there is sufficient information available to recommend the continuation of the centre's licence without additional conditions.

Improvements were recommended in the following areas of practice:

- Providing information regarding legal parenthood
- Witnessing
- The quality management system: quality indicators and audits
- Staffing
- Third party agreements
- Processes involved in multiple births minimisation
- The assessment of staff competence
- Procedures related to confidentiality and privacy
- Payment of fees

The Person Responsible has responded to all recommendations within the report, as detailed in the 'Areas of practice which require the attention of the Person Responsible' on pages 27 – 39. If the Person Responsible's proposed actions are implemented, all the non-compliances detailed in the report will be addressed. The inspectorate will continue to monitor the implementation of the proposed corrective actions.

The inspectorate recommends that the Executive Licensing Panel requires that the Person Responsible implements the proposed actions in response to the recommendations detailed in this report within the prescribed timeframes.

Details of Inspection findings

Brief description of the centre and its licensing history:

The Edinburgh Assisted Conception Unit has been licensed since 1992. The licence was last renewed on 1 March 2009 and includes: Procurement and distribution of gametes and embryos; Processing of gametes and embryos; In vitro fertilisation (IVF); Intra cytoplasmic sperm injection (ICSI); Storage of sperm, eggs and embryos; Insemination; Treatment with donor gametes and donor embryos; Preimplantation Genetic Diagnosis (PGD); Use of embryos in training. The centre is open Monday to Friday 08:00 – 16:00, Saturday 09:00 - 13:00 and on every second Sunday 09:00 - 13:00. Oocyte recovery takes place 4 (occasionally 5) days per week on weekdays and embryo transfers occur Monday to Saturday.

In the period 1 January 2007 – 31 December 2009, success rates at the centre for patients aged <35, 35-37, 38-39, 40-42 and >42 years, for IVF/ICSI, FET and DI, were in general in line with national averages. A positive exception was that IVF/ICSI success rates in the age groups <35, 35-37 and 38-39 years were all above the national averages.

The laboratory space available for incubators was increased in 2009 to enable extended culture of embryos to the blastocyst stage. The centre also obtained a licence to perform PGD in 2009.

The Person Responsible (PR), a consultant gynaecologist and sub-specialist in reproductive medicine, has held the post of PR since 1998. He has completed the HFEA PR Entry Programme.

*Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 1 April 2009 – 31 March 2010
IVF fresh	262
ICSI fresh	286
FET	104
DI	15
Egg share	0
Egg donation	7

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓
Research	None

*These data were extracted from the HFEA register for the period 1 April 2009 and the 31 March 2010. 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.

Updated actions since the centre was inspected on 20 July 2010:

In response to the report's recommendations, the PR has proposed corrective actions, detailed in pages 27 – 39 of the report, in the following areas:

- Providing information regarding legal parenthood
- Witnessing
- The quality management system: quality indicators and audits
- Staffing
- Third party agreements
- Processes involved in multiple births minimisation
- The assessment of staff competence
- Procedures related to confidentiality and privacy
- Payment of fees

All recommendations in the report will be addressed by the PR's responses and planned actions. The implementation of the action plans will be monitored by the HFEA Executive to ensure the centre's future compliance.

1. Focus of inspections for 2010-12

Providing information to patients in relation to costed treatment plans and parenthood
What the centre does well. There was said by staff at the centre, to be currently no activity requiring the development of processes and procedures for consenting patients regarding legal parenthood issues. The centre provides treatment to self funding patients but is a 'not for profit' organisation. Self funding patients and the NHS commissioning bodies are therefore charged the same amount for treatment packages. Patients are provided a price list in patient information and are advised during pre-treatment consultation what treatment package is recommended and how much it will cost. Staff said that patients were never charged more than the amount specified for their treatment package.
What they could do better. The centre's licence includes the use of donor gametes and embryos in treatment. Standard Licence Condition (SLC) T33b requires that standard operating procedures (SOPs) for all activities authorised by this licence. The PR should therefore develop appropriate processes and procedures for informing and consenting patients regarding legal parenthood issues, to comply with SLC T33b.

Consent - particularly consent to disclosure to registry researchers and consent to storage
What the centre does well. Consenting practices at the centre were considered compliant with CoP requirements, including those regarding consent to disclosure of identifying information to researchers and consent for storage. Patients are provided with appropriate information regarding their treatment and opportunities to obtain further information at consultations before treatment. Counselling is also offered regarding the implications of consenting. The centre has standard operating procedures (SOP) for obtaining patient consents, which include verification of the patient's identity when consents are taken. The centre also provides information and consent forms to patients regarding the use of surplus embryos in research studies and training. All relevant consents are collected a reasonable time after information and the consent forms have been provided. It is verified by staff before egg collection that all required consents have been taken. Quality indicators (QIs) for consent taking have been established and have been audited. The SOP for consent taking also includes the taking of consents to disclosure of identifying information for for researchers. Such consents were observed in patient records on inspection. The PR commented on inspection that he thought it was unfair that centres were expected to obtain such consents, which has resource implications, without obvious benefit to the centre. The centre has a SOP for the withdrawal of consent for embryo storage which includes the provision of a 12 month 'cooling off' period and dispute resolution processes. An

annual audit of gametes and embryos in storage is performed which ensures that consent for storage is present in the patient records.

What they could do better.

No issues were identified on this inspection

Multiple births

What the centre does well.

The centre is in most areas compliant with the requirements of Direction 0003. The centre has a MBMS with elective single embryo transfer (eSET) criteria, which was submitted to the HFEA. Multiple pregnancy and birth rates are monitored and the MBMS is reviewed annually. A detailed review of the MBMS was performed in June 2010, as a result of an audit of the 2009 treatment outcome data. This review led to nine changes in the MBMS implementation process to improve the SET uptake rate. Another important change is that local treatment commissioners will now fund two 'rounds of treatment'. Each round will consist of a fresh IVF/ICSI cycle with eSET and storage of unused good quality embryos, followed by frozen embryo transfers until all the stored embryos are used. The PR considers this a significant advance on the previous arrangement of funding three fresh cycles.

The centre provides patients with written and verbal information regarding the risks of multiple births before treatment and at embryo transfer. A log is kept of patients eligible for eSET who have double embryo transfers. The log is in the format described in Direction 0003 and includes the reason for non-compliance. Outcomes in this patient group were specifically analysed in the recent MBMS review and this has led to process changes being made. A log of patients in whom three or more embryos were transferred is also maintained but there are no entries in the last two years as no such transfers have been performed. The PR stated that the centre would not transfer more than two embryos to a patient in any circumstances.

