Interim Inspection Report

Date of Inspection: 16 June 2010
Length of inspection: 8.5 hours
Inspectors: Andy Leonard; Paula Nolan

Inspection details:
This report covers the pre-inspection analysis, the visit and information received from the centre between 17 June 2009 and 16 June 2010.

Date of Executive Licensing Panel: 10 September 2010

Purpose of the Inspection report
The purpose of the inspection is to assess a centre's compliance with the HF&E Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice, 8th edition (CoP) to ensure that centres are providing a quality service for patients. The report summarises the findings of the 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	Birmingham Women's Hospital Assisted Conception Unit
Centre Number	0119
Centre Address	Assisted Conception Unit, Birmingham Women's Hospital, Edgbaston, Birmingham, B15 2TG
Telephone Number	0121 6272700
Person Responsible	Dr Sue Avery
Licence Holder	Mr Steve Peak
Licence Number	L0119/15/c
Date Licence issued	01/12/07
Date Licence expiry	30/11/2012
Additional conditions applied to this licence	None

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Recommendation to the Executive Licensing Panel

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

Improvement actions were originally recommended to correct eight major non-compliances and eleven other non-compliances

On 1 September 2010:
Five out of eight non-compliances had been corrected. Those outstanding concerned:

- The accuracy of data provided via the EDI system regarding consents to disclosure for registry research
- Competence re-assessment programmes (two non-compliances noted)

Six out of eleven other non-compliances had also been corrected. Those outstanding concerned:

- Donor recruiting and screening
- Document review
- Equipment traceability
- Third party agreements
- HPC registration of scientific staff

The PR has indicated in the report that plans are in place to implement all remaining recommendations within the required deadlines.

The inspectorate recommends that the Executive Licensing Panel requires that the PR ensures the implementation of the remaining recommendations within the prescribed timeframes.

Details of Inspection findings

Brief description of the centre and its licensing history:

The Assisted Conception Unit at the Birmingham Women's Hospital has been licensed by the HFEA since 1992. The unit has a good history of regulatory compliance and the current licence, last renewed on 1 December 2007 and active until 30 November 2012, has no additional conditions. The centre was last inspected on 17 July 2008.

Treatment is provided to patients funded by local primary care trusts as well as to self funding patients. The centre performs insemination, IVF and ICSI, PGD and PGS, egg, sperm and embryo storage, procurement and processing of patient and donor gametes, treatment with donor gametes and chemically assisted hatching. The centre has an egg sharing programme and recruits sperm donors. The centre is open 6 days a week, 08:00 to 17:00 Monday to Friday and 09:30 to 12:00 on Saturday. Egg collections are carried out on Monday, Wednesday and Friday; other procedures (e.g. IUI, DI and ET) are performed when required.

In the period 1 January 2007 – 31 December 2009, fresh IVF/ICSI, frozen embryo transfer (FET), and donor insemination (DI) live birth success rates at the centre, in patients aged <35, 35-37, 38-39, 40-42 and >42 years, were all in line with national averages.

There have been no significant changes in the centre in terms of activity, patient demographics or premises in the last year.

The Person Responsible (PR) is a consultant embryologist and has completed the HFEA PR Entry Programme

*Activities of the Centre in the year 1 March 2009 – 28 February 2010:

Type of treatment	Number of treatment cycles
IVF fresh	300
ICSI fresh	211
FET	148
DI	27
Egg share	11
Egg donation	3
Other licensable activities	**✓ or not applicable (N/A)**
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓
Research	✓ (R0173; R0184; R0186)

*These data were extracted from the HFEA register for the period indicated above. The data may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems

Updated actions since the centre was inspected, as of 1 September 2010:

The PR has already taken appropriate corrective actions in response to the report which show that the centre is now compliant with the following areas of practice:

- Assessment of witnessing practices against SOPs
- Establishment of QIs for witnessing
- Re-assessment of staff competences to perform manual and electronic witnessing
- Consistency of SOPs relating to sperm donation
- Donation SOPs and checklists
- Egg / sperm donor information
- Letter sent to GPs
- Accreditation of genetic testing laboratory
- Payment of HFEA fees

1. Focus of inspections for 2010-12

Witnessing

Evidence of how the centre demonstrates compliance with Guidance Note 18 of the CoP, including the requirement to double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process.

