Renewal Inspection Report

Date of Inspection: 25 May 2010
Length of inspection: 14 hours
Inspectors:
Angela Sutherland
Ellie Suthers
Bryan Woodward
Chris Hall
Siobhan Kelly

Inspection details:
The report covers the pre-inspection analysis, the visit and information received between 20 May 2009 and 25 May 2010.

Date of Executive Licence Panel: 12 August 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 Code of Practice to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence renewal 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 centre's licence renewal application.

Centre details

Centre Name	Glasgow Centre for Assisted Reproduction
Centre Number	0250
Licence Number	L0150 3/b
Centre Address	21 Fifty Pitches Way Cardonald Business Park Glasgow G514FD
Telephone Number	0141 891 8749
Person Responsible	Professor Richard Fleming
Licence Holder	Dr Mark Gaudoin
Date Licence issued	05 July 2007
Licence expiry date	31 October 2010
Additional conditions applied to this licence	Nil

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Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

This purpose-built IVF centre was designed to conform to the European Union Tissues & Cells Directive (EUTD). It is situated in a business park on the outskirts of Glasgow, close to the Southern General Hospital. The centre was initially granted a licence for treatment and storage on 1 November 2006 and provides treatment to self-funded and NHS patients.

This centre has never had any additional conditions added to the licence.

The renewal application includes notification of the centre's intention to provide PGD services in the future. Discussion with the PR has confirmed that this plan is in the beginning stages and he will liaise with the HFEA and submit an application to vary the centre's licence when they are ready to proceed.

Activities of the Centre:

Type of treatment	Number of treatment cycles from 01/02/2009–01/02/2010
Egg donor only	12
Donor insemination	36
Fresh IVF	365
Frozen IVF	22
Fresh ICSI	281
Frozen ICSI	21

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

*This data was extracted from the HFEA register for the period 01 February 2009 – 01 February 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.

Summary for licensing decision:

In considering overall compliance, the Inspector considers that they have sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit to conclude that:

- The PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended).
- The premises are suitable.
- The practices are suitable.
- The centre has submitted appropriately completed documentation in application for renewal of their licence.
- The centre has submitted an application fee to the HFEA in accordance with requirements.

Recommendation to the Executive Licensing Panel:

The inspector considers that, overall there is sufficient information available to recommend the renewal of this centre's licence for a period of four years without additional conditions.

The inspector also recommends that the Executive Licensing Panel requires that the Person Responsible complies with following recommendations within the prescribed timeframes set out in the inspection report:

- The PR should review whether there are any barriers to the prompt payment of HFEA fees and take steps to ensure they are paid within 28 days in compliance with standard licence condition T9(d).

Since the inspection visit the PR has provided evidence suggesting that the centre is compliant with this licence condition. The matter has been referred to the HFEA finance department to resolve the discrepancy.

- The PR should review witnessing practice to ensure that all critical points of the clinical and laboratory processes are witnessed as required by T71 and G18.4(j).

Since the inspection the PR has submitted a reviewed SOP that is now compliant with this licence condition.

- The PR should ensure that all staff competence assessments are completed and include assessment of staff knowledge and understanding of all of the key scientific and technical processes and principals relevant to their designated tasks as required by T15.

Since the inspection the PR has provided evidence that staff competency programmes that were already in place will be completed and programmes for the centre's embryologists have now been developed and will be completed.

- The PR should review incidents related to patient confidentiality breaches including analysis and remedial actions in order to devise a plan to minimise the risk of recurrence and protect the confidentiality of all patients and donors at the centre as required by S33 of the HFE Act 1990 (as amended).

This has been an ongoing issue at the centre and the PR has provided useful background information including plans to continually monitor staff performance in this area.

- The PR should ensure that an effective, documented recall procedure is developed that includes a description of the responsibilities and actions to be taken by the involved parties.

Since the inspection the PR has provided evidence that this standard operating procedure is now in place,

- The PR should ensure the development of a traceability standard operating procedure that covers all steps in the treatment process from procurement to treatment or disposal, including equipment and operators to fulfil the requirements of T87 and T99.

Since the inspection the PR has provided evidence that this standard operating procedure is now in place and is compliant with T87 and T99

- The PR should review and revise the process undertaken to submit treatment data to the HFEA to ensure compliance with Direction 0005.

Since the inspection the PR has provided evidence that this ongoing issue is being addressed and that two staff members have been allocated to the submission of treatment data to the HFEA.

- The PR should consider review of the centre's incident reporting standard operating procedure to include notification to the HFEA of less serious incidents and near misses as recommended by G27.5.

Since the inspection the PR has provided evidence that these incidents have been analysed and will be monitored as discussed above, however, the Executive recommends a commitment from the PR that all adverse incidents including near misses will be reported to the HFEA.

- The PR should consider implementing a document control procedure that requires annual review of all centre documents annually as recommended by G31.6.

Since the inspection the PR has provided evidence that the centre's document control policy has been updated to include annual review.

Details of Inspection findings

1. Risk to patients and children born as a result of treatment services

Focus

- **The risks of fertility treatment to the health of patients and children born as a result of treatment**

- **Welfare of the Child** – all assisted conception processes should only be conducted in a manner that takes into account the welfare of any child that may be born as a result of treatment services

- **Ensuring patients receive treatment using the correct gametes or embryos** – patients should have confidence that the gametes or embryos used in their treatment are either their genetic gametes or embryos created with their gametes (or in the case of donor gametes that the gametes used are from the correct donor)

- **Ensuring donor gametes are only used where appropriate screening has taken place** – the health of patients and children, born as a result of treatment services, could be at risk if gametes from unscreened donors are used in the provision of treatment services

- **Inspection theme 2010 - 2012** – the focus of inspection for 2010 – 2012 should include the following areas
    - Witnessing

- **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.

    - Staff competence assessment.
    - Adverse Incidents.
    - Complaints.
    - Staff competence assessment.

▶ Take account of the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth (Principle 4).
What the centre does well: **Welfare of the child (Guidance note 8):** Five sets of patient records were audited during the inspection. Documented evidence that consideration had been given to the welfare of the child as required by S13(5) of the HFE Act 1990 was found in each case. Discussion during the inspection confirmed that before any woman is provided with treatment services at the centre consideration is given to the welfare of the child born as a result, in compliance with T58. A process exists whereby any staff member can raise concern regarding existing children or children yet to be conceived (including anonymously) which are then discussed in a multidisciplinary review meeting. The requirement to consider the welfare of the child is built into several standard operating procedures including Patient Assessment, Obtaining Consent and Implications Counselling for Donation. All patients undertake a consent consultation before any documentation is signed during which welfare of the child is discussed and a counsellor is available to all patients and donors. Compliance with the completion of welfare of the child documentation is included in a six monthly audit schedule as part of the “Documentation requirements” audit.
What they could do better:

▶ Conduct all licensed activities with skill and care and in an appropriate environment, in line with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring (Principle 7).
What the centre does well: **Donor recruitment, assessment and screening (guidance note 11):** The centre has a detailed standard operating procedure guiding the process to be followed when selecting and recruiting donors (T33b) this was seen to include steps to be taken if the decision is made to deny treatment including the offer of counselling. They no longer actively recruit donors but have one current donor who directly approached the centre. The inspection team examined five sets of patient records which confirmed that all donors had been selected on the basis of their age and each file included a documented health and medical history in compliance with T52a. All of the files sampled contained completed screening results for HIV, Hepatitis B, Hepatitis C, Syphilis, Chlamydia and CMV in compliance with T52 and other tests required by professional body guidelines.

The laboratory in which the tests are carried out is CPA accredited as required by T53a.

Donor and patient information was provided to the inspection team that included information specific to egg donation, egg sharing, sperm donation and sperm sharing. This information was found to be comprehensive, up to date and patient specific.

Egg sharing arrangements (guidance note 12):
The centre has a well established egg sharing programme although according to information submitted to the HFEA they did not provide any cycles between February 2009 and February 2010. Post inspection the PR confirmed that several egg sharing cycles were carried out over that time period.

Sperm sharing:
The centre has in the past provided a sperm sharing service but has not done so since 2008.

Comprehensive standard operating procedures provided to the HFEA have been established to guide the processes to be followed with egg and sperm sharing patients, including managing introduction, consultation, implications counselling and organisation of treatment.

Payment for donors (guidance note 13):
During the inspection the centre's donor payment log was examined and five sets of egg donor and five sets of sperm donor records were seen. All were found to be compliant with the requirements of HFEA Direction 0001 including receipts and an itemised expenses summary for each patient.

The centre has a third party agreement with Nordic Cryobank for the supply of donor sperm. The PR confirmed verbally during the inspection that each imported sample includes the appropriate documentation to ensure his confidence in the centre's compliance with regard to import and payment of donors. Post inspection he confirmed that this confidence is derived from the content of the third party agreement.

Surrogacy (guidance note 14):
The self assessment questionnaire provided by the PR before the inspection confirmed compliance with the requirements of guidance note 14 therefore surrogacy was not prioritised during the inspection.

Quality management (guidance note 23):
The centre has a well established quality management system that is available electronically to all staff. It includes a quality manual and quality policy and evidence of review outcomes and action plans were provided during the inspection that confirmed compliance with T32 and T33.

The centre has training and reference manuals for both clinical and scientific activity. These are available both on line and in hard copy format (T33).

The quality manager demonstrated hard copy and electronic standard operating procedures for both clinical and scientific procedures. A review schedule for each standard operating procedure was provided at inspection and each documented procedure observed at the time of inspection was seen to be in date, document controlled and authorised (T31).

The quality management system includes measurable “quality control targets” that when discussed with the Quality Manager appeared to satisfy the key quality indicator requirements of T35.

During inspection a comprehensive audit schedule was provided that documents the intention to conduct audits at five and seven month intervals. These included documentation, customer focus, work environment and analysis of data.

What they could do better.

► Ensure that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose (Principle 8).

What the centre does well:

Third party agreements (guidance note 24):
A full list of the centre’s third party agreements was provided during the inspection (T111/T115). Five were audited and found to be compliant with the requirements of T114 and all contained a date for both parties review the agreement.

What they could do better:

► Ensure that all staff engaged in licensed activity are competent and recruited in sufficient numbers to guarantee safe clinical and laboratory practice (Principle 9).

What the centre does well:

Person responsible (guidance note 1):
The PR at the centre is a consultant health care scientist specialising in reproductive endocrinology. He is appropriately qualified and experienced to fulfil his role and was found at inspection to have discharged his duties and responsibilities as required by T9. He is suitably qualified, has completed the Person Responsible Entry Programme (T9), is registered with the Health Professions Council (HPC) and is an Honorary Professor at Glasgow University.

Staff (guidance note 2):
The centre has a nominated registered medical practitioner (T16) and, through the self assessment questionnaire, the PR has expressed confidence that all staff are of such character to be suitable persons to carry out the activities on the licence as required by S.17(1)(a) of the HFE Act 1990 (as amended).

The centre currently has a vacancy for one full time nurse but the nurse manager confirmed during interview that she is actively recruiting and the current staffing level is adequate. Both junior and senior nursing staff confirmed that their current work loads are manageable; they do not undertake enforced overtime and are able to take all breaks and holidays.

It was noted that activity has significantly increased at the centre between 2007 and 2009 however with the recruitment of one full time embryologist the laboratory appears to be adequately staffed. All scientific staff are registered with the HPC.

Evidence provided during the inspection confirmed that all staff undergo a through induction programme and records had been kept of ongoing education and professional development as required by T15.

What they could do better:

Person responsible (guidance note 1):
The centre is taking on average 32 days to pay fees.

The PR should review whether there are any barriers to the prompt payment of HFEA fees and take steps to ensure they are paid within 28 days in compliance with standard licence condition T9(d).

Staff (guidance note 2):
During the inspection it was confirmed that while a comprehensive programme for assessment of staff competence has been developed it has not been completed by all staff and does not include all key competencies for laboratory and nursing staff. None of the records reviewed appeared to include assessment of staff knowledge and understanding of all of the key scientific and technical processes and principals relevant to their designated tasks as required by T15.

The PR should ensure that all staff competence assessments are completed and include assessment of staff knowledge and understanding of all of the key scientific and technical processes and principals relevant to their designated tasks as required by T15.

► Report all adverse incidents (including serious adverse events and reactions) to the HFEA, investigate all complaints properly, and share lessons learned appropriately (Principle 11).

What the centre does well:

Adverse incidents (guidance note 27):
The centre's adverse incident log was provided during the inspection. It contained evidence of a through multidisciplinary response to incidents including review of relevant procedures to minimise the risk of recurrence as recommended by G27.5.

Complaints (guidance note 28):
A comprehensive complaints management standard operating procedure was provided during the inspection. A complaints log was seen to be active as recommended by G28.7 and evidence was provided that the standard operating procedure had been adhered to in every instance including the parameters guiding the resolution of complaints.

What they could do better:

Adverse incidents (guidance note 27):
The Centre's incident log was matched against centre records during the inspection. It was found that while all serious adverse incidents had been reported to the HFEA in compliance with T120 several less serious incidents and near misses had not been reported as required by HFEA Direction 0011.

The PR should consider review of the centre's incident reporting standard operating procedure to include notification to the HFEA of less serious incidents and near misses as required by HFEA Direction 11.

2. Patient Experience

Focus

- **Ensuring patients and donors are treated fairly and that any treatment is conducted in suitable premises by trained competent staff** – treatment should only be carried out in licensed premises and staff must been trained and competent to perform their jobs. All patients and donors should be treated fairly and without discrimination

- **Guaranteeing patients, donors and partners' independent decision making** – this should be done through the careful giving of appropriate and accurate information and the offering of counselling, and the subsequent taking and recording of effective consents

- **Outcome data** – variation in quality of practice and subsequent treatment results

- **Inspection theme 2010 - 2012** – the focus of inspection for 2010 – 2012 should include
  the following areas
  - Information about the cost of treatment (costed treatment plans)
  - Legal parenthood

- **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.

  - There were no specific areas of concern raised by the SAQ or previous inspection report in this area.

▶ Treat prospective and current patients and donors fairly, and ensure that all licensed activities are conducted in a non-discriminatory way (Principle 1).
What the centre does well: **Treating people fairly (guidance note 29):** The centre has developed and implemented eligibility criteria for treatment based on clinical and scientific standards and professional guidance. Evidence was provided at the inspection that all patients and donors are provided with treatment carried out on suitable licensed premises by staff trained and competent to perform their designated tasks.
What they could do better.
▶ Have respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors (Principle 2).
What the centre does well: **Counselling (guidance note 3):** The counsellor has been accredited with BICA since 2009 and is a member of the BICA

executive board (T14).

Counselling is offered to all patients at the centre with an uptake of 31%. The service has been audited and a break down of the types of counselling offered was provided during the inspection. Counselling information is displayed in the patient waiting area and various standard operating procedures provided by the PR included the requirement to offer counselling as required by schedule 3 of the HFE Act 1990 (as amended).

The centre provided several patient specific standard operating procedures including implications for surrogacy for surrogates and intended parents and implications for donation of gametes and embryos including egg share in compliance with T33(b). These were noted to be thorough, document controlled and up to date with respect to the new HFEA parenthood legislation.

The counsellor obtains patient feedback as an indicator of the quality of the service and provided evidence of analysis of the results in compliance withT35. She reported that she is currently working with BICA on a project to develop nationally applicable quality indicators for counselling.

Confidentiality and privacy (guidance note 30):
A tour of the centre satisfied the inspection team that treatment is provided to patients and donors in premises that provide for their privacy, dignity and comfort. This included the men's production room, the counselling room and procedure rooms.

Patient records are stored securely within cabinets that are locked after hours in an office that is locked when no staff are present.

The self assessment questionnaire confirmed that the centre has a standard operating procedure in place that covers all aspects of data control, traceability and confidentiality as required by T44.

What they could do better.

Confidentiality and privacy (guidance note 30):
Analysis of the centre's incident log revealed eight internally reported breaches of patient confidentiality between 14 January 2010 and 13 May 2010. While these varied in mechanism and severity and included near misses, this trend may suggest that review of these incidents and resultant plans to minimise risk of recurrence had not been effective.

The PR should review these incidents including analysis and remedial actions in order to devise a plan to minimise the risk of recurrence and protect the confidentiality of all patients and donors at the centre as required by S33 of the HFE Act 1990 (as amended). An update regarding progress with this plan should be provided before the Executive Licensing Panel on 12 August 2010.

► Give prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions (Principle 5).

What the centre does well:

Information to be provided prior to consent (guidance note 4):
The centre submitted all patient information leaflets prior to the inspection. These were

audited and found to be compliant with the requirements of the appropriate licence conditions.

During the tour of the centre it was noted that the HFEA licence was on display (T5) and information regarding counselling, complaints and support groups was readily available.

The PR reported that each patient or donor undergoes a “consent consultation” and the process guiding this was seen to be included in various treatment specific and consent standard operating procedures. An information checklist is used by staff to ensure that all appropriate information is provided in compliance with schedule three of the HFE Act 1990 (as amended).

Costed treatment plans
The centre provides information to patients regarding the cost of their treatment before it commences. This includes a comprehensive price list and algorithms that guide patients through the potential costs of various treatment options (G4.3).

What they could do better.

► Ensure that patients and donors have provided all relevant consents before carrying out any licensed activity (Principle 6).

What the centre does well:

Consent to treatment, storage, donation and disclosure of information (guidance note 5):
The centre has a standard operating procedure to guide staff through the consent process and individual requirements of specific treatment options were seen to be built into treatment specific standard operating procedures in compliance with T33 and T57.

Evidence was seen during the inspection of audits of donor consents. To confirm evidence that appropriate consent was obtained for treatment, use, storage, and donation of gametes, 5 randomly selected patient files were reviewed. Appropriate treatment, storage, use and donation consents were found on all files reviewed. This included disclosure of information to researchers. (Schedule 3 of the HFE Act 1990 (as amended)).

The centre currently has written effective consent for the storage of all cryopreserved samples as required by schedule three of the HFE Act 1990 as amended.

Legal parenthood (guidance note 6):
The PR confirmed that all staff has received training in the new parenthood provisions. No areas of concern were raised by the SAQ and no audit of parenthood consent was carried during this inspection.

What they could do better.

Live Birth Rates

Relative success rates HFEA held register data 01January 2006 to 31 December 2009 show that the Centres success rates are in line with national averages.
Evidence of how the centre improves its live birth rates and reduces the number of multiple births: **Multiple births (guidance note 7):** The centre has a multiple birth minimisation strategy that has been submitted to the HFEA and its content found to be compliant with Direction 0003. HFEA data for the period 01 February 2009 to 01 February 2010 identifies a multiple birth rate of the centre of 19%. The PR reported that the centre currently has a 30-40% uptake for elective single embryo transfer and documented evidence in patient records was provided of the centre's attempts to enforce the elective single embryo policy. Several members of centre staff attended the HFEA eSET workshop on March 2010. A log of instances where eligible patients have not opted for a single embryo transfer as required by Direction 0003 was seen at inspection. Information provided by the PR post inspection suggests a multiple birth rate of 25%.
What the centre could better.

3. Protection of embryos

Focus

- **Safe procurement, processing, storage, application and disposal of gametes and embryos** – gametes and embryos must only be procured, processed, used, stored and disposed off in accordance with the law.
- **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:

  - Cryostore facilities
  - Witnessing

▶ Have respect for the special status of the embryo when conducting licensed activities (Principle 3).
What the centre does well: **Procuring, processing and transporting gametes and embryos (guidance note 15):** The centre has several standard operating procedures guiding critical procurement, processing and transport procedures including processing an egg sharing donor, shipping of gametes between GCRM and another licensed centre and the IVF/ICSI agonist protocol in compliance with T33b. Laboratory key performance indicators were provided in the form of ICSI success rates, fertilisation rates and egg yield rates. A programme of audit of key performance indicators was observed that involves the generation of indicators every six months monitored against monthly audit in compliance with T35. Key aspects of procurement and processing procedures are included in the audit programme through the measurement, analysis and improvement, monitoring and measuring and analysis of data audits as required by T36. Five sets of patient records were audited during the inspection which confirmed that the justification for the use of their gametes or embryos was documented in each case. (T49) **Storage of gametes and embryos (guidance note 17):** The centre is licensed to store sperm, eggs and embryos. During the inspection it was confirmed that all dewers are alarmed and secure as required by T24. An effective bring forward system was observed and the most recent stored sample audit found no discrepancies.
What they could do better: **Procuring, processing and transporting gametes and embryos (guidance note 15):** While all other aspects of the centre's transport and distribution of gametes and embryos procedures were identified as compliant in the self assessment questionnaire, they do not have a documented recall procedure as required by schedule 3A(11) of the HFE Act 1990 (as amended).

The PR should ensure that an effective, documented recall procedure is developed that includes a description of the responsibilities and actions to be taken by the involved parties.

► Ensure that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose (Principle 8).

What the centre does well:

Imports and exports (guidance note 16):
From 01 October 2009 the centre has imported 57 samples (ampoules or straws) and five embryos. There is a third party agreement in place with Nordic Cryostore, who supplied all but one of the samples. The PR confirmed that each sample is received with the appropriate documentation to satisfy him that the requirements of HFEA direction 0006 have been met.

Traceability (guidance note 19):
The self assessment questionnaire submitted prior to the inspection confirmed that all gametes and embryos are traceable from procurement to treatment or disposal as required by T99.

The centre has a traceability standard operating procedure as required by T87 and the effectiveness of the system is monitored using quality indicators (T35).

ICSI (guidance note 21):
The self assessment questionnaire states that the centre has an ICSI standard operating procedure (T33(b)), that the procedure has been validated (T72) and quality indicators exist that monitor ICSI performance through survival, development to two pronucleate and cleavage rates (T35).

Evidence that all relevant staff had received ICSI training was provided in compliance with T15(a).

Premises and facilities (guidance note 25):
Information provided by the PR and centre staff and a tour of the centre confirmed that licensed activities take place on premises that are fit for their intended purpose. The centre operates from a principal location in Glasgow with satellite facilities in Edinburgh.

Evidence was provided that the critical working areas at the centre are compliant with the air quality requirements of T20. The most recent test results were from May 2010.

Equipment and materials (guidance note 26):
The self assessment questionnaire states that the centre has documented procedures for the operation of all critical equipment that outlines actions to be taken in the event of malfunction or failure as required by T27.

The self assessment questionnaire states that all critical procurement and processing procedures at the centre are validated. This was confirmed with observation of the centre's validation folder and relevant standard operating procedures were sampled. (Schedule 3A (11) of the HFE Act 1990 (as amended). Evidence was provided that several pieces of equipment had been repaired and recalibrated in compliance with T25.

The centre maintains a frequent monitoring system (FMS) that covers all required equipment monitoring and alarms including dewers, refrigerators, incubators and emergency alarms satisfying the requirements of T24.
What they could do better: **Witnessing (guidance note 18):** During the inspection it was observed that only one step for the movement of oocytes during ICSI preparation was witnessed despite the movement occurring in two steps. The PR should review witnessing practice to ensure that all critical points of the clinical and laboratory processes are witnessed as required by T71. Currently the disposal of sperm is not witnessed at the centre. The PR should consider reviewing current procedures to include the witnessing of sample disposal as recommended by G18.4(j). **Traceability (guidance note 19):** While a standard operating procedure was submitted that covered the traceability of consumables and reagents (T99), this does not include the traceability of equipment, for example incubators or operators. The PR should ensure the development of a traceability standard operating procedure that covers all steps in the treatment process from procurement to treatment or disposal, including equipment and operators to fulfil the requirements of T100(f) and T99.

4. Good governance and record keeping

Focus

- **Where gametes or embryos are used complete and accurate information should be recorded and reported to the HFEA in a timely manner** – incomplete and / or inaccurate information may lead to the wrong information being provided to offspring and / or researchers
- **Ensuring gametes and embryos are only stored in accordance with effective consent and within the statutory timeframe**
- **Ensuring identifying information is only disclosed in accordance with consent**
- **Inspection theme 2010 - 2012** – for this period, this should include the following:
  - Patient consent to the disclosure of information, held on the HFEA register, for use in research
  - Consent issues in relation to the storage of embryos (including cooling off period)

- **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.

  - There were no specific areas of concern raised by the SAQ or previous inspection report in this area.

▶ Maintain accurate records and information about all licensed activities (Principle 10)
What the centre does well: **Record keeping and document control (guidance note 31):** All patient records sampled during the inspection were seen to be well organised in good order and completed to a high standard. • The inspection team sampled 138 IVF and 39 DI treatments from the period 01/04/09 to 31/03/10. These were drawn from reports produced directly from the Centre's Acubase system. Two (1%) of the 138 IVF treatments in the audit sample were found to be unreported at the audit date. All 39 DI treatments in the audit sample had been reported.
What they could do better: **Record keeping and document control (guidance note 31):** While all sampled documents at the centre were seen to be document controlled in compliance with T34, in most cases the review date appeared to be up to every three years. The PR should consider implementing a document control procedure that requires annual review of all centre documents annually as recommended by G31.6. • Of the 175 cycles in the audit sample that had been reported to the HFEA during

the period 01/04/09 to 31/03/10, 41 (23%) were reported to the HFEA within five working days of the treatment and thus 134 (77%) of the treatments had been reported late (i.e. outside the period stipulated in applicable Directions during the period (Direction 0005 para.3; and D2008/06 para.5).

- Analysis of the timeliness of reporting treatments in the audit sample by treatment type identified a significant variance in the proportion treatments reported within five working days (i.e. 15% or IVF and 54% of DI treatments).
- The PR should review and revise the process undertaken to submit treatment data to the HFEA to ensure compliance with Direction 0005.

Conduct all licensed activities with regard for the regulatory framework governing treatment and research involving gametes or embryos within the UK, including: maintaining up-to-date awareness and understanding of legal obligations responding promptly to requests for information and documents from the HFEA, co-operating fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare (Principle 13).

What the centre does well:

The centre provided all the information as required by the application process prior to inspection. All members of staff were open and cooperative and any additional information required was provided without difficulty.

What they could do better.

5. Changes / improvements since the last inspection on 20 May 2009

Breach from previous inspection 20.05.09	Action required	Time scale	Changes notes at inspection 25.05.10
Incident management The centre's internal incident log included several incidents that had not been reported to the HFEA.	The PR should ensure notification to the HFEA, of adverse incidents and the subsequent provision of a confirmation/conclusion report. Centres must report all adverse incidents to the HFEA by telephone within 12 working hours of the identification of the adverse incident and submit an adverse incident report form within 24 working hours in compliance with A.4.3 and S.9.4.2.	With immediate effect	The Centre's incident log was matched against centre records during the inspection. It was found that while all serious adverse incidents had been reported to the HFEA in compliance with T120, several less serious incidents and near misses had not been reported as recommended by G27.5.
Complaints management The centre's internal complaints log included three complaints that appeared to have remained "open" for an extended period of time without resolution.	In order to demonstrate compliance with CoP S.9.2.2 the PR should revise the centre's procedures to include a clear process for resolution of outstanding complaints.	20 August 2009	Post inspection the PR confirmed that the centre's standard operating procedure has been updated and that all complaints are now resolved within a timeframe specified in the standard operating procedure. This was verified during the inspection and a robust complaints procedure found to be in place.
Payment of fees The centre is taking an average 33 days to pay HFEA invoices. **Please see Appendix C below. Discussion with the HFEA**	The PR should review whether there are any barriers to the prompt payment of HFEA fees and take steps to ensure they are paid within 28 days in compliance with standard	With immediate effect	The centre is now taking on average 32 days to pay fees. It remains the case that the PR should review whether there

Finance department confirmed that this centre is largely compliant in this area. There were two outstanding invoices (one likely to have been lost in post) that dramatically skewed the average payment time.	licence condition A.16.3.		are any barriers to the prompt payment of HFEA fees and take steps to ensure they are paid within 28 days in compliance with standard licence condition T9(d).
Cryostore Facilities During inspection of cryo-storage facilities it was noted that one new dewer (no. 5) which is dedicated to quarantine samples had not been connected to the FMS alarm system.	The PR should alarm this dewer in order that it is covered by the same level of security as other stored samples in compliance with A.10.13.	20 August 2009	During the inspection it was confirmed that this dewer is now fitted with an alarm.
Staff competencies Staff training and competency assessments are not being adequately reviewed or documented. Staff training folders across all disciplines provided at inspection contained no evidence of initial or reviewed competency assessment and sign off of critical skills. **This was also a recommendation in the report of the previous inspection of 10 May 2007.**	To ensure and provide evidence that the centre is compliant with CoP S.6.2.9 it is recommend that the competence of all staff is reviewed and assessments are performed and documented at intervals specified by the quality management manual.	20 August 2009	Post inspection in 2009 the PR confirmed that a staff competence SOP had been established. During the renewal inspection it was confirmed that while a comprehensive programme for assessment of staff competence has been developed not all staff have been assessed and not all key competencies for laboratory and nursing staff are included.
Laboratory Practice The centre does not participate in inter-centre comparisons.	The centre should participate in inter-centre comparisons (e.g. external quality assessment schemes). The results of	To be reviewed at the time of the next inspection	The centre now takes part in National External Quality Assessment Scheme.

	these comparisons should be evaluated and documented and relevant findings used to improve the service in compliance with CoP S.9.2.6.		

Non compliance from previous inspection 20.05.09	Action required	Time scale	Changes noted at inspection 25.05.10
Witnessing On review of the centre's documented witnessing policy it was found that procedures for witnessing embryo movement during culture/extended culture were not included in the written procedure.	The PR should ensure that the centre's documented witnessing policy is reviewed in consideration of G.13.1.	20 August 2009	The PR reported post inspection in 2009 that this standard operating procedure had been updated and this was confirmed during the renewal inspection. However, at the time of the inspection a number of non compliances with guidance (now at 18.4) were noted.
Laboratory Practice The standard operating procedure for "Shipping of Gametes or Embryos" between GCRM and another licensed centre" is not fully compliant with Alert 21. Aspects including requirements for the labelling of samples. This was discussed and amendment agreed with the laboratory director on the day of inspection.	The PR should review and amend of the centre's documented 'Shipping of gametes/embryos between centres' policy in order to ensure full compliance with requirements of Alert 21.	20 August 2009	The PR reported post inspection in 2009 that this standard operating procedure had been updated and this was confirmed during the renewal inspection.

Assessment of compliance with statutory requirements

This page summaries the assessment of the extent to which the centre has complied with the Act, licence conditions and Directions.

Fully Compliant = the centre has met the statutory requirement
Not compliant = the centre has not met the statutory requirement

"X" in the assessment box denotes that compliance with the Licence Condition was not assessed during this inspection
"N/A" in the assessment box denotes that compliance with the Licence Condition is not applicable to this centre

Licence Condition	Assessment
Licensing	
T1	Compliant
T2	Compliant
T3	Compliant
T4	Compliant
T5	Compliant
T6	Compliant
T7	Compliant
Person Responsible	
T8	Compliant
T9	Compliant
T10	Compliant
Personnel	
T11	Compliant
T12	Compliant
T13	Compliant
T14	Compliant
T15	Not compliant
T16	Compliant
Facilities / Premises	
T17	Compliant
T18	Compliant
T19	Compliant
T20	Compliant
T21	Compliant

Licence Condition	Assessment
Equipment and Materials	
T22	Compliant
T23	Compliant
T24	Compliant
T25	Compliant
T26	Compliant
T27	Compliant
T28	Compliant
T29	Compliant
T30	Compliant
T31	Compliant
Quality Management	
T32	Compliant
T33	Compliant
T34	Compliant
T35	Compliant
T36	Compliant
Records and Information	
T37	Compliant
T38	Compliant
T39	Compliant
T40	Compliant
T41	Compliant
T42	Compliant
Data protection and Confidentiality	
T43	Compliant
T44	Compliant
T45	Compliant
Patient Records	
T46	Compliant
T47	Compliant
T48	Compliant
Patient Selection Criteria and Laboratory Tests	
T49	Compliant
T50	Compliant
T51	Compliant
Donor Selection Criteria and Laboratory Tests	
T52	Compliant
T53	Compliant
T54	Compliant
T55	NA

Licence Condition	Assessment
Welfare of the Child, Provision of Information, Counselling and Consent	
T56	Compliant
T57	Compliant
T58	Compliant
T59	Compliant
T60	Compliant
T61	Compliant
T62	Compliant
T63	Compliant
T64	Compliant
T65	Compliant
Procurement of Gametes and Embryos	
T66	Compliant
T67	Compliant
T68	Compliant
T69	Compliant
T70	Compliant
Processing and Use of Gametes and Embryos	
T71	Compliant
T72	Compliant
T73	Compliant
T74	Compliant
Storage of Gametes and Embryos	
T76	Compliant
T77	Compliant
T78	Compliant
T79	Compliant
T80	Compliant
T81	Compliant
T82	Compliant
T83	Compliant
T84	Compliant
T85	Compliant
Embryo Testing	
T86	NA
T87	NA
T88	NA
T89	NA
T90	NA
T91	NA

Licence Condition	Assessment
Use of Embryos in Training Staff	
T92	NA
T93	NA
T94	NA
T96	NA
T97	NA
T98	NA
Traceability and Coding	
T99	Not compliant
T100	Not complaint
T101	Compliant
T102	Compliant
T103	Compliant
T104	Compliant
Import, Export and Transportation / Distribution of Gametes and Embryos	
T105	Compliant
T106	Compliant
T107	Compliant
T108	Compliant
Receipt of Gametes and / or Embryos	
T109	Compliant
T110	Compliant
Third Party Agreements	
T111	Compliant
T112	Compliant
T113	Compliant
T114	Compliant
T115	Compliant
T116	Compliant
T117	Compliant
Identification, investigation, reporting, recording and notification of serious adverse events and reactions	
T118	Compliant
T119	Compliant
T120	Compliant
T121	Compliant
T122	Compliant

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 required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical area of non compliance is an area of practice which poses a significant 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	Reference	Action required	Timescale for action	PR Response	Executive Review
None					

Major area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor 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	Action required	Timescale for action	PR Response	Executive Review
Person Responsible (guidance note 1): The centre is now taking on average 32 days to pay fees.	The PR should review whether there are any barriers to the prompt payment of HFEA fees and take steps to ensure they are paid within 28 days in compliance with standard licence condition T9(d).	By 25 August 2010	Our analysis for the stated period (a 100% audit) disagrees with the figure provided. We suspect that the discrepancy may lie in delays within the HFEA office. Please see the attached review of payments with comments.	The centre's analysis of invoice payment times suggests an average 25.1 days (see attached summary in supporting documents). This has been forwarded to the HFEA finance department who will liaise directly with the centre to resolve the discrepancy.
Witnessing (guidance note 18): During the inspection it was observed that only one step for the movement of oocytes during ICSI preparation was witnessed despite the movement occurring in two steps. Currently the disposal of sperm is not witnessed at the centre.	The PR should review witnessing practice to ensure that all critical points of the clinical and laboratory processes are witnessed as required by T71 and G18.4(j).	Before Executive Licensing Panel on 15 August 2010.	The standard practice and forms have been modified in accordance with these corrections. See attached lab practice form for both (FRM-Lab055)	The Executive is satisfied with this response.

Staff (guidance note 2): During the inspection it was confirmed that while a comprehensive programme for assessment of staff competence has been developed it has not been completed by all staff and does not include all key competencies for laboratory and nursing staff.	The PR should ensure that all staff competence assessments are completed and include assessment of staff knowledge and understanding of all of the key scientific and technical processes and principals relevant to their designated tasks as required by T15.	To be completed by next inspection. The PR should provide a detailed plan including timelines for the resolution of this non compliance before Executive Licensing Panel on 12 August 2010.	We have been working to establish the staff competency packs. They are now comprehensively in place, and include detailed assessment of knowledge (please see attached page 33 of 51 of embryologist pack). These are aimed to require a full year to establish a complete record. Sections 1 & 2 have been completed within the designated time-scales. Section 3 is being worked through currently.	The Executive is satisfied with this response.
Confidentiality and privacy (guidance note 30): Analysis of the centre's incident log revealed eight internally reported breaches of patient confidentiality between 14 January 2010 and 13 May 2010. While these varied in mechanism and severity and included near misses, this trend	The PR should review these incidents including analysis and remedial actions in order to devise a plan to minimise the risk of recurrence and protect the confidentiality of all patients and donors	Ongoing. The PR should provide a detailed plan including an audit of practice and timelines for the resolution of this non compliance before the Executive Licensing Panel on	See attached Document 'Incident Log: Confidentiality Issues' Those incidents not reported to the HFEA were deemed to not constitute any 'risk' to patients, but constitute areas where staff training could be highlighted and potential risks discussed. They include mainly information to GPs who are bound by professional confidentiality standards.	The Executive recommends a commitment from the PR that all adverse incidents will be reported to the HFEA.

may suggest that review of these incidents and resultant plans to minimise risk of recurrence had not been effective.	at the centre as required by S33 of the HFE Act 1990 (as amended).	12 August 2010.	SOP- Admin071 (attached) Email correspondence from GCRM has been written to address three of the incidents. The variety of the origin of the incidents indicates less a failure to address to the training, more the broad spectrum of areas where mistakes can be made. <u>Extracted from our response to the report</u> The Audit of confidentiality breaches has been completed (attached). In fact it had been audited prior to the inspection, and it had also been addressed on numerous occasions during the disciplinary issues of an individual member of staff. As advised at the inspection, in response to the series of confidentiality issues, a member of staff was dismissed (end of 2009). The report states that, between 14th Jan 2010 and 13th May, there were 8 confidentiality breaches, of various derivations. Three of the 8 were correspondence to the wrong GP, due to problems within the database software. We have	

			approached the software controllers and hopefully they will not recur. Three of the remaining events were email correspondence – with no personal details involved. Of the remaining 2, one was outwith our control as it had been opened by the Post Office- inappropriately. The other was correspondence with the correct GP, but discussing subjects which the patient had requested to be omitted. Our practice has been revised accordingly <u>The Plan</u> 1. Weekly Admin meetings have commenced to ensure continual training on matters such as process and confidentiality. These meetings also give staff an opportunity to discuss any issues. 2. Extra Admin staff have been taken on to reduce burden. 3. SOP-071 as above to address email correspondence. 4. Staff training day scheduled for July 6th	

Procuring, processing and transporting gametes and embryos (guidance note 15): While all other aspects of the centre's transport and distribution of gametes and embryos procedures were identified as compliant in the self assessment questionnaire, they do not have a documented recall procedure as required by schedule 3A(11) of the HFE Act 1990 (as amended).	The PR should ensure that an effective, documented recall procedure is developed that includes a description of the responsibilities and actions to be taken by the involved parties.	By 25 August 2010	SOP lab045 has been amended to include the demands of the documented recall procedure as advised. Please see attached.	The Executive is satisfied with this response.
Traceability (guidance note 19): While a standard operating procedure was submitted that covered the traceability of consumables (T87), this does not include the traceability of equipment, for example incubators or operators.	The PR should ensure the development of a traceability standard operating procedure that covers all steps in the treatment process from procurement to treatment or disposal, including equipment and	By 25 August 2010	The SOP Lab 046 and the basic laboratory form (Lab FRM055, attached) have been amended.	The Executive is satisfied with this response.

Record keeping and document control (guidance note 31): • Of the 175 cycles in the sample audited during the inspection, that had been reported to the HFEA during the period 01/04/09 to 31/03/10, 41 (23%) were reported to the HFEA within five working days of the treatment and thus 134 (77%) of the treatments had been reported late (i.e. outside the period stipulated in applicable Directions during the period	operators to fulfil the requirements of T99 and T100(f). • • • • The PR should review and revise the process undertaken to submit treatment data to the HFEA to ensure compliance with Direction 0005.	The PR should provide a detailed plan including timelines for the resolution of this non compliance before Executive Licensing Panel on 12 August 2010.	All sampled documents were compliant with the one year schedule, because more than 90% of all documents have been reviewed within that time. The reasons for the absence of annual review in the occasional document, lay in the indecision with regard to archiving, which is the PR's responsibility. The quality manual SOP has been amended to address the need for annual review (attached). The policy document required no amendment. <u>Timeliness of reporting</u> This has been addressed in response to the audit undertaken at the time of the inspection. Effectively we have taken on two new members of staff to resolve this issue. The first is an embryologist who was needed to cover the increased workload that had	The Executive is satisfied with this response.

(Direction 0005 para.3; and D2008/06 para.5). • Analysis of the timeliness of reporting treatments in the audit sample by treatment type identified a significant variance in the proportion treatments reported within five working days (i.e. 15% or IVF and 54% of DI treatments).			caused the delayed data recording in the first place. The second is a clinical administrator whose primary function is to complete the necessary data points prior to reporting. Both are in place	

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	Action required	Timescale for action	PR Response	Executive Review
Adverse incidents				

(guidance note 27): The Centre's incident log was matched against centre records during the inspection. It was found that while all serious adverse incidents had been reported to the HFEA in compliance with T120 several less serious incidents and near misses had not been reported as recommended by G27.5.	The PR should consider review of the centre's incident reporting standard operating procedure to include notification to the HFEA of less serious incidents and near misses as recommended by G27.5.	Recommendation only.	Addressed in the response above.	
Record keeping and document control (guidance note 31): While all sampled documents at the centre were seen to be document controlled in compliance with T34, in most cases the review date appeared to be up to every three years.	The PR should consider implementing a document control procedure that requires annual review of all centre documents annually as recommended by G31.6.	Recommendation only.	The quality manual SOP has been amended to address the need for annual review (attached). The policy document required no amendment.	The Executive is satisfied with this response.

Additional information from the Person Responsible
Please see attached supporting documents provided by the PR. Agreed factual inaccuracies have been amended within the body of the report.

HFEA Executive Licence Panel Meeting

12 August 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 1

Centre 0250 (Glasgow Centre for Reproduction Medicine) - Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy and Information (Chair) Mark Bennett, Director of Finance & Facilities Danielle Hamm, Policy Manager	Terence Dourado

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

The following papers were considered by the Panel:

- Cover page
- Inspection Report
- Application for Renewal of Licence
- Previous Minutes including variations:
  - 27 May 2010, variation to permit use of embryos created with non quarantined sperm in treatment involving surrogacy.
  - 17 September 2009, variation to permit use of embryos created with non quarantined sperm in treatment involving surrogacy
  - 30 September 2009, interim
  - 26 July 2007, renewal

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 Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that the Licence Committee had granted the Centre a treatment and storage licence on 1 November 2006. The Centre, purpose-built for IVF, had conducted around 730 treatment cycles between 1 February 2009 and 1 February 2010.

2. The Panel had regard to its Decision Tree. It was satisfied that the application was submitted in the form required and contained the supporting information required by General Direction 0008. It was also satisfied that the appropriate fee had been paid.

3. The Panel was satisfied that the application designated an individual to act as the Person Responsible (PR) and that the PR had consented to act as such.

4. The Panel was satisfied that the PR possesses the formal qualifications required as a Professor of Reproductive Medicine. Furthermore, the Panel was satisfied that the PR had at least two years practical experience directly relevant to the licensed activity because he has thirty years experience of working in reproductive medicine.

5. The Panel was satisfied that the character of the PR is such as is required for supervision of the licensed activities and that the PR will discharge the duties under section 17 of the Act.

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

7. The Panel was satisfied that the premises to be licensed are suitable for the conduct of licensed activities there based on the evidence provided within the Inspection Report.

8. The Panel was satisfied that the application does not involve the use of embryos for training purposes, nor does it involve the testing of embryos. However, it noted that the Centre does intend to provide PGD services in the future. The PR confirmed that he will liaise with the HFEA and submit

an application to vary the Centre's licence in respect of this when it is appropriate to do so.

9. The Panel considered the areas of concern and recommendations made in the report, and the PR response to them, and noted that none were critical and all had been or were being addressed.

10. The Panel noted its concern over the number of patient confidentiality breaches recorded within a relatively brief time period. The Panel firmly supported the recommendation that the PR should devise a robust plan of to protect the confidentiality of patients as required by S33 of the HFE Act 1990 (as amended). However, it noted that the PR had since developed a plan of action to address this.

11. Also, the Panel welcomed the PR's response to the recommendation about the timeliness of submitting treatment data to the HFEA, stating that effectively two members of staff were taken on to address this. The Panel suggested that these staff might also address the submission of information regarding the Centre's egg sharing programme.

Decision

12. The Panel had regard to the 'Guidance on Periods for which New or Renewed Licences should be Granted'. The Panel took into account evidence of the matters set out in paragraph 4.3 and noted paragraph 4.4 of the guidance which states the '[Executive Licensing Panel] will normally only grant a renewal licence for treatment/ storage/ non-medical fertility services licence for a period of up to four years where the evidence before it reveals no concerns in the matters specified in paragraph 4.3 above'.

13. As it was satisfied that the evidence before it revealed no concerns regarding the requirements set out in paragraph 4.3, the Panel agreed to renew the Centre's treatment and storage licence for a period of four years with no additional conditions placed upon it.

14. The Panel endorsed the Inspector's recommendations and noted that the PR had already made progress to resolve the issues raised. The Panel urged the PR to continue this effort, especially on confidentiality and timely data submission.

Signed: Date: 13/8/10

Peter Thompson (Chair)