Data submitted to the HFEA and in the centre's MBMS review indicate that the centre's annualised multiple pregnancy rate (MPR) declined between 2008 and 2009 from 31.8% to 25.5%. The 25.5% MPR in 2009 may lead to a multiple birth rate (MBR) above 24% in April 2009 – March 2010, non-compliant with Direction 0003 (version 1). The inspectorate notes the recent review and changes to the MBMS, which will enhance patient awareness of the risks of multiple births and target eSET at a wider patient group. These changes may allow the centre to comply with the 20% MBR target for April 2010 – March 2011 (Directions 0003, version 2). Indeed recent data from April 2010 to the time of the inspection indicated an MPR of 21%. The inspectorate recommends that the PR continues to monitor the centre's MBMS to ensure that the 20% MBR target for 2010/2011 is achieved.

What they could do better.

The PR said that when patients do not comply with an eSET recommendation, it is not noted by clinical staff in the patient record why this has occurred and that the patient couple have been advised regarding the risks of multiple pregnancy, non-compliant with Direction 0003.

Validation of critical equipment and processes

What the centre does well.

The centre was compliant with the requirements of SLC T24 regarding equipment validation and T72 regarding the validation of processes.

Detailed and appropriate validation documentation was observed on inspection for all equipment the Laboratory Manager (LM) considers essential to the processing of gametes and embryos, these being air flow cabinets, incubators, freeze machines, ICSI stations, centrifuges and associated heated surfaces.

A detailed laboratory process map was also provided with validation for each process using studies in the scientific literature and the centre's historical data set. Clinical processes have also been validated, an example being the use of estradiol monitoring during stimulation, which has been validated using a published study from the centre.

What they could do better.

No issues were identified on this inspection

Witnessing

What the centre does well.

The witnessing practices at the centre were, with one exception (the recording of witnessing signatures), compliant with the requirements of HFEA CoP Guidance Note 18.

The centre has a witnessing SOP which has been assessed by the LM for compliance with CoP Guidance Note 18. All witnessing was said by the LM to be performed manually and contemporaneously; this is stated in the witnessing SOP. Records of witnessing checks at all required steps were observed in patient records inspected, which usually included the name, status and signature of the operator and the witness. The competence of all witnesses has been assessed and was seen to have been documented in training records.

QIs have been established for witnessing which involve an annual audit of witnessing checks in patient records for all treatments carried out in the previous year. This was discussed with the LM and the inspectorate would recommend a more frequent audit of a sample of patient records to more rapidly detect if problems arise.

What they could do better.

Review of witnessed checks in a sample of patient records indicated that a signature was missing from two witnessing checks, non-compliant with SLC T71. Signatures against witness checks in the patient record are also not timed, which could lead to non-compliance with CoP Guidance 18.7.

Gamete and embryo donation – reimbursement, information provision and screening

What the centre does well.

Due to resource implications, sperm donors are currently not recruited at the centre nor is egg sharing provided as a treatment activity. Egg donors are also not actively

recruited however egg donors known to a patient couple are accepted. There have also been some cases of embryo donation at the centre.

The centre has an SOP for donor consent taking and screening which includes the requirement that all donors must be offered counselling prior to donation. The donor SOP is also compliant with Licence Condition T52 and professional body guidelines, regarding the range of screening tests performed and the use of age and donor medical history for donor assessment. A review of three sets of egg donor records confirmed that screening tests were performed as stated in the donor SOP, by an appropriately accredited (CPA UK Ltd) laboratory. The donor SOP also includes that in cases of embryo donation, both gamete providers are screened as donors and the embryos are quarantined for 180 days until retesting of the providers.

The centre uses detailed checklists within donor records to ensure all requirements for donor recruitment and screening are met. All staff undertaking donor recruitment have had training on the centre's donor recruitment processes and the relevant HFEA CoP requirements. Centre staff have also audited donor records for completeness regarding consent forms, screening and information provided to donors, as a QI for the recruitment process. There are plans to introduce further QIs.

Information provided to donors indicates that a recipient of donated gametes, on request, will be provided with appropriate anonymous information regarding the donor and any donor-conceived children. The information also discusses the non-identifying and identifying information about the donor which can be provided to donor–conceived offspring when they reach 18 years of age.

The centre maintains a donor database which logs donor use and outcomes. The database allows the centre to enforce the 10 family limit and inform the donor, if requested, of the number of persons born as a result of the donation, the sex and the year of birth.

The SOP for the payment of donors and a donor reimbursements log were reviewed by the inspectorate. The payment process and evidence collected in the log complied with the requirements of Direction 0001

What they could do better.
No issues were identified on this inspection.

Welfare of the Child (in relation to basic partner treatment services only)

What the centre does well.
The centre offers a full range of treatment services therefore this theme was not relevant at this inspection. It was stated by centre staff that a welfare of the child assessment is performed on all patients at the centre, including those attending for basic partner treatment services.

What they could do better.
No issues were identified on this inspection

Embryo testing (if applicable)

What the centre does well.

After reviewing pre-implantation genetic diagnosis (PGD) activities at the centre, the inspectorate considers them to be compliant with the requirements of CoP Guidance Note 10, except for the minor issues discussed below.

The licence variation to allow PGD treatment at the centre was approved by the HFEA on 12 August 2009. The approval process included a review by the inspectorate and the Licence Committee of the PGD SOPs, patient information and consent forms, which found them to be compliant with CoP requirements. At the time of this inspection, three patients had been treated using PGD since the licence was granted, all for conditions which have been previously approved by a HFEA licence Committee. The centre expects to treat 15 PGD patients per year in the future.

The centre has documented validated procedures for embryo biopsy and the manipulation and transportation of blastomeric genetic material to the testing laboratory. The competence of staff providing the PGD service has been assessed and documented. The LM confirmed that the centre has not performed sex selection for social reasons or transferred biopsied embryos in the same cycle as non-biopsied embryos.

Staff from the testing laboratory confirmed that it is accredited by an appropriate body (CPA UK Ltd), that the PGD genetic testing methodologies have been validated and that competence assessments are documented for all staff.

What they could do better.

QIs, as required by SLC T35, have not yet been established for the PGD process, nor has the process been recently audited against the SOPs, regulatory requirements or QIs, as required by SLC T36. Both non-compliances result from the slow development of this recently licensed service. Now three patients have been treated however, the LM will undertake a review of the PGD process and SOPs, which will include the establishment of QIs and audit of the process against the SOPs and regulatory requirements.

2. Changes/improvements since the last inspection on 19 August 2008

The centre has developed a PGD service and in 2009 obtained a licence variation to provide PGD treatment.

The centre has developed storage space in the laboratory to provide more space for incubators. This has allowed increased culture of embryos to the blastocyst stage.

The Nurse Manager at the centre at the time of the last inspection has recently left the centre. She has been replaced by an experienced senior fertility nurse with managerial experience who has been at the centre for some years.

Area for improvement and action required	Action taken as evidence during this inspection
1) In the year to July 2008 the centre took an average 31 days to pay invoices according to HFEA Finance Department. This is potentially a breach of Licence Condition A.13.3. The Person Responsible should liaise with the Finance Department to review the arrangements for payment of invoices and ensure that there are no barriers to the prompt payment of invoices.	HFEA Finance reported that invoices in the year to 6 March 2010 had been paid in an average of 34 days (range 17 – 84 days). If an invoice in July 2009 which took 84 days to be paid is withdrawn from the analysis, the centre has taken an average of 30 days to pay each invoice. The PR should note that Chair's Letter CH(10)02 requires payment of HFEA invoices within 28 days and that he is obliged under Licence Condition T9d to ensure fees are paid within the written specified timescale. The PR should therefore take appropriate actions to meet the 28 day payment deadline. .
2) Flooding events have been logged in the centre's incident log. They have not been reported to the HFEA as adverse incidents. This is potentially non compliant with Directions D.2007/3. The PR should review the centre's adverse incident reporting procedures to ensure that they reflect the HFEA reporting requirements The flooding incidents should be reported retrospectively to the HFEA as soon as practicable and any future flooding incidents should be reported within with 12 working hours. The PR should ensure that premises and facilities are suitable for the activities for which the centre is licensed and provide a safe working environment for all staff in	The flooding incident was reported to the HFEA soon after the last inspection in August 2008. No subsequent flooding incidents have been reported to HFEA or documented in the centre's incident log which was reviewed on inspection. An SOP for incident reporting was observed on inspection which was compliant with HFEA requirements. The PR stated on inspection that the centre has had no water leaks recently and a shower room on the floor above has been repaired so it does not leak into the centre. The centre's corridor has also been fitted with waterproof flooring appropriate for a clinical area, replacing the carpet seen in some areas at the last inspection.

Area for improvement and action required	Action taken as evidence during this inspection
compliance with S.6.3.2. It is recommended that the PR seek guidance from local health and safety representatives on the measures that are required to ensure the safety and suitability of the premises following any flooding.	This area of practice was considered by the inspectorate to be now compliant with HFEA requirements.
3) Some long-standing equipment and critical laboratory processes have not been validated, which is a breach of standard licence condition A.11.11 and S.7.8.3. It is recommended that the centre identifies critical procedures and prepares a prioritised plan for the validation of all equipment and procedures which impact on gamete and embryo quality and safety.	Issues related to process and equipment validation are discussed in Section 1, Focus of Inspections, 2010-2012: Validation
4) The PR stated that most third party agreements (TPAs) are in place and are subjected to annual review. A file of TPAs was evidenced. The PR noted that one TPA outstanding was that sent to the hospital's procurement department. Centre Management should continue to make progress in the establishment of documented agreements with third parties when an activity takes place which influences the quality and safety of gametes and embryos in compliance with the requirements of Code of Practice, Standards S.4.2.10.	The TPA with the hospital procurement department was out of date and a TPA has not yet been established with the genetic testing laboratory which supports the PGD programme. The PR considered that the departure of the Nurse Manager, who had also held the QM role, had put the review of TPAs behind schedule. The inspectorate considers the centre is not compliant with Licence Condition T111 which requires that TPAs are established with all suppliers of goods and services that influence the quality and safety of gametes and embryos.
5) The emergency resuscitation trolley had not been subject to daily checks in compliance with the centre's own procedures and with UK Resuscitation Council Guidelines. The Nurse co-ordinator provided assurances at the time of the inspection that checking procedures would be implemented according to protocol.	The log of daily checks of the resuscitation trolley was reviewed on inspection. The log was seen to be appropriately completed. This area of practice was considered by the inspectorate to be now compliant with best practice (i.e. the UK Resuscitation Council Guidelines)
6) Egg donors have not been routinely screened for Neisseria Gonorrhoea or subject to karyotype analysis contrary to	Issues related to donor screening are discussed in Section 1, Focus of Inspections, 2010-2012: Gamete and

Area for improvement and action required	Action taken as evidence during this inspection
recommendations of professional body guidelines and thus Code of Practice, 7th Edition, G.4.9. The PR should review the protocol for screening of prospective donors after consideration of the BFS guidelines, as recommended by Code of Practice, 7th Edition, G.4.9.1. The rationale for any non-compliance with guidelines should be documented. If screening procedures are changed, patient information should be updated to include all of the screening tests carried out. The PR should also ensure a system is in place which guarantees that all tests required by the screening protocol are performed on every donor.	embryo donation – reimbursement, information provision and screening. Given what is stated there however, it can be said that this area of practice was considered by the inspectorate to be now compliant with HFEA requirements.
7) Some information was not provided, for example, waiting times (G.5.3.1.b), information about withdrawal of consent, how to do so and the consequences of so doing (G.5.2.1 b-d), options in the event of death (G.5.2.1 f,g), the risks of gamete collection (G.5.3.1g) and the uncertainty regarding the association between ovarian cancer and ovarian induction (G.5.3.1 i). The PR should review all written and verbal information provided to patients to ensure it complies with all requirements of the Code of Practice	The Nurse Manager stated that all patient information was reviewed after the last inspection for compliance with the CoP and was modified as appropriate. Subsequent reviews have been performed given the regulatory changes when the 8th edition of the CoP was released. Patient information observed on inspection satisfied all relevant CoP requirements and was document controlled and up to date. This area of practice was considered by the inspectorate to be now compliant with HFEA requirements.
8) Organisational chart was considered inaccurate The organisation chart should be updated to accurately reflect the management structure of the centre	A recently updated organisational chart was provided on inspection and was considered appropriate given CoP requirements. This area of practice was considered by the inspectorate to be now compliant with HFEA requirements.

3. Areas of concern

The analysis of the centre's self assessment questionnaire and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked during the inspection visit to this centre.

Area of concern	Inspection findings	Assessment of whether the action taken meets the requirement or is more action required
1) GN1 PR: The SAQ says the PR spends less than 20% whole time equivalent on the role	The PR is contracted for nine sessions per week and considers that he needs spend <20% of his time on the PR role. The inspectorate considers the PR has been well supported by an experienced management team, which allows him to delegate and limit the amount of time he spends in the PR role. The centre is generally compliant and well organised. Indeed, only one non-compliance from the last inspection remains non-compliant.	The inspectorate considers there are no regulatory issues associated with this SAQ response.
2) GN2 Staffing: In the SAQ, the PR assessed the centre as being less than fully compliant with SLC T12, in that the centre was not operating with a full staff compliment.	The inspectorate were informed by the PR that the centre is short of establishment in administrative staff by 1.5 whole time equivalents (WTE) and in nursing staff by 0.6 WTE. In this latter situation however 2.6 WTE fertility nurses have been replaced by 2.0 WTE maternity nurses. The centre also does not currently have a QM. An experienced internal QM replacement is being organised on a part-time basis and a Quality Assistant remains in post to support the quality management system (QMS). The centre was said by the PR and Lead	Observations on inspection indicate that staff shortages are not causing direct risk to patients. The PR must though continue to control the centre's activity to fit the staffing and other resources available. The inspectorate notes that the absence of a QM is retarding QMS development, which may indirectly affect patients. For example in several areas of activity, QIs have not been developed or processes recently audited against SOPs and regulatory

Area of concern	Inspection findings	Assessment of whether the action taken meets the requirement or is more action required
	Nurse to control centre activity at a safe level given the staffing and other resources available. There have been no incidents or complaints from patients related to staff shortages.	requirements. TPAs also need to be reviewed. The current lack of a QM is non-compliant with CoP Guidance 23.3a and 23.4. A replacement QM is though being organised.
3) GN2 Staffing: In the SAQ, the PR stated that all staff working in the embryology laboratory were not registered with the Health Professionals Council (HPC), potentially non-compliant with SLC T14.	There are five HPC registered staff in the laboratory and one trainee who is not HPC registered, hence the negative response in the SAQ. This staff member is however working to HPC registration at an appropriate pace. Staffing levels in the laboratory were considered appropriate for the activity level.	The inspectorate considers there are no regulatory issues associated with this SAQ response.
4) GN3 Counselling: In the SAQ, the PR stated that the centre had not established QIs or objectives for counselling, as required by SLC T35.	This SAQ answer was incorrect as, on inspection, evidence of QIs and objectives relevant to counselling were provided. A questionnaire is used to assess patient awareness and uptake of the counselling service and their satisfaction with it. The centre has also carried out audits of the counselling service, and taken corrective actions to improve it.	The inspectorate considers there are no regulatory issues associated with this SAQ response.
5) GN3 Counselling: In the SAQ, the PR stated that the centre's counsellor was not	Evidence that the counsellor is working towards accreditation with BICA was provided on inspection. The counsellor expects to attain	The inspectorate considers there are no regulatory issues associated with this SAQ response.

Area of concern	Inspection findings	Assessment of whether the action taken meets the requirement or is more action required
accredited by the British Infertility Counselling Association (BICA) but was working towards accreditation.	accreditation within 3 months of the inspection.	
6) GN4 Information In the SAQ, the PR stated that the centre had not established QIs or objectives for the provision of information, as required by SLC T35.	The Lead Nurse confirmed that QIs have not been established for the provision of information to patients.	The centre does not currently have QIs for the provision of information to patients and is thus non-compliant with SLC T35. Further actions need to be taken to correct this non-compliance
7) GN4 Information In the SAQ, the PR stated that the centre had not audited in the last two years, as required by SLC T36, how far procedures for the provision of information comply with the approved protocols, the regulatory requirements and QIs.	No evidence could be provided that the processes related to information provision to patients have been recently audited against the SOPs, regulatory requirements or QIs, as required by SLC T36.	The centre is non-compliant with SLC T36 since no evidence was available of a recent audit of the processes involved in information provision to patients against the SOPs, regulatory requirements or QIs. Further actions need to be taken to correct this non-compliance.
8) GN4 Information In the SAQ, the PR stated that relevant staff could not provide documented evidence of the	No evidence of the assessment of staff competencies for information provision to patients was provided on inspection. The Lead Nurse stated however that she is modifying the hospital's	The absence of evidence of the assessment of staff competencies for information provision to patients is non-compliant with SLC T15a. Further actions need to be taken to correct this non-

Area of concern	Inspection findings	Assessment of whether the action taken meets the requirement or is more action required
assessment of their competence to provide information to those consenting to: a) treatment; b) donation of gametes for treatment; c) donation for use in training. This situation is contrary to SLC T15a.	key skills framework and annual appraisal system to develop a competency assessment programme for the centre's nursing staff. This will allow individualised assessment of competencies key to each nurse's role. The programme will be developed as rapidly as possible.	compliance.
9) GN5 Consent In the SAQ, the PR stated there was not an SOP for taking effective consent, as required by SLC T33b	This SAQ answer is now incorrect. A SOP for consent taking was provided on inspection and was considered to document consenting processes which are compliant with CoP requirements.	The inspectorate considers there are no regulatory issues associated with this SAQ response.
10) GN5 Consent In the SAQ, the PR stated that the centre had not established QIs or objectives for consent taking, as required by SLC T35	A QI for consent taking has been established. It involves an annual audit in 120 patient records from the previous year, of all consent forms found and expected to be found given the treatments provided. The Lead Nurse also stated that all consents are checked in patient records on the day of egg collection before treatment commences.	The inspectorate considers there are no regulatory issues associated with this SAQ response. The inspectorate suggests however that the centre considers documenting the results of the check of each patient record for consents, carried out on the day of egg collection. Weekly or monthly review of the log of such documented checks could be used as another QI for consent taking, which will more rapidly highlight non-conformities in the consenting process than the annual audit.

Area of concern	Inspection findings	Assessment of whether the action taken meets the requirement or is more action required
10) GN5 Consent In the SAQ, the PR stated that the centre did not have an agreement in place with third parties who obtain consent, non-compliant with Directions 0010	The PR stated on inspection that the centre has no third parties who obtain patient consent. Thus no TPAs are required.	The inspectorate considers there are no regulatory issues associated with this SAQ response.
11) GN10 PGD In the SAQ, the PR stated that the centre had not audited in the last two years, as required by SLC T36, how far embryo biopsy and PGD processes comply with the approved protocols, the regulatory requirements and QIs.	This issue has been addressed in Section 1, Focus of Inspections 2010 - 2012, Embryo Testing on page 10.	This issue has been addressed in Section 1, Focus of Inspections 2010 - 2012, Embryo Testing on page 10.
12) GN10 PGD In the SAQ, the PR stated that the centre had not evaluated the ability of the third party testing laboratory to meet the required standards, as required by SLC T112	The PR stated that he has not formally assessed the ability of the genetics testing laboratory to meet the required standards of the CoP, nor is there a TPA in place requiring the laboratory to comply with those standards.	The lack of formal assessment of the ability of the genetics testing laboratory to meet the required standards of the CoP is non-compliant with SLC T112. Further actions need to be taken to correct this non-compliance.

Area of concern	Inspection findings	Assessment of whether the action taken meets the requirement or is more action required
13) GN11 Donor treatments In the SAQ, the PR stated that the centre had not audited in the last two years, as required by SLC T36, how far processes for selecting and recruiting donors comply with the approved protocols, the regulatory requirements and QIs.	No evidence could be provided that the processes related to selecting and recruiting donors, have been recently audited against the SOPs, regulatory requirements or QIs, as required by SLC T36.	The centre is non-compliant with SLC T36 since no evidence was available of a recent audit of the processes related to selecting and recruiting donors, against the SOPs, regulatory requirements or QIs. Further actions need to be taken to correct this non-compliance
14) GN11 Donor treatments In the SAQ, the PR stated that relevant staff could not provide documented evidence of the assessment of their competence in selecting and recruiting donors, as required by SLC T15a.	The Lead Nurse stated that nurses who participate in donor selection and recruitment, undergo an in-house training programme which includes all HFEA CoP requirements in this area. The training programme is documented in staff records. Repeat assessment of staff competencies for donor selection and recruitment will be included in the competency assessment framework, currently being developed by the Lead Nurse.	Some evidence of training in donor selection and recruitment is present. The absence of evidence of the repeated assessment of competence in this area, at a frequency specified in procedures, is however non-compliant with SLC T15a. Further actions need to be taken to correct this non-compliance.
15) GN15 Procuring, processing and transporting In the SAQ, the PR stated that an effective recall procedure, including a description of the responsibilities and actions to be taken, was not in place, as is	The transportation protocol describes an appropriate recall procedure. The LM considers that the PR answered the question incorrectly	The inspectorate considers there are no regulatory issues associated with this SAQ response.

Area of concern	Inspection findings	Assessment of whether the action taken meets the requirement or is more action required
required by SLC 122.		
16) GN15 Procuring, processing and transporting In the SAQ, the PR stated that the centre does not have a procedure for handling returned material, as required by Schedule 3A to the HF&E Act (1990) as amended.	The transportation protocol describes an appropriate procedure for handling returned material. The LM considers that the PR answered the question incorrectly.	The inspectorate considers there are no regulatory issues associated with this SAQ response.
17) GN17 Storage In the SAQ, the PR stated that relevant staff could not provide documented evidence of the assessment of their competence in storing cryopreserved materials, as required by SLC T15a.	This SAQ answer is now incorrect. On inspection, the LM provided documentary evidence that the competence of laboratory staff to cryopreserve samples is assessed. This assessment is documented in an SOP which describes the regular assessment of the competence of laboratory staff to perform multiple key activities.	The inspectorate considers there are no regulatory issues associated with this SAQ response.
18) GN18 Witnessing In the SAQ, the PR stated that the centre had not established QIs or objectives for witnessing, as required by SLC T35.	This SAQ answer is now incorrect. On inspection, the LM provided evidence that witnessing is retrospectively audited in patient records. This audit is performed annually and encompasses a check in patient records of every witnessing step performed in the last year to ensure it has been	The inspectorate considers there are no regulatory issues associated with this SAQ response.

Area of concern	Inspection findings	Assessment of whether the action taken meets the requirement or is more action required
	correctly documented. The frequency of audit of witnessing for QI purposes was discussed with the LM and a more frequent audit was recommended by the inspectorate.	
19) GN19 Traceability In the SAQ, the PR stated that the centre had not established QIs or objectives for traceability, as required by SLC T35.	The LM said that the recently released HFEA guidance related to QIs has provided useful. A protocol for monitoring QIs, including those for traceability, is in development.	The centre does not currently monitor QIs and objectives related to traceability. The centre is thus non-compliant with SLC T35. Further actions need to be taken to correct this non-compliance.
20) GN19 Traceability In the SAQ, the PR stated that the centre had not audited in the last two years, as required by SLC T36, how far traceability procedures comply with the approved protocols, the regulatory requirements and QIs.	No evidence could be provided that the processes related to ensuring traceability, have been recently audited against the SOPs, regulatory requirements or QIs, as required by SLC T36.	The centre is non-compliant with SLC T36 since no evidence was available of a recent audit of the processes related to ensuring traceability against the SOPs, regulatory requirements or QIs. Further actions need to be taken to correct this non-compliance.
21) GN19 Traceability In the SAQ, the PR stated that relevant staff could not provide documented evidence of training or competency assessment	The LM regularly checks laboratory sheets to ensure they are appropriately completed. This includes a check of all traceability information. The results are logged in staff training files as an assessment of their competence in several areas	The checking process described by the LM should be formally documented in SOPs as an assessment of competence, to comply with SLC T33. It should also be performed at an appropriate frequency, also documented. Further actions need

Area of concern	Inspection findings	Assessment of whether the action taken meets the requirement or is more action required
related to traceability procedures, as required by SLC T15a.	(e.g. witnessing and traceability).	to be taken to correct this non-compliance.
22) GN22 Research and Training In the SAQ, the PR stated that the centre had not established QIs or objectives relevant to compliance with training licence requirements, as required by SLC T35.	The centre uses embryos for training and research and has appropriate patient information on these matters. The SOP for research and training is being reviewed by the LM and this will include the development of QIs.	The centre currently has no documented QIs for the processes involved in the donation and use of embryos in training and research. The centre is thus non-compliant with SLC T35. Further actions need to be taken to correct this non-compliance.
23) GN22 Research and Training In the SAQ, the PR stated that the centre had not audited in the last two years, as required by SLC T36, how far procedures designed to ensure compliance with training licence requirements, also comply with the approved protocols, the regulatory requirements and QIs.	Little evidence could be provided that the processes related to research and training, have been recently audited against the SOPs, regulatory requirements or QIs, as required by SLC T36. The LM noted that the SOP was only introduced in October 2009 and was reviewed for compliance against the CoP during its development. Thus while the SOP may be compliant with the requirements, the compliance of the processes as performed in the laboratory remain to be audited.	The centre is non-compliant with SLC T36 since little evidence was available of a recent audit of the processes related to research and training, against the SOPs, regulatory requirements and QIs. Further actions need to be taken to correct this non-compliance.

Area of concern	Inspection findings	Assessment of whether the action taken meets the requirement or is more action required
24) GN22 Research and Training In the SAQ, the PR stated that relevant staff could not provide documented evidence of training in providing information to those consenting to donation for training purposes, as required by SLC T98.	No evidence of training or the assessment of staff competencies, for the provision of information to those consenting to embryo donation for research and training, was available on inspection. The Lead Nurse stated that she is developing a competency assessment programme for the centre's nursing staff. This will allow individualised assessment of competencies key to each nurse's role and will include information provision to patients.	The centre is non-compliant with SLC T15a, since no evidence was available of the assessment of staff competencies for the provision of information to those consenting to embryo donation for research and training. Further actions need to be taken to correct this non-compliance.
25) GN23 Quality Management In the SAQ, the PR stated that access to training and reference manuals was limited, non-compliant with SLC T33	This SAQ answer was incorrect. The LM provided evidence that training and reference manuals are present.	The inspectorate considers there are no regulatory issues associated with this SAQ response.
26) GN23 Quality Management In the SAQ, the PR stated that the centre was less than fully compliant with SLC T31 which requires, where relevant, that SOPs detail the specifications for critical materials and reagents.	This SAQ answer was incorrect. The LM provided evidence that laboratory SOPs, where relevant detail the specifications for critical materials and reagents used in gamete and embryo processing	The inspectorate considers there are no regulatory issues associated with this SAQ response.

Area of concern	Inspection findings	Assessment of whether the action taken meets the requirement or is more action required
27) GN24 TPAs In the SAQ, the PR stated that the centre was less than fully compliant with SLC T112 which requires the centre to evaluate the ability of all third parties to meet the required standards**.**	The PR confirmed on inspection that the centre have yet to evaluate the ability of third parties to comply with HFEA CoP requirements. This was said to be because of the departure of the QM. The PR will ensure this is addressed when the new QM is appointed.	The centre has not evaluated the ability of third parties to comply with HFEA CoP requirements and is thus non-compliant with SLC T112. Further actions need to be taken to correct this non-compliance
28) GN24 TPAs In the SAQ, the PR stated that the centre was less than fully compliant with SLC T114 with regard to the contents of the TPAs it has developed.	The PR confirmed on inspection that TPAs have not all been reviewed to ensure their contents comply with the requirements of SLC T114. This was said to be because of the departure of the QM. The PR will ensure this is addressed when the new QM is appointed.	The centre has not reviewed all TPAs to ensure their contents comply with the requirements of SLC T114 and is thus non-compliant with this SLC. Further actions need to be taken to correct this non-compliance.
29) GN24 TPAs In the SAQ, the PR stated that the centre was less than fully compliant with SLC T116, regarding it being stated in all TPAs that the third party should comply with all relevant SLCs and Guidance in the HFEA CoP.	The PR confirmed on inspection that TPAs have not all been reviewed to ensure they require the third party to comply with all relevant SLCs and guidance in the HFEA CoP. This was said to be because of the departure of the QM. The PR will ensure this is addressed when the new QM is appointed.	The centre has not reviewed all TPAs to ensure they require the third party to comply with all relevant SLCs and guidance in the HFEA CoP. The centre is thus non-compliant with SLC T116. Further actions need to be taken to correct this non-compliance.
30) GN26 Equipment and materials In the SAQ, the PR stated that	Appropriate equipment validation documentation was observed on inspection for all essential items of equipment. This SAQ response is considered to	The inspectorate considers there are no regulatory issues associated with this SAQ response.

Area of concern	Inspection findings	Assessment of whether the action taken meets the requirement or is more action required
the centre was less than fully compliant with SLC T24 requiring equipment validation.	be now incorrect	
31) GN26 Equipment and materials In the SAQ, the PR said that the centre was less than fully compliant with SLC T27 in that procedures for the operation of all critical equipment did not state what to do if the equipment malfunctions or fails.	The LM stated that it is standard practice in the laboratory for all equipment failures to be reported to her and that this is documented in SOPs. Equipment failures in the clinical areas are reported to the Lead Nurse.	The inspectorate considers there are no regulatory issues associated with this SAQ response.
32) GN30 Confidentiality and Privacy In the SAQ, the PR stated that the centre were less than fully compliant with SLC T33b, regarding there being a SOP to ensure that all information is kept confidential and only disclosed in circumstances permitted by law.	The hospital policy for confidentiality and records management is used by the centre. All patient records were seen on inspection to be stored with appropriate security. All staff have signed a confidentiality agreement.	The inspectorate considers there are no regulatory issues associated with this SAQ response.
33) GN30 Confidentiality and Privacy	No evidence could be provided that the processes used to ensure that all information is kept	The centre is non-compliant with SLC T36 since no evidence could be provided that the processes

Area of concern	Inspection findings	Assessment of whether the action taken meets the requirement or is more action required
In the SAQ, the PR stated that the centre had not audited in the last two years, as required by SLC T36, how far procedures to ensure that all information is kept confidential comply with the approved protocols, the regulatory requirements and QIs.	confidential have been recently audited against the SOPs, the regulatory requirements and QIs, as required by SLC T36.	used to ensure that all information is kept confidential have been recently audited against the SOPs, the regulatory requirements and QIs. Further actions need to be taken to correct this non-compliance.
34) GN30 Confidentiality and Privacy In the SAQ, the PR stated that relevant staff could not provide documented evidence of training in maintaining confidentiality, as required by SLC T15a.	Training regarding the confidentiality of patient records and HFEA requirements in this area, has recently been provided to staff. This training was seen to be documented in staff training records. All staff have signed a confidentiality agreement.	The inspectorate considers there are no regulatory issues associated with this SAQ response.
35) GN30 Confidentiality and Privacy In the SAQ, the PR indicated that the centre's procedure for the control of confidential documents was less than fully compliant with SLC T44 in documenting processes for establishing and maintaining data security and accuracy,	No evidence could be provided that the hospital policy used for confidentiality and records management, documents processes for: Establishing and maintaining data security and accuracy; Resolving discrepancies; Preventing unauthorised disclosure; Traceability; Responding to requests for access; Providing authorised access to confidential records; and controlling the accessibility of confidential records to unauthorised personnel.	The centre is non-compliant with SLC T44 since no evidence could be provided that the hospital policy for confidentiality and records management complies with the requirements of this SLC. Further actions need to be taken to correct this non-compliance

Area of concern	Inspection findings	Assessment of whether the action taken meets the requirement or is more action required
resolving discrepancies, preventing unauthorised disclosure, traceability, responding to requests for access, providing authorised access to confidential records, and controlling the accessibility of confidential records to unauthorised personnel.		
36) GN31 Record Keeping In the SAQ, the PR stated that the centre had not established QIs or objectives relevant to submission of data to the HFEA, as required by SLC T35.	The PR confirmed that QIs have not been established for electronic data interface (EDI) data entry to the HFEA. Possible QIs were discussed with the PR, as was the ability to generate error reports from the EDI system.	The centre does not currently have QIs for EDI data entry and is thus non-compliant with SLC T35. Further actions need to be taken to correct this non-compliance.

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions require are given as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical are of non compliance is an area of practice which poses a significant direct risk of causing harm to a patient, donor or to an embryo. A critical area of non compliance requires immediate action to be taken by the Person Responsible

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
No issues identified			

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 or to an embryo through the procurement, use, storage or distribution of gametes and embryos, which do not comply with the centre's licence;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several "other" areas of non compliance, none of which on their own may be major but which together may represent a major area of non compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
GN18 Witnessing: Review of witnessed checks in a sample of patient records, indicated that signatures were missing from two witnessing checks, non-compliant with SLC T71. Signatures for witness checks are also not timed, which could lead to non-compliance with CoP Guidance 18.7.	The PR should ensure that all witnessing checks are contemporaneously signed and timed on the laboratory sheet when a witness check occurs. This action should be completed by 15 November 2010.	The issue of signing witness sheets contemporaneously has been raised at multidisciplinary meetings on several occasions and will be raised again at the next meeting, where the need to record the witness record in the correct format (including timing) will be emphasised. The frequency of audit of laboratory witnessing sheets will be increased from annual to weekly and feedback will be given by the Consultant Embryologist at the multidisciplinary meeting on performance. On the basis of data obtained during weekly audit, the witnessing system will be kept under review by the Consultant	The Lead Inspector is satisfied with the actions taken and the planned audits, to respond to this non-compliance. There are no remaining regulatory concerns associated with this matter, assuming all actions are implemented. The issue will therefore be monitored by the Compliance Team.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
		embryologist and any weak points addressed by changes to the system, the paperwork or by re-training of staff. If performance improves to meet the standard required (100% contemporaneous signatures, all with the correct format), the frequency of audit may be reduced. It is planned in the longer term to aim for a monthly audit of the witnessing system, rather than annual and this adjustment will be built into the quality management system once the short term goals have been achieved.	
GN23 QMS: The centre is non-compliant with SLC T35, as QIs have not yet been established for: 1) The PGD process 2) The provision of information to patients 3) Traceability 4) The donation and use of embryos in training and	Appropriate QIs for all critical processes at the centre should be documented in SOPs, along with the methods and frequencies of monitoring, by 15 November 2010. Monitoring and review of QIs should then progress at the frequencies specified in SOPs.	The Consultant embryologist is currently developing QIs in the area of PGD, traceability and the donation and use of embryos in training. These QIs will either be incorporated into the existing overarching SOP covering QIs in the lab (Analysis of key performance indicators in the laboratory) or in individual protocols. See section below for	The Lead Inspector is satisfied with the actions taken and planned in response to this non-compliance. There are no remaining regulatory concerns associated with this matter, assuming all actions are implemented. The issue will therefore be monitored by the Compliance Team.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
research 5) EDI data entry		more detail.	
GN23 QMS: The centre is non-compliant with SLC T36, as processes for: 1) PGD 2) Information provision to patients 3) Selecting and recruiting donors 4) Traceability 5) The donation and use of embryos in training and research 6) Confidentiality of information have not recently been audited against the SOPs, regulatory requirements or QIs	An annual schedule for the audit of all critical processes against the approved SOPs, the regulatory requirements and QIs, should be developed by 15 November 2010. The audit schedule should then be implemented. The inspectorate should be updated on a quarterly basis regarding progress with the audit schedule.	As we are in our first year of clinical practise and have only carried out three cycles so far, it will not be possible to develop a full set of quantitative key performance indicators (KPIs) for PGD with warning and control limits, as is the case for all other critical laboratory parameters. However, it should be possible to define a basic set of QIs based on good laboratory practise and literature precedent which will be incorporated into the current comprehensive protocol for the analysis of laboratory KPIs by the Consultant Embryologist. These QIs will then be analysed at an appropriate frequency according to a strict schedule defined in this SOP and presented at the monthly quality meetings, as is the case with all other current laboratory KPIs. The centre shall audit the	The Lead Inspector is satisfied with the actions planned in response to this non-compliance. There are no remaining regulatory concerns associated with this matter, assuming all actions are implemented. The issue will therefore be monitored by the Compliance Team.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
		processes related to confidentiality of information against SOPs, regulatory requirements and QIs. An independent quality audit for traceability along the lines described in the recently published HFEA document (HFEA quality indicators, 2010) will be developed by the Consultant Embryologist and the Quality officer. This will be inserted into the systems audit schedule and will be carried out alongside the other systems audits, according to an approved schedule. We aim to develop and carry out the first of these audits before the deadline suggested. A new protocol on the donation and use of embryos in research and training is currently being written by the Consultant Embryologist. Quality indicators for this process will be incorporated into the protocol and analysed at an appropriate frequency (probably quarterly or bi-annually) by clinical	

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
		audit. The PR will audit processes related to confidentiality of information against the SOPs, regulatory requirements and QIs.	
GN23 QMS: The inspectorate notes that the absence of a QM is retarding QMS development. This may indirectly affect patients. The current lack of a QM is non-compliant with CoP Guidance 23.3a and 23.4.	The PR should progress with the centre's plan to appoint a replacement QM as quickly as possible. The PR should advise the Executive when the new QM is in position.	The unit has been given leave to approach a very experienced quality manager currently working in NHS Lothian with a view to arranging for him to have an input into the management of our own area. He is currently the quality manager of laboratories and the blood bank and is extremely experienced, having overseen many CPA inspections within Lothian. His work in the blood bank means he is fully conversant with EU regulations for cells and tissues and his recent involvement with Reproductive Medicine Laboratory mean he is also familiar with HFEA requirements in the area of quality management. We are trying to negotiate an appropriate amount of time which	The Lead Inspector is satisfied with the actions taken and planned in response to this non-compliance. There are no remaining regulatory concerns associated with this matter, assuming all actions are implemented. The issue will therefore be monitored by the Compliance Team.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
		would allow the Quality manager to attend all our quality meetings, the Annual management review and provide over-arching advice about our quality systems which would then be put in place by our Quality officer.	
GN24: TPAs: The centre is not compliant with SLC T111, which requires that TPAs are established with all suppliers of goods and services that influence the quality and safety of gametes and embryos.	The PR should ensure that TPAs are reviewed and that up to date TPAs are in place with all suppliers of goods and services that influence the quality and safety of gametes and embryos (e.g. the hospital procurement department and the genetic testing laboratory). This action should be completed by 15 November 2010.	The TPA for the hospital procurement department and the Genetics laboratory are currently being developed by The Consultant Embryologist and the Quality officer.	The Lead Inspector is satisfied with the actions planned in response to this non-compliance. There are no remaining regulatory concerns associated with this matter, assuming all actions are implemented. The issue will therefore be monitored by the Compliance Team.

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 good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
GN7: MBMS: The PR said that when patients do not comply with a recommendation for eSET, it is not noted by clinical staff in the patient record why this has occurred and that the patient couple have been advised regarding the risks of multiple pregnancy, non-compliant with Direction 0003.	The PR must ensure that when patients do not accept a recommendation for eSET, it is noted by clinical staff in the patient record why this has occurred and that the patient couple have been advised regarding the risks of multiple pregnancy. This action should be completed by 15 November 2010.	When a patient does not comply with our recommendation for eSET, the member of the medical staff who carries out the embryo transfer will record the reasons for refusal and the detail of any discussion which took place between patient, Dr and embryologist in the medical notes. Details of such patients will also be detailed in the summary log, along with cycles where a double embryo transfer has been recommended due to poor embryo quality. Patients have been advised of the risks of multiple pregnancy in our medical and nursing consultations and they have been given an information sheet regarding the risk of multiple pregnancy.	The Lead Inspector is satisfied with the PR's response. There are no remaining regulatory concerns associated with this matter, assuming all actions are implemented. The issue will therefore be monitored by the Compliance Team.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
GN2 Staffing: The centre is non-compliant with SLC T15a as no evidence was available for the assessment at documented intervals of staff competencies for: 1) Information provision to patients 2) The provision of information to those consenting to embryo donation for research and training 3) Donor selection and recruitment	The PR should develop and document processes, which will ensure the on-going assessment and documentation of nursing staff competencies. Regular update reports on this matter should be provided to the inspectorate, on request, and the actions should all be completed by 15 February 2011.	The PR and Lead nurse will work towards complying with this and aim to achieve this within the dateline suggested.	The Lead Inspector is satisfied with the actions planned in response to this non-compliance. There are no remaining regulatory concerns associated with this matter, assuming all actions are implemented. The issue will therefore be monitored by the Compliance Team.
GN23 QMS: The frequent review by the LM of laboratory sheets for their correct completion, used as a test of staff competence for traceability processes, is not documented in SOPs, non-compliant with SLC T33.	This test should be formally documented in the competency assessment SOP, to comply with SLC T33. It should also be performed at an appropriate frequency, also documented.	The Consultant Embryologist will review the Competency Asessment protocol to comply with SLCT33. This assessment will be carried out in association with the other competency assessments, as detailed in the SOP.	The Lead Inspector is satisfied with the actions planned in response to this non-compliance. There are no remaining regulatory concerns associated with this matter, assuming all actions are implemented. The issue will therefore be monitored by the Compliance Team.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
GN24 TPAs: The centre's TPA arrangements are non-compliant is several ways: 1) The centre has not evaluated the ability of third parties (e.g. the genetics testing laboratory) to comply with HFEA CoP requirements, and is thus non-compliant with SLC T112. 2) The centre has not reviewed all TPAs to ensure their contents comply with the requirements of SLC T114 3) The centre has not reviewed all TPAs to ensure they require the third party to comply with all relevant SLCs and guidance in the HFEA CoP. The centre is thus non-compliant with SLC T116	The PR should ensure that the TPAs are reviewed. Up to date TPAs, compliant with SLCs T114 and T116, should be in place with all suppliers of goods and services that influence the quality and safety of gametes and embryos. All third parties should be evaluated for their ability to comply with HFEA CoP requirements, to comply with SLC T112. Quarterly update reports on this matter should be provided to the inspectorate and the actions should all be completed by 15 February 2011	A comprehensive TPA to cover the genetics and biochemistry testing laboratories and the courier company used to transport gametes is currently under preparation by the Consultant embryologist and the Quality officer. This TPA will include a requirement for the third party to comply with relevant SLCs and the HFEA guidance in the relevant area. The centre's TPA with third parties providing consumables and plastics are also currently under review and it is hoped that most of the current TPAs with these companies can be superceded by an over-arching TPA with the NHS Lothian procurement department who procure goods for us from these suppliers.	The Lead Inspector is satisfied with the actions planned in response to this non-compliance. There are no remaining regulatory concerns associated with this matter, assuming all actions are implemented. The issue will therefore be monitored by the Compliance Team.
GN4: Providing information: The centre's licence includes	The PR should ensure that appropriate processes and	The PR had a draft SOP for informing and consenting patients	The Lead Inspector is satisfied with the actions

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
the use of donor gametes and embryos in treatment. The centre does not however have appropriate processes and SOPs for informing and consenting patients regarding legal parenthood issues, non-compliant with SLC T33b.	SOPs for informing and consenting patients regarding legal parenthood issues are developed, to comply with SLC T33b. This action should be completed by 15 November 2010.	regarding legal parenthood and the inspectors did not request to see this. This will be finalised in the next 3 weeks. We aim to comply with SLC T33b by 15 November 2010.	taken in response to this non-compliance. There are no remaining regulatory concerns associated with this matter.
GN30 Confidentiality and Privacy The centre is non-compliant with SLC T44 since no evidence could be provided that the hospital policy for confidentiality and records management, complies with the requirements of this SLC.	The PR should ensure that a SOP for confidentiality and records management is developed. It should document processes for: Establishing and maintaining data security and accuracy; Resolving discrepancies; Preventing unauthorised disclosure; Traceability; Responding to requests for access; Providing authorised access to confidential records; and controlling the accessibility of confidential records. This action should be completed by 15 November 2010.	We have a hospital policy for confidentiality and records keeping and the inspectors had not asked to see this. We shall audit our hospital policy against Section 33A of the HF & E Act to ensure compliance. We shall review various items raised in the actions required and aim to complete this by 15 November 2010. We are confident with our data security, accuracy, resolving discrepancies, responding to requests fro access , providing authorised access to confidential records and controlling accessibility of confidential records. We hope to resolve the matter of traceability by upgrading	The Lead Inspector is satisfied with the actions planned in response to this non-compliance. There are no remaining regulatory concerns associated with this matter, assuming all actions are implemented. The issue will therefore be monitored by the Compliance Team.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
		our Filemaker database. We will be having discussions with our IT department to discuss whether we can integrate our "stand alone" database with the Trust IT system with limited access for users on the licence.	
GN1 PR: Payment of fees: The PR has not ensured payment of all invoices from the HFEA within 28 days, non-compliant with SLC T9d. The inspectorate notes however that the centre is one of the quickest to pay HFEA invoices, averaging 34 days.	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 15 November 2010.	The PR will discuss this issue with Senior Management and Finance Department and should be able to adhere to the deadline.	The Lead Inspector is satisfied with the actions taken in response to this non-compliance. There are no remaining regulatory concerns associated with this matter.

Additional Information from the Person Responsible

HFEA Executive Licence Panel Meeting

7 October 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 2

Centre 0201 – (Edinburgh Assisted Conception Unit) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy & Information (Chair) Mark Bennett, Director of Finance & Facilities Nick Jones, Director of Compliance	Joanne McAlpine

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 noted that this centre had been licensed since 1992 and the centres licence was last renewed in March 2009.

2. The Panel noted that the centre has carried out over 500 treatment cycles during the period of 2009/10.

3. The Panel noted that the centre had reported an overall multiple pregnancy rate at the time of the inspection 21%. The centre is likely to meet the 20% multiple live birth rate for 2010/11 if the Person Responsible (PR) continues to make progress.

4. The Panel noted that at the time of the inspection, the PR has responded to all recommendations within the report.

5. The Panel noted the PR's comments for addressing register information relating to consent to disclosure for research. However, the law requires centres to collect this information for research.

6. The Panel noted that the Inspectorate recommended that the centre's licence continue without additional conditions.

Decision

7. The Panel agreed with the Inspectorate's recommendations made in the report. The Panel agreed to the continuation of the centre's licence with no additional conditions.

Signed:  Date: 14/10/2010

Peter Thompson (Chair)