Interim Inspection Report

Date of Inspection: 23 March 2011
Purpose of inspection: Interim inspection of treatment and storage licence
Length of inspection: 8.5 hours
Inspectors: Sara Parlett and Anthony Knox

Inspection details:
The report covers the pre-inspection analysis, the visit and information received between 15 May 2008 and 10 June 2011.

Date of Executive Licensing Panel: 14 June 2011.

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 Code of Practice 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 Executive Licensing Panel which makes the decision about the continuation of the centre's licence.

Centre details

Centre Name	Glasgow Royal Infirmary
Centre Number	0037
Licence Number	L0037-13-D
Centre Address	Assisted Conception Services Unit, Walton Building 84 Castle Street Glasgow Scotland, G4 0SF
Telephone Number	0141 211 0505
Person Responsible	Dr Helen Lyall
Licence Holder	Professor Scott Nelson
Date Licence issued	01/01/2009
Licence expiry date	31/12/2013
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Summary for licensing decision:

In considering overall compliance, the inspection team considers that they have sufficient information drawn from documentation submitted by the centre prior to the inspection and from observations and interviews conducted during the inspection visit to draw a conclusion on the continuation of the centre's licence.

The Executive Licensing Panel is asked to note that at the time of the inspection, there were a number of areas of practice that required improvement, including one critical area, five major areas of non-compliance and seven other areas of non-compliance.

Since the inspection visit, the Person Responsible (PR) has provided evidence that the following recommendations have been fully implemented:

Other areas of concern

- To request an explanation from the European bank supplying donor sperm, regarding the evidence suggesting that a donor may have been paid rather than reimbursed.
- To revise the welfare of the child (WoC) assessment SOP to include the requirement to assess the surrogate's partner, if she has one, in surrogacy cases.

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

Critical area of concern

- **To take appropriate action regarding the continued storage of the patient material being stored without valid consent.**

  For recommendations, refer to page 24.

Major areas of concern

- To complete the validation of critical processing procedures.
- To establish quality indicators (QIs) for donor recruitment and selection and traceability processes.
- To ensure that donor recruitment and selection and traceability processes are audited against compliance with approved protocols, regulatory requirements and QIs.
- To establish a third party agreement (TPA) with the external laboratory undertaking analysis of blastomeres for pre-implantation genetic diagnosis (PGD).
- To ensure that the laboratory incubators are the subject of appropriate monitoring, alerts, alarms and corrective action, as required, to detect malfunction and defects and to ensure that the critical parameters are maintained within acceptable limits at all times.

Other areas of concern

- To revise the PGD standard operating procedure (SOP) to include an additional witnessing step.
- To revise the centre's patient information leaflet referring to storage periods of gametes and embryos.
- To ensure that approved SOPs are in place for each piece of critical equipment and that they document the action to be taken in the event of malfunctions or failure.
- To revise the centre's "data confidentiality" SOP to include the process for responding to applications for access to confidential records.
- To ensure that all staff can provide documented evidence of the assessment of their competence.

Recommendation to the Executive Licensing Panel:

The inspector considers that, overall, there is sufficient information available to recommend the continuation of the centre's licence years without additional conditions. In making this recommendation it is noted that the PR has responded to all recommendations made in this inspection report.

Details of Inspection findings

Brief description of the centre and its licensing history:

The centre was first licensed to carry out treatments in 1992 and has a good history of regulatory compliance.

The centre is divided between two sites within the Glasgow Royal Infirmary. Consultations, scans and administrative services are located within the Walton Building. The waiting room, men's production room, quiet room, operating theatre, four bedded recovery area, laboratory and cryostore are located within the Queen Elizabeth Building.

The Walton Building is no longer scheduled for demolition and there have been no further developments with regards to locating the unit within a single site at the Glasgow Royal Infirmary.

There has been a change of PR and Licence Holder (LH) since the last inspection in May 2008. The previous LH, Dr Helen Lyall, took over the role of PR in May 2009. Dr Lyall has successfully completed the PR Entry Programme (PREP) (7th Code of Practice (CoP) edition).

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 1 November 2009 – 31 October 2010*
In vitro fertilisation (IVF)	404
Intracytoplasmic sperm injection (ICSI)	364
Frozen embryo transfer (FET)	205
Donor insemination (DI)	18
Intrauterine insemination (IUI) (01/01/2010 – 31/12/2010)	257

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

*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.

Outcomes*

For IVF/ICSI, HFEA held register data for the period 1 January 2007 to 31 December 2009 show the centre's success rates are in line with national averages with the following exceptions:

- The below 35 age group is significantly below the national average.
- The 38-39 age group is significantly below the national average.

Please refer to page 10 of the report.

For the year 2010, the centre reported 258 cycles of partner IUI, with 33 pregnancies. This equates to a 13% pregnancy rate.

1. Focus of inspections for 2010-12

Providing information to patients in relation to costed treatment plans and parenthood
What the centre does well. **Costed treatment plans** Patients are provided with personalised costed treatment plans prior to treatment (CoP Guidance 4.3). The centre's "fee schedule" provided to patients details the costs of the various treatment packages offered and additional costs. Patients are invoiced in advance of treatment. A patient invoice reviewed at inspection clearly lists the separate charges as per the "fee schedule". The senior nurse explained that once treatment commenced, no additional charges would be made, for example in the event of additional drugs or scans being required. It was further noted that services such as counselling are not charged for and there is no restriction on the number of times a patient could see the counsellor. **Legal parenthood** Centre staff interviewed demonstrated an understanding of the legal parenthood provisions. The centre has a SOP for obtaining consent to parenthood, including the procedure to follow if consent to parenthood is withdrawn (Licence Condition T33 (b)). The information leaflet given to patients prior to treatment was reviewed and is comprehensive. In addition, centre staff confirmed that verbal information is given at the time of obtaining consent. A legal parenthood consent audit performed in March 2011 was reviewed and included corrective action taken (Licence Condition T36). Four sets of records of patients who have undergone treatment using donor sperm were reviewed. Consent to legal parenthood was obtained appropriately in all cases.
What they could do better. Nothing noted at the time of inspection.

Consent - particularly consent to disclosure to researchers and consent to storage

What the centre does well.

Consent to disclosure of identifying information to researchers

The centre seeks patient consent to identifying information from the HFEA register being disclosed to researchers. Registry information demonstrates that 72% of all patients who have been registered at the centre since October 2009 have opted in for disclosure.

An audit of ten patient and partner consents to identifying information from the HFEA register being disclosed to researchers, against that recorded on the HFEA register, was performed at inspection and no discrepancies were noted.

Consent to storage

Consent to the storage of patient material is obtained by clinical staff. The laboratory manager explained that prior to storage, staff confirm that consent to storage is present and completed appropriately. This check step is recorded on the laboratory freeze form.

A two year rolling audit of stored material is conducted by the centre, the schedule for which was seen (CoP Guidance 17.16 (a)). The last full audit summary was reviewed and showed that only administrative discrepancies were found. Corrective action was taken to resolve these discrepancies (Licence Condition T36).

The centre's "taking/withdrawing/varying informed consent" SOP describes the cooling off period (HFE Act 1990 (as amended), Schedule 3, paragraph 4A (4)) and the procedure to follow if one gamete provider withdraws their consent to embryo storage (HFE Act 1990 (as amended), Schedule 3, paragraph1 and CoP Guidance 5.35). Centre staff interviewed were aware of the cooling off period and when this can be applied.

What they could do better.

Consent to storage

Prior to February 2005, seven dewars of sperm samples were stored under the licence for centre 0037, but located in and managed by the Glasgow University Department of Obstetrics and Gynaecology. These were relocated to the centre in February 2005. A full audit of these tanks at the beginning of 2010 showed that a number of samples were in storage with limited information with which to trace the patients at the time of consent expiry and a number being stored without valid consent (HFE Act 1990 (as amended), Schedule 3, paragraph 8 (1)). The centre reported this as an incident in February 2010 and has kept the HFEA fully informed regarding this situation. A concerted effort was made to contact all patients with samples in storage without valid consent with the limited information available.

The PR confirmed that sperm samples for 145 patients are currently in storage without valid consent and the patients are deemed 'lost to contact'.

On inspection, the laboratory manager explained that prior to 2005 there was no procedure in place for maintaining contact with patients with material in storage. Because of this, staff are unsure as to the centre's legal standing if material was to be allowed to perish and patients later make contact.

The PR confirmed that the legal opinion of the Scottish Central Legal Office had been sought on her behalf by the Trust in December 2010, although evidence of this was not available on inspection. This opinion has not yet been received.

The centre's current bring forward system was described by the laboratory manager. Annually, a full list of all stored material is generated from the centre's database. Patients for whom storage consent will expire the following year are then contacted.

One set of embryos is currently in storage without valid consent, having expired on 8 November 2010 (HFE Act 1990 (as amended), Schedule 3, Paragraph 8(2)). The laboratory manager confirmed that the patient had been contacted in line with the current bring forward system and the centre had received written confirmation that they would consent to the donation of embryos to research. However, this confirmation was received without sufficient notice to allow for consenting and use in research before the expiry date. The centre staff then felt obliged to give additional time to inform the patients of this and allow them to make an alternative decision, including extending storage for use in their own treatment. Later on the day of inspection, the laboratory manager confirmed that the patient had made contact that day and agreed to send written confirmation to allow the embryos to perish. The inspector was concerned that the embryos had been in storage for four months without valid consent. The laboratory manager explained that he agreed that the current bring forward system is not fit for purpose.

The laboratory manager described a new, detailed, bring forward system, currently in draft format, that will make it the patient's responsibility to maintain contact with the centre. The plans for the new bring forward system have also been forwarded for legal advice as to the appropriateness of the system.

Multiple births

What the centre does well.

The centre's verified multiple pregnancy rate for 2009 was 29.7%. This is expected to meet the live birth rate target of 24% for 2009 (Directions 0003).

In compliance with Directions 0003, the centre has a documented record of

its multiple birth minimisation strategy (MBMS), including how the centre identifies suitable cases for elective single embryo transfer (eSET), including criteria in relation to patient selection and embryo assessment (Directions 0003, 5 (a)).

The PR and laboratory manager confirmed that audits and evaluations of the progress and effectiveness of the strategy are carried out on an annual basis and the 2009-2010 audit was reviewed. The laboratory manager confirmed that a preliminary audit of year two of the MBMS (data up to the end of December 2010) shows a multiple pregnancy rate of 23.8%. This is expected to meet the live birth target of 20% for year two. Centre staff explained that when the MBMS was first introduced, it resulted in a reduction in clinical pregnancy rates (as evidenced in the centre's success rates on page 6 of the report). As a result, the strategy was revised and the success rates have now improved. The centre is now considering its options for how to reduce multiple births further to meet the new live birth target of 15% from April 2011. Two options are to expand the strategy to include FETs and/or introduce a blastocyst culture programme. Centre staff explained that one issue with introducing blastocyst culture is the requirement for funding for additional laboratory staff at the weekend.

The centre maintains a summary log of cases in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer required by Directions 0003, 3 (c). Centre staff confirmed that where two embryos were transferred to a patient meeting eSET criteria, an explanation of the reasons for this are recorded in the patient's records (Directions 0003, 7).

The centre maintains a summary log of cases in which three embryos have been transferred (Directions 0003, 1 (b)). The log indicated that all patients were over the age of 40 (CoP Guidance 7.4 (b)) and there were no ongoing twin pregnancies. An explanation of the reasons for this was seen to be detailed in one set of patient notes reviewed (Directions 0003, 1 (a)).

The centre's patient information leaflet was reviewed and includes comprehensive details of the risks of multiple pregnancy (CoP Guidance 7.6).

What they could do better.

Nothing noted at the time of inspection.

Validation of critical equipment and processes

What the centre does well.

Critical equipment has been validated and validation records for a heated stage and class II cabinets were reviewed (Licence Condition T24). Records of revalidation of a laser used for PGD after repair were also seen (Licence Condition T25). It was observed that equipment with critical measuring functions are calibrated against traceable standards (Licence

Condition T24).

The laboratory manager explained that all validation records will be grouped together as one documented qualification review for each piece of critical equipment, an example of one such equipment qualification review for a freeze machine was reviewed.

What they could do better.

The laboratory manager explained that the critical processes were validated, but the documented evidence supporting this was in progress (Licence Condition T72). The laboratory manager is planning to use the Association of Clinical Embryologists (ACE) process validation template for this purpose. Validation of well established procedures will be based on reference to published literature and historic centre data. New processes, including vitrification and the use of a low oxygen culture system, will undergo a more in-depth validation prior to introduction.

Witnessing

What the centre does well.

The laboratory manager confirmed that the identification of samples and the patients or donors to whom they relate is witnessed by two members of staff at all critical points of the clinical and laboratory processes. Centre SOPs were reviewed and covered all critical points, with one exception (detailed below). A witnessing step observed during the inspection was in accordance with the centre's SOP (Licence Condition T71).

The centre is planning to use an electronic witnessing system and some hardware installed for this purpose was observed. The laboratory manager explained that the finance to pay for the ongoing costs of this system was currently being discussed with Trust management.

Four sets of patient notes audited at inspection were found to include records of all required witnessing steps, including the date and time of the procedure (Licence Condition T71). The initials of the person performing the procedure and the person witnessing the procedure are documented. A separate list of the names, status, initials and signature of all staff authorised to witness is maintained in accordance with CoP Guidance 18.8.

Evidence of competence assessments of staff performing witnessing steps was seen (Licence Condition T15 (a)).

The laboratory manager explained that the witnessing procedure is audited annually. The most recent audit report, from March 2011, was reviewed and noted no discrepancies. The laboratory assistant responsible for data entry also checks completeness of witnessing records at the time of data input from laboratory records onto the centre's database. An omitted witnessing record would be raised as a non conformance via the centre's

quality management system (Licence Condition T36).

What they could do better.

The PGD SOP does not document the requirement for witnessing at the time of transfer of embryos between dishes prior to embryo biopsy (Licence Condition T33 (b)). A review of one set of PGD patient notes demonstrated that this is witnessed in practice.

Gamete and embryo donation – reimbursement, information provision and screening

What the centre does well.

The centre is continuing to develop its donor programme and to date have ten registered sperm donors. The centre's donor assessment and screening procedures are supported by a SOP that is compliant with Licence Condition T52 and T53 (c). Five sets of sperm donor records were audited during the course of the inspection. This sample of records provided evidence that:

- Donors are being selected on the basis of their age, health and medical history, provided in a questionnaire and through a personal history and medical examination performed by a clinician (Licence Condition T52 (a)).
- Donors are being selected in accordance with the screening requirements of Licence Condition T52 and relevant professional bodies[1].
- Donor sperm is quarantined for a minimum of 180 days, followed by repeat testing in accordance with Licence Condition T53 (c). In one set of notes reviewed, the donor was found to be positive for a sexually transmitted disease and all stored samples were discarded in 2009.

Centre staff confirmed that the laboratory tests required by Licence Condition T52 have been carried out by a qualified laboratory which has been accredited by Clinical Pathology Accreditation (CPA) (UK) Ltd (Licence Condition T53 (a)).

The centre maintains detailed records on its database and can provide donors with information regarding the number, sex and year of birth of persons born as a result of donation (HFE Act 1990 (as amended), Schedule 31ZD (3)). The donor coordinator explained that no such requests have been made to date.

Payments made by the centre to donors are for travelling expenses only. The donor coordinator stated that reimbursement for loss of earnings had

[1] The 2008 UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors produced by BFS, BAS, ACE and RCOG.

not been requested. The donor coordinator explained that copies of the travel receipts are made and filed within the donor notes, this was confirmed during review of one set of donor records (Directions 0001).

What they could do better.

The centre has not established QIs for the recruitment, assessment and screening of donors (Licence Condition T35).

Audits have not been performed in the last two years for donor recruitment, assessment and screening activities (Licence Condition T36).

Relevant staff do not have documented competence assessments for donor recruitment, assessment and screening activities (Licence Condition T15 (a)).

The centre has imported donor sperm from the European Economic Area. The centre has written confirmation that the donors are processed in accordance with the laws applicable in this country, as per General Directions 0001 and 0006. However, the accompanying essay of one donor in a set of notes reviewed stated that one of the reasons for becoming a donor was for economic reasons. This would suggest the donor was paid rather than compensated for loss of earnings and/or expenses.

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

What the centre does well.

Not applicable. This centre does not solely provide basic partner treatment services.

What they could do better.

Embryo testing (if applicable)

What the centre does well.

The centre is licensed for PGD and completed thirty cycles from April 2010 – March 2011. The procedure for biopsying embryos for embryo testing has been documented in a SOP, reviewed on inspection (Licence Condition T33 (b)).

The laboratory manager confirmed that no sex selection for social reasons had been conducted (Licence Condition T88 (d)) and that biopsied embryos are not transferred in the same cycle as non-biopsied embryos (Licence Condition T88 (b)).

The diagnostic analysis of blastomeres for PGD is undertaken by an external laboratory. A copy of the CPA (UK) Ltd certification for this laboratory was provided (Licence Condition T21).

The PGD service is comprehensively audited every six months. The latest report was reviewed and included referral data, waiting times, performance data from the laboratory performing the analysis, treatment outcomes and benchmarking data, using European Society of Human Reproduction and Embryology (ESHRE) criteria (Licence Condition T36). The laboratory manager confirmed that two biopsy practitioners have been fully competency assessed, with two more close to completion. The laboratory manager explained that they have a reciprocal agreement with an external practitioner to perform an independent competence assessment prior to final approval. Evidence of participation in the cytogenetic European quality assessment scheme was seen (Licence Condition T15 (a)).
What they could do better. The centre does not have a TPA with the external laboratory undertaking analysis of blastomeres for PGD, non compliant with Licence Condition T111. The quality manager explained that they were aware of the requirement, but the Health Authority would not sanction the formation of such an agreement, as both the assisted conception unit and the testing laboratory fell under the same health authority and therefore the same legal entity. The Health Authority has stated that because they are the same legal entity, a TPA cannot be entered into.

2. Changes / improvements since the last inspection on 14 May 2008

Area for improvement	Action required	Action taken as evidence during this inspection
The centre takes an average of 48 days to pay treatment fees. The HFEA payment terms are 28 days. Payment outside these terms is a breach of standard licence condition A13.3 which states that in consideration of the grant of the licence (or its variation to designate the individual named in this licence as Person Responsible), the Person Responsible agrees that s/he will pay to the Authority any additional fee, as defined in section 16(6) of the Act, within 28 days of the date of the notice of such additional fee.	The PR should put in place procedures to ensure that fees due to the HFEA are paid within the 28 day limit.	The HFEA finance department reported that the centre is now paying within the required 28 days. **No further action is required.**
One set of records showed that the patient had had three embryos transferred but she had only consented to have two transferred. This is a breach of standard S.7.5.4(c).	Procedures should be put in place to ensure that appropriate consent to the number of embryos transferred is obtained including when the patient changes her mind during treatment.	An "integrated care pathway" form is used at the centre to follow the patient through treatment. This has been modified to include additional check stages to prompt staff to ask patients to amend their consent forms prior to the transfer of three embryos. One set of notes was reviewed at inspection where three embryos had been transferred. Both partners had consented to the transfer of this number. The centre may include a further check step, which the patient signs just prior to transfer, to confirm the number of embryos to be transferred, as previously

Area for improvement	Action required	Action taken as evidence during this inspection
		discussed with them. **No further action is required.**
In one set of records the woman had consented to stored embryos being used by her husband in the event of her death. This would effectively mean that the female partner would become a donor, but there was no evidence of screening being undertaken to allow this. This is a breach of standard S.7.6.7.		The "integrated care pathway" form has been amended to include additional check stages to complete should this be requested. This includes the need to give information pertaining to becoming a donor and the requirement for additional screening. **No further action is required.**
The processes used in carrying out licensable activities have not been validated. This is a breach of standard S.7.8.3.		Refer to page 11 of report. **Further action required.**
Competency assessments have not been done for embryologists. This is a breach of S.6.2.9.		Refer to page 19 of report. **Further action is required.**
Success rates for the centre were displayed in the waiting room but no national statistics were given for comparison. This is non-compliance with G.5.3.1(e) in the Code of Practice.		Centre success rates were seen clearly displayed alongside national data. **No further action is required.**
Patient information stated that there was no limit on the length of time eggs can be stored for. This should be amended to reflect the storage period permitted for gametes.		The centre's "storage of sperm, eggs and embryos" patient information leaflet refers to storage up to the patient's age of 55 years. Further revision is required to reflect the requirements of the HF&E (statutory storage period for embryos and gametes) Regulations 2009.

Area for improvement	Action required	Action taken as evidence during this inspection
		Further action is required.
Patient information stated that by law the maximum number of embryos that could be replaced was two. This should be amended to reflect the current guidance in the Code of Practice.		Patient information clearly states the number of embryos that can be transferred, as per CoP Guidance 7.3 and 7.4. **No further action is required.**

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 requirement or whether any further action is required
Is the centre operating with a full staff complement. Licence Condition T12.	The PR explained that in her opinion the centre is not operating with a full staff complement. A workforce calculation for clinical staff was performed a year ago, indicating the need for additional staff, but no action has been taken by the Trust. The PR explained that there is no slack in the system currently. For example, if one patient requires longer than the appointed time in a consultation, this has a knock on effect on waiting times for the whole clinic. The HFEA has received 73 patient questionnaires relating to the centre since the previous inspection and a trend of comments regarding long waiting times was seen. The counsellor has reported that she works over her contracted hours and that there is a long waiting time for referrals. The counsellor feels that this post should be full time to meet the demands of the centre's counselling service.	Whilst it is recognised that there are no immediate regulatory concerns regarding patient care and services at the centre, the PR should closely monitor the current situation. The PR should consider a further review of the resources available to meet the current activity levels. In the event that staffing cannot be increased, the overall activity levels of the centre may need to be revised.

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
	The PR confirmed that a new consultant embryologist had been employed and was starting imminently. Vacancies have also been approved for one trained and one trainee embryologist.	
Can all staff provide documented evidence of the assessment of their competence in the performance of their designated tasks. Licence Conditions T12 and T15 (a).	The laboratory manager explained that his current priority is to review all laboratory SOPs. Laboratory staff have been involved in this review, to ensure consistency of practice. Once a SOP has been approved for use, competence assessments relevant to the procedure documented are carried out for all relevant members of staff and the assessments are documented. The laboratory manager stated they were approximately 25% of the way through this process. Documented competence assessments were seen for some processes, including semen analysis and laboratory data logging. The laboratory manager confirmed that the centre participates in the UK national external quality assessment scheme (NEQAS) for semen analysis and intends to sign up to the NEQAS embryo grading scheme. Training folders reviewed for two nurses included evidence of training and attendance at seminars and conferences. Evidence that clinical SOPs are signed off to show relevant staff have read and understood them was also seen. However, nursing staff cannot	Further action is required.

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
	provide documented evidence of the assessment of their competence in all designated tasks.	
Has the centre established QIs or objectives relevant to traceability. Licence Condition T35.	QIs have not been established relevant to traceability.	Further action is required.
Have all licensed activities or activities carried out in the course of providing treatment services that do not require a licence, been audited against compliance with the approved protocols, the regulatory requirements and quality indicators in the last two years. Licence Condition T36.	Audits have been performed for the majority of licensed activities. Audits reviewed at inspection included storage, witnessing, consent and confidentiality processes and the counselling service. Quality indicators relevant to procurement and processing procedures, including fertilisation rates, cancellation rates, clinical pregnancy rates and multiple birth rates are audited on a monthly basis. Audits have not been performed in the last two years for traceability and donor recruitment and selection processes.	Further action is required.
Does your centre ensure that all relevant data relating to anything coming into contact with those gametes or embryos (equipment and results of equipment performance monitoring,	The laboratory manager confirmed that all data is traceable and the centre's traceability procedure was reviewed at inspection. Some data, for example equipment used, is currently recorded on daily laboratory sheets. The laboratory manager explained that although traceability is maintained by this method, the centre plans to record more information on the	No further action is required.

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
materials and consumables, for example) is traceable. Licence Condition T102.	centre's database, to enable data to be interrogated more readily.	
Does the centre assess both those commissioning the surrogacy arrangement and the surrogate and the surrogate's partner, if she has one? Licence Condition T56.	The PR stated that it was Trust policy not to support surrogacy cases. However, there is the possibility that this opinion may change in the future. The PR agreed to amend the centre's SOP to require a WoC assessment of the surrogate's partner, if she has one.	Further action is required.
Are all licensed premises in the same building? HFE Act 1990 (as amended) Schedule 2, S.4(2)(d)).	The centre is divided between two buildings, linked by a corridor.	No further action is required.
Is there a documented procedure in place outlining the actions to be taken in the event of malfunction or failure of all critical equipment. Licence Condition T27.	The laboratory manager explained that all laboratory SOPs are in the process of being reviewed and updated. Approved SOPs are not yet in place for all critical equipment. An incubator SOP reviewed included detailed instructions for re-calibration, but did not outline more general actions to be taken in the event of malfunction or failure.	Further action is required.

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
Is equipment or materials that affect critical processing or storage parameters (e.g. temperature, pressure, particle counts, microbial contamination levels) the subject of monitoring, alerts, alarms and corrective action. Licence Condition T24.	The laboratory incubators are monitored daily by laboratory staff and have auto dial out alarms, but for a power failure only. An out of hours change in critical parameters (e.g. temperature), which is not caused by a power failure, would go uncorrected. This could pose a significant risk of causing harm to embryos in the incubator. One corrective action identified by the centre following an incident reported to the HFEA in 2009, was to install temperature alarms. The laboratory manager explained that the finances for this were not available. Centre policy is to monitor the carbon dioxide concentration in the incubators daily. The centre's carbon dioxide monitor broke down in January 2011 and they are currently borrowing a monitor from another unit when possible. The order for a new monitor has now been approved, but the delivery date is not known.	Further action is required.
Does your centre have a SOP to ensure that all information is kept confidential and only disclosed in circumstances permitted by law?	The centre's "data confidentiality" SOP describes processes to ensure all information is kept confidential.	No further action is required.

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
Licence Condition T43 and T33 (b).		
Does the centre's SOP for the control of access to health data and records, document the systems in place for considering and responding to applications for access to confidential records and for correctly identifying applicants? Licence Condition T44 (d).	The centre's "data confidentiality" SOP does not include the process for responding to applications for access to confidential records.	Further action is required.

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
At the time of inspection: • one set of embryos • sperm samples of 145 patients were being stored without valid consent. HFE Act 1990 (as amended), Schedule 3, paragraph 8 (1) and (2).	**Embryos** The PR must take appropriate action regarding the continued storage of these embryos and inform the Executive of the action taken. By the time the PR responds to this report. **Sperm samples** The PR should provide the Executive with a copy of the written request for independent legal advice regarding the storage of the 145 patients' samples without consent and the proposed new	The embryos in question have been allowed to perish. A copy of this letter is appended, as is a copy of the SOP detailing the new bring forward	The Executive is satisfied with the PR's response. **No further action is required.** The centre has submitted a copy of the written request for independent legal advice, dated

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	bring forward system. The PR should provide an update regarding when this advice is expected to be obtained. By the time the PR responds to this report. The PR must inform the Executive immediately once legal advice has been obtained. The PR should submit an action plan, detailing the action to be taken, to the Executive within one month of receiving legal advice.	system. The time scale over which the advice is expected is completely out of the control of the PR. It is dependent on the Central Legal Office (CLO). The PR confirms an action plan will be submitted within one month of the advice being obtained.	10 December 2010. The centre has also submitted a SOP for the bring forward system for sperm, template patient letters and a template patient decision form. The Executive is satisfied with the PR's response, but expects this issue to be resolved within a reasonable time period. It is recommended that the Executive continues to closely monitor progress regarding the samples in storage without valid consent.

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
The validation of critical processing procedures has not been completed. Licence Condition T72. **This was an issue at the last inspection.**	The PR should ensure that the validation of critical processing procedures is completed. The PR should submit an action plan, including a summary of all procedures that require validation and timeframes for completion, by the time the PR responds to this report. The PR should submit quarterly reports to the Executive regarding the progress of the implementation of this plan until it is completed. For full completion by March 2012.	All areas of practise have been set up using best practise principles and have been subject to validation using key performance indicators over a number of years. However, at present there is no formal document which decribes the basis for practise or the detailed validation of individual procedures. Therefore, the PR	The PR contacted the Executive on 3 May 2011 to request an extension to the timescale for submitting an action plan, to allow for a more detailed plan to be developed by herself and the consultant embryologist. The Executive agreed that a timescale of submission of this detailed plan by 23 June 2011 would be

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
		and Consultant Embryologist are preparing a formal process validation report addressing this issue which will be submitted on completion.	appropriate. It is recommended that the Executive continues to monitor progress.
QIs have not been established for donor recruitment and selection and traceability processes. Licence Condition T35	The PR should ensure QIs are established for the process of donor recruitment and selection and traceability. 23 June 2011.	Appropriate QIs are currently being devised and will be included into the SOP for donor recruitment	The Executive is satisfied with the PR's response. The PR is asked to submit the SOPs documenting the QIs established for donor recruitment and selection and traceability processes by 23 June 2011.
Audits against compliance with the approved protocols, the regulatory requirements and QIs have not been performed in the last two years for donor recruitment and selection and traceability processes.	The PR should ensure that audits against compliance with the approved protocols, the regulatory requirements and QIs are performed for donor recruitment and selection and traceability processes.	This audit will be incorporated into the annual audit schedule of the Quality Management	The Executive is satisfied with the PR's response. The PR is asked to submit the audit reports for donor

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Licence Condition T36	23 September 2011.	System.	recruitment and selection and traceability processes by 23 September 2011.
The centre does not have a TPA with the external laboratory undertaking analysis of blastomeres for PGD. Licence Condition T111.	The PR should ensure that a TPA, meeting the requirements of Guidance Note 24, is put in place with the external laboratory undertaking analysis of blastomeres for PGD. Recognising that this may require further discussions with the Health Authority, the timeframe for holding a signed written agreement is 23 September 2011.	A TPA has been written and is currently being discussed with Clinical Genetics and it is hoped that a finalised version will be agreed in the near future.	The Executive is satisfied with the PR's response. The PR is asked to inform the Executive when the TPA, signed by both parties, is in place.
The incubators are not subject to appropriate monitoring, alerts and alarms to ensure that the critical parameters are maintained within acceptable limits at all times. Licence Condition T24.	The PR should ensure that the incubators are the subject of appropriate monitoring, alerts, alarms and corrective action, as required, to detect malfunctions and defects and to ensure that the critical parameters are maintained within acceptable limits at all times. Immediately.	The PR has informed hospital management. Quotes are being obtained for the required alarms. This matter has been escalated and is being taken seriously.	The Executive is satisfied with the PR's response. The PR is asked to provide a further update to the Executive by 23 June 2011.

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
The PGD SOP does not document the requirement for witnessing at the time of transfer of embryos between dishes prior to embryo biopsy. Licence Condition T33 (b).	The PR should ensure that the PGD SOP is revised to incorporate this witnessing step. 23 June 2011.	The PGD SOP is currently under review by the Consultant embryologist and this witnessing step will be detailed within it before it is re-issued.	The Executive is satisfied with the PR's response. The PR is asked to submit a copy of the revised PGD SOP to the Executive by 23 June 2011.
The accompanying essay of one sperm donor, whose sperm was imported from the European Economic Area, suggests that the donor was paid rather than reimbursed. Directions 0001 and 0006 (Schedule 1, 1(e)).	It is acknowledged that the centre has obtained written confirmation that no money or other benefits had been given to the sperm donor, except in accordance with Directions 0001. However, the information noted in the donor's essay has raised questions regarding the assurances given. The PR is requested to ask for an explanation from the supplying European bank and inform the Executive of the outcome.	An explanation has been requested by the PR from the European Bank. The e mail detailing their response will be forwarded.	The PR has submitted a copy of the explanation received from the European bank. The Executive is satisfied with the PR's response. **No further action is required.**

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	23 June 2011.		
The centre's "storage of sperm, eggs and embryos" patient information leaflet refers to storage up to the patient's age of 55 years. HF&E (statutory storage period for embryos and gametes) Regulations 2009.	The PR should ensure that the centre's patient information leaflet is revised to reflect the requirements of the HF&E (statutory storage period for embryos and gametes) Regulations 2009. 23 June 2011.	The Quality manager is currently updating this document to reflect current regulations.	The Executive is satisfied with the PR's response. The PR is asked to submit a copy of the revised leaflet to the Executive by 23 June 2011.
The centre's WoC assessment SOP does not include the requirement to assess the surrogate's partner, if she has one, in surrogacy cases. Licence Condition T33 (b)	The PR should ensure that the centre's WoC assessment SOP is revised to incorporate this requirement. 23 June 2011.	The PR is currently revising this SOP	The PR has submitted a revised WoC assessment SOP, documenting the requirement to assess the surrogate's partner, if she has one, in surrogacy cases. **No further action is required.**
Approved SOPs are not yet in place for all critical equipment. The approved SOPs that are in place do not outline the general actions to be taken in the event of malfunction or failure.	The PR should ensure that approved SOPs are in place for each piece of critical equipment and these SOPs must document the action to be taken in the event of malfunctions or failure.	A new SOP detailing appropriate use of all critical equipment and steps to be taken in the event of a malfunction is	The Executive is satisfied with the PR's response. The PR is asked to submit a copy of the

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Licence Condition T27.	23 September 2011.	currently being written by the Consultant Embryologist	SOP to the Executive by 23 September 2011.
The centre's "data confidentiality" SOP does not include the process for responding to applications for access to confidential records. Licence Condition T44 (d).	The PR should ensure that the centre's SOP is revised to include the process for considering and responding to applications for access to confidential records and correctly identifying applicants. 23 June 2011.	The Quality manager is currently updating the data confidentiality SOP to include the process for responding to applications for confidential records	The Executive is satisfied with the PR's response. The PR is asked to submit a copy of the revised SOP to the Executive by 23 June 2011.
Competence assessments Licence Condition T15 (a) **This was an issue at the last inspection.**	The PR should ensure that all staff can provide documented evidence of the assessment of their competence in the performance of their designated tasks. By the time of the next inspection. The PR should submit a detailed plan, including a summary of all staff and the competence assessments they need to complete, including timeframes, by 23 June 2011. The PR should submit quarterly reports to the Executive regarding the progress of the implementation of this plan until	Staff competency has previously been assessed by analysis of KPIs and regular sign off of appropriate SOPs. However, more formal competency assessment documentation is now being developed by all section heads. Interim competency	The PR has submitted a plan detailing the competence assessments required. The plan does not include competence assessments for WoC assessment, donor recruitment and selection or traceability processes.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	it is completed.	assessment areas for each discipline are included with this document as evidence that we are addressing this issue as a matter of urgency. It is expected that finalised competency assessment records will be available by 23rd June 2011 alongside an SOP detailing the annual requirements of each discipline. Subsequent completion of competency records will be monitored by the Quality manager.	It is recommended that these activities are added to the plan. It is recommended that the Executive continues to monitor progress within the timescales indicated.

Additional Information from the Person Responsible

HFEA Executive Licence Panel Meeting

14 June 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 1

Centre 0037 (Glasgow Royal Infirmary) – Interim Inspection Report (Treatment and Storage)

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy & Information (Chair) Nick Jones, Director of Compliance Juliet Tizzard, Head of Policy	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 has been licensed by the HFEA since 1992 and according to the Inspectorate has a good history of regulatory compliance.

2. The Panel noted that the centre is divided between two sites within the Glasgow Royal Infirmary.

3. The Panel noted that the centre offers a full range of treatments including IVF, ICSI, FET, Donor Insemination, IUI and Storage of Eggs, Sperm and Embryos and in the period November 2009 to October 2010 carried out approximately 1350 treatment cycles in total.

4. The Panel noted that since the last inspection in May 2008, the centre has changed the Person Responsible (PR) and Licence Holder (LH), both of whom were approved by a previous Licence Committee.

5. The Panel noted at the time of the inspection the Inspectorate observed areas of practice that required improvement, including one critical area, five major and seven other areas of non-compliance.

6. The Panel noted that some of the areas of non-compliance that were identified on this inspection were also previously identified on the inspection in May 2008.

7. The Panel noted that since the inspection the PR has responded to the report positively and has made progress with implementing some of the recommendations made in the report.

8. The Panel noted that on those areas of non-compliance that have not yet been addressed, the PR has given her full commitment to implement them within the specified timescale.

9. The Panel noted the Inspectorate's recommendation, that they are satisfied that there is sufficient information available to recommend the continuation of the centre's licence with no additional conditions.

Decision

10. The Panel endorsed the Inspectorate's recommendation to the continuation of the centre's licence, with no additional conditions. The Panel would encourage the PR to rectify the outstanding recommendations in the report within the timescales specified.

Signed:  Date: 29/6/11.
Peter Thompson (Chair)