The centre uses an electronic witnessing system to identify sample containers against the patient record, at all critical points of the clinical and laboratory processes (Licence Condition T71). Manual witnessing is performed if the electronic witnessing system fails. All witnessing is carried out contemporaneously (Licence Condition T71).

The centre has documented standard operating procedures (SOPs) for manual and electronic witnessing. Elements of these SOPs (those used for witnessing sperm preparation) have recently been assessed for compliance with CoP guidance note 18 (Licence Condition T33b and T36). The electronic witnessing protocol includes manual witnessing in addition to electronic witnessing at three key steps, gamete collection, insemination of oocytes in vitro and embryo transfer.

Manually witnessed procedures are all timed, dated and signed by the processor and witness contemporaneously in the patient records. A summary of electronic witnessing steps is stored in patient records however the detailed witnessing records are stored on the centre server. This situation is compliant with CoP guidance note 18.7, however it is suggested that the electronic system's detailed witnessing report is printed out at the end of each treatment and stored in the patient records.

Staff were said by the PR to be trained and competency assessed to perform manual and electronic witnessing at induction. Existing staff were trained and competency assessed when the electronic witnessing system was fitted, and training is provided by the manufacturer when the system is upgraded (Licence Conditions T12 and T15a).

What the centre does well.

Elements of the witnessing practices (those used during sperm preparation) have been assessed for compliance with witnessing SOPs and CoP guidance note 18 (Licence Condition T33b and T36). This involved a detailed analysis of the sperm preparation pathway and the time-lags between different witnessing steps on the pathway. This provided a good example of using the data collected from technologically advanced equipment, i.e. the electronic witnessing system, to review and refine processes in a manner which could not previously be easily achieved.

What they could do better:

Elements of the witnessing practices (those used during sperm preparation) have been assessed for compliance with witnessing SOPs and CoP guidance note 18 (Licence Condition T33b and T36). The remainder of the witnessing practices must also be assessed against the SOPs and CoP guidance note 18, to comply with Licence Conditions T33b and T36.

Quality indicators (QIs) have not been established for witnessing, contrary to Licence Condition T35.

The competence of staff to perform manual and electronic witnessing is not re-assessed and documented at a specified frequency, contrary to Licence Conditions T12 and T15a. It is important that such re-assessment of competence is performed, because manual witnessing can then be used with confidence if the electronic system fails.

Parenthood

Evidence of how the centre demonstrates compliance with Guidance Note 6 of the Code of Practice in relation to legal parenthood:

The centre has established written procedures which ensure that: 1) Consent forms are completed for parenthood prior to treatment with donor gametes and embryos; 2) Patients are fully informed about parenthood laws prior to signing consent forms (Licence Condition T33b). The partner's consent (or absence of consent) for the patient's treatment with donor gametes is also recorded.

Procedures are also in place which ensured that: 1) Where a patient has withdrawn her consent to her nominated second parent being treated as the legal parent, or has more recently consented to a different person being the legal parent, that the original nominated second parent is notified in writing of the withdrawal of consent (Licence Condition T65). 2) Treatment is not provided when a person has withdrawn their consent to be the second parent of a child without telling the women being treated (Licence Condition T64b).

In compliance with Licence Condition T60, information regarding parenthood legislation is provided by nurses during consultation with patients using donor gametes. All patients in this group are advised of their right to withdraw parenthood consent. Nurses taking consents for legal parenthood have had training regarding the changes in the law in this area and which consent forms to use.

What the centre does well: No areas identified at this inspection

What they could do better: No issues identified at this inspection

Patient consent to the disclosure of information, held on the HFEA Register, for use in research
Evidence that the centre provides information to patients about the disclosure of identifying information, held on the HFEA Register, for use in research. (Guidance Note 5, section 5.26 of the Code of Practice) In discussion, centre staff demonstrated their awareness and understanding of the CoP requirements related to the consent for disclosure of information for use in research. The new HFEA consent forms which came into force on 1 October 2009 are used by nursing staff to consent all patients. These include the facility to consent to disclosure of information to researchers. The inspectorate considers consenting practices with respect to the disclosure of registry information to researchers were compliant.
What the centre does well: No areas identified at this inspection
What they could do better. An audit was performed on patient/partner consents for disclosure for registry research stored in the patient records against the consenting decision entered on the HFEA Register. The consents of seven patients or partners were audited, the consents being for generic consent, non-contact research and contact research. In three cases, discrepancies were noted between the consenting decisions in the patient records and those entered on the HFEA Register. In a further one case, no evidence was available in the patient record to justify the consent decisions entered on the HFEA Register. The PR should note that Direction 0005, paragraph 8, requires that 'when a PR is satisfied with the accuracy of the (EDI) data for their licensed centre, they must sign off this data', while Direction 0005, paragraph 9, requires that the PR must ensure before they sign off their data, that all registration forms relating to patients undergoing treatment have been filled in accurately. The inaccurate submission of information related to consent for disclosure for registry research, puts the PR at risk of non-compliance with Direction 0005. Moreover, it may produce a situation where information may be disclosed when appropriate consent to do so is not in place, thus breaching Schedule 3 to the HF&E Act (1990), as amended.

Information about the cost of treatment
Evidence of how the centre demonstrates that it has introduced personalised costed treatment plans for all patients (Guidance Note 4, section 4.3 of the Code of Practice) Both self funding and NHS funded patients are treated. Self funding patients are provided with a price list on which treatment costs are detailed. Their personal treatment plan and costs, including potential drug costs, are then discussed in a clinical consultation. The inspectorate considers the cost information provided to patients was clear and easily understood and the centre complies with CoP guidance in this area.
What the centre does well: No areas identified at this inspection
What they could do better. No issues identified at this inspection

Consent issues in relation to the storage of embryos (including cooling off period)

Evidence of how the centre demonstrates compliance with Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended) and Guidance Note 5 of the Code of Practice relating to the withdrawal of consent to storage of embryos intended for use in treatment:

The centre has revised its standard operating procedure (SOP) for embryo storage review and patient information to reflect the change in the initial embryo statutory storage period to 10 years (Licence Condition T33b). The consents for storage of gametes and embyos are taken by nurses as part of patient work-up. That consents are in place are checked by the embryologists when preparing a patient's laboratory sheets and also just before the freezing process is commenced. This ensures that storage consents are in place for all gametes and embryos when placed in storage, as required by Schedule 3 to the HF&E Act 1990 (as amended).

The centre operates a 'bring forward' gamete and embryo storage database (CoP guidance note 17.7) which is checked monthly for samples approaching expiry of consent within the next month, for disposal if further consent for storage is not obtained. The centre also sends an annual letter to patients with forms to withdraw storage consent if they so wish, or to sign for payment of another year's storage fee.

Gametes and embryos in storage have been audited against the storage records and storage consents in patient records within the last two years (CoP guidance note 17.16). This audit is done dewar by dewar on a rolling basis. The PR stated that effective consents are in place for all gametes and embryos in storage, as required by Schedule 3 to the HF&E Act (1990) as amended.

The centre has a SOP which documents the process to be followed when one gamete provider withdraws embryo storage consent (Licence Condition T64 and T65). It includes the provision for a one year 'cooling off' period' (in the event it falls within the consented storage period) and a letter to be sent to both partners regarding the withdrawal of consent and the 'cooling off period'. Patients are provided with information regarding the right to withdraw storage consent before such consents are signed.

What the centre does well: No areas identified at this inspection

What they could do better. No issues identified at this inspection

Multiple Births

Evidence of how the centre demonstrates compliance with Guidance Note 7 of the Code of Practice in relation to multiple births:

The centre has a multiple births minimisation strategy (MBMS) with elective single embryo transfer (eSET) criteria, which was submitted to the HFEA in compliance with Direction 0003. This MBMS has been developed with seven other fertility units in the West Midlands and is commonly applied and reviewed between these centres. Currently, eSET criteria are that the patient is in their first IVF/ICSI treatment cycle, is aged less than 37 years AND that one or more top grade embryos is available for transfer; OR that the patient has a history of multiple

Evidence of how the centre demonstrates compliance with Guidance Note 7 of the Code of Practice in relation to multiple births:

pregnancy (irrespective of age) or is at special risk if a multiple pregnancy developed.

The MBMS is discussed by clinicians and nurses with patients at the patient orientation evening meeting before treatment commences, at initial consultation, and at information provision consultations. Patients are provided with written information regarding the MBMS and the risks of multiple births. Patients are also advised verbally and in writing early in treatment that, because of those risks, if they fulfil the criteria for eSET clinicians at the centre will only perform a single embryo transfer. If patients are not prepared to accept this rigorous approach, they are advised regarding other fertility centres they may attend.

As required by Direction 0003, a log of eSET non-compliances is maintained, however it was said by the PR to contain no cases due to the approaches taken by the centre. The three embryo transfer log contains only one case in the last two years which was related to a frozen embryo transfer in a patient of more than 40 years of age.

Multiple birth rates are monitored quarterly at the centre and the MBMS is reviewed across the participating group of centres on a regular basis. A review of the MBMS in 2009, undertaken by the PR in March 2010, was provided to the inspectorate. It stated that 183 eSETs were performed in fresh IVF and ICSI cycles in 2009; i.e. 42% of all ETs were eSET. The pregnancy rate in eSET patients in 2009 was 51%, against an overall pregnancy rate of 36%. The overall multiple pregnancy rate in fresh IVF and ICSI cycles was 13%.

A key component of the MBMS is the use of blastocyst culture and transfer. In 2009, 67 eSET patients having fresh IVF or ICSI treatment had a single blastocyst transfer (i.e. 37% of eSET cases) at a pregnancy rate of 63%. 82% of all blastocyst transfers were in eSET patients.

The successful implementation of the MBMS and the multiple pregnancy rate of 13% for 2009, indicate the centre is actively implementing the requirements of Direction 0003 to minimise multiple births at the centre.

What the centre does well:
The frequent monitoring and audit of multiple births and review of the MBMS across a defined set of centres, allows more rapid data collection and effective refinement of the MBMS and its delivery. It is a good example of the effective inter-centre collaboration needed to develop and validate improved practices and processes in the fertility sector.

What they could do better. No issues identified at this inspection

Donation processes, screening, information provision and reimbursements

Evidence of how the centre demonstrates compliance with Guidance Notes 11, 12, 13 and 20 of the Code of Practice in relation to donations:

Donor recruitment, assessment and screening: Guidance Note 11

The centre recruits sperm donors and has egg donation and sharing programmes. The centre has SOPs for donor recruitment, screening and consent taking (Licence Condition T33b). The QM stated that the egg and sperm donor recruitment processes and associated SOPs are under review and that he aims to amalgamate the separate SOPs into a common egg and sperm donor recruitment pathway document.

The current donor SOPs are compliant with the requirements of Licence Condition T52 regarding the range of screening tests performed and the use of donor medical history for donor assessment. Screening tests are carried out by an external CPA accredited company (Licence Condition T53a).. A review of four sets of egg donor records confirmed that screening tests performed were compliant with those required by Licence Condition T52. It is stated in the sperm donation SOP that sperm providers are re-tested for HIV and hepatitis B and C, 6 months or more after their final donation, compliant with Licence Condition T53c

The centre monitors QIs for donor recruitment and selection (Licence Condition T35). QIs include the pregnancy rate for each donor and a retrospective audit of the screening tests stored in donor records. There are plans to introduce further QIs as part of the review of the recruitment processes.

Donor information and SOPs state that the recipient, on request, will be provided with appropriate anonymous information regarding the donor and any donor-conceived children. The information and SOPs also discuss the information about the donor which can be provided to donor–conceived offspring when they reach 16 years of age (anonymised information about the donor) then at 18 years of age (donor identifying information) (CoP guidance note 20.2d).

The QM demonstrated an electronic donor database which details the donor's progress through the donation process, as well as logging donor use and outcomes including the sex and date of birth of any donor-conceived offspring. The databases also highlight if the donor has placed restrictions on gamete use. The databases therefore allow the centre to enforce the 10 family limit and inform the donor, if requested appropriately, of the number of persons born as a result of the donation, the sex and the year of birth (HF&E Act 1990 (as amended) 31ZD (3)).

All sperm and egg donors must have counselling prior to donation and this is detailed in the donor recruitment SOPs (Licence Condition T58).

The centre has not provided donor embryos for some time. Embryos coming to the end of the consented storage period are perished or donated to research programmes at the centre.

Evidence of how the centre demonstrates compliance (Continued)

Egg sharing arrangements: Guidance Note 12
Patient information, discussion with nursing staff and review of egg sharer records indicated that egg providers in egg sharing arrangements are treated in the same way as other donors (CoP guidance note12.2). Eleven egg sharing cycles were completed at the centre in the year to 28 February 2010. The donor coordinator confirmed that treatment services are provided to the egg share donor in the course of the donation cycle (Direction 0001, section 6).

Payment of donors: Guidance Note 13
The egg and sperm donor coordinators in discussions on inspection had a clear understanding of Direction 0001 regarding the reimbursement of donors for lost pay and reasonable expenses. It was stated that few donors requested reimbursements. Reimbursements were justified on the basis of verbal statements from the donors regarding their hourly rate of pay; the Lead Scientist considered that photocopying wage slips may have privacy implications for the donor. Reimbursement for travel and other expenses requires tickets and receipts to be presented if possible; these are not however kept by the centre. All reimbursements are logged on a donor payment sheet, along with the rationale for the payments, and signed by the payee and the donor. These arrangements are compliant with Direction 0001.

Donor assisted conception: Guidance Note 20
Discussion with staff indicated that the recipients of donor gametes are advised verbally regarding the importance of informing any resulting child at an early age that the child results from the use of donated gametes (Licence Condition T63a). Possible ways to do this are discussed with the patients (Licence Condition T63b). The centre does not use gametes, or embryos created using gametes, from donors who are anonymous, unless for sibling use (Licence Condition T54).

What they could do better.

Donor recruitment, assessment and screening: Guidance Note 11
The donor SOPs and checklists are in the process of being reviewed by the centre. The current versions of these documents were considered by the inspectorate and the non-compliances listed below were noted. These should be addressed by the review.

The Lead Scientist stated that the practice at the centre is to select donors on the basis of the age limits stated in professional body guidelines (Human Fertility 11 (2008), 201 - 210), as required by guidance note 11.15 and compliant with the age limits stated in guidance note 11.2 and 11.3. This is supported by a review of donor records on inspection and by several discussions in the last year between the Lead Inspector and the Lead Scientist. It was noted however that the egg and sperm donor recruitment SOPs and checklists do not make clear that age is a criteria for egg and sperm donor selection, which leaves the centre at risk of non-compliance with Licence Condition T52a.

The egg and sperm donor screening SOPs and checklists were non-compliant with professional body guidelines and thus CoP guidance note11.15, in that they did not include a

What they could do better *(Continued)*

physical examination of the donor or an assessment of the risk of prion disease. It was stated by the Lead Scientist that egg donors have a physical examination as part of their preparation for treatment but that sperm donors are not physically examined at present.

In the sperm donation SOP, the screening tests listed at page 6 ('confidential screening checklist'), at page 2 ('Logistics Recruitment of Sperm Donors') and at page 3 ('Issues discussed in addition to separate information/counselling') are inconsistent with each other. This may cause confusion or the omission of some of the required screening tests.

It is stated in the egg donation SOP and checklist that patient identity is verified using photographic identity documents. It does not however state this in the sperm donor SOPs and checklist. This leaves the centre at risk of non-compliance with CoP guidance note 11.6.

The egg donor information on page 1 uses the term 'anonymous volunteer donors' when considering the different types of egg donor recruited. It later states that non-identifying donor information is accessible to children conceived using their gametes at 16 years of age, and identifying donor information is available when they are 18 years old. Thus it is clear, if the document is read and understood, that donors are not anonymous. Use of the term 'anonymous volunteer donors' may cause some donors confusion or, may give them the impression they can remain anonymous to donor-conceived offspring.

A letter is sent by the centre to the egg donor's General Practitioner (GP), if the donor so consents to disclosure. This letter advises the GP of the donor's proposed treatment and asks if there is any reason why the prospective donor should not be used. This is referenced to 'Section 4.5 of the HFEA CoP' but is not found in the HFEA CoP 8th edition. CoP guidance regarding contacting the GP for this purpose has changed somewhat and the PR should review the letter's content against the CoP 8th edition to bring it up to date.

Documented evidence of the assessment of staff competence in selecting and recruiting donors was not available, non-compliant with Licence Conditions T12 and T15a. Staff stated that the recently published Royal College of Nursing guidelines regarding fertility nurse competencies, are being used to develop a competency assessment framework for nursing staff at the centre. This will include an assessment regarding selecting and recruiting donors.

Payment of donors: Guidance Note 13

The egg donor information indicates that egg donors can be paid reasonable expenses and compensation for loss of earnings, up to a total of £250. It goes on to state 'Two separate payments of £125 will be made for expenses……..The 1st once initial screening is complete……the 2nd approximately 2 weeks after egg collection. Likewise the sperm donor SOP indicates a payment of 50% of expenses, i.e. £125, on the completion of the course of donation, with the payment of the balance of the expenses after the post-quarantine screen is completed. These arrangements, detailed in the egg donor information and sperm donor SOP are non-compliant with Direction 0001. They are also at odds with the compliant reimbursement practices which were discussed on inspection with the egg and sperm donor

What they could do better *(Continued)*

coordinators, as detailed in the evidence for compliance. This was discussed on inspection

and the QM accepted that the documents need to be reviewed to reflect the compliant donor reimbursement practices at the centre.

Validation of critical processes and equipment

Evidence of how the centre demonstrates compliance with Guidance Notes 15 and 26 of the Code of Practice in relation to validation:

A large folder was seen on inspection containing validation data and documents for all critical procurement and processing procedures. For example, validation documents for the sperm processing methods were provided. The centre is compliant with Licence Condition T72.

Validation documentation was also available for all critical equipment, as required by Licence Condition T24. This includes incubators, air flow cabinets, microscopes, ICSI rigs, heat blocks, centrifuges, the electronic witnessing system, freeze machines and cryostorage tanks.

It is documented in procedures that equipment sent for repair is revalidated on its return before being used in treatment (Licence Condition T25). This was evidenced as having occurred for a powered media syringe.

What the centre does well: No areas identified at this inspection

What they could do better. No issues identified at this inspection

Welfare of the child (in centres offering basic partner treatment services)

Evidence of how the centre demonstrates compliance with Guidance Note 8 of the Code of Practice in relation to welfare of the child assessment:

The centre offers a full range of treatment services therefore this theme is not relevant at this centre. The PR and nursing staff stated however that welfare of the child assessment is performed on all patients, including those attending for basic partner treatment services.

What the centre does well: N/A

What they could do better. N/A

Embryo testing

Evidence of how the centre demonstrates compliance with Guidance Notes 9 and 10 of the Code of Practice in relation to embryo testing:

The licence variation to approve PGS and PGD at the centre was approved in April 2010. At the time of the inspection, no patients had progressed through the PGS or PGD treatment pathways. The QM, who as the Lead Scientist coordinates the programme, advised the inspectorate however that five patient couples are 'in the system'.

Evidence of how the centre demonstrates compliance with Guidance Notes 9 and 10 of the Code of Practice in relation to embryo testing *(Continued):*

The centre has a documented procedure for embryo biopsy which the inspectorate considers adequately documents the process and contains witnessing at all required points in the process, as required by Licence Conditions T33b and T71. The embryo biopsy process has been previously validated, as required by Licence Condition T72. QIs, as required by Licence Condition T35, have been established for embryo biopsy, comprising embryo survival and blastomere integrity. Since no patients have yet to progress to embryo biopsy, no monitoring has yet been performed. Systems are though in place to do so when patients are treated.

The competence of staff performing embryo biopsy has been assessed and documented, as required by Licence Conditions T12 and T15a.

The centre has documented procedures for PGS and PGD which the inspectorate considers adequately document the processes required to collect and dispatch blastomeres to the testing laboratory, and to receive results. The protocols contain witnessing at all required points, as required by Licence Conditions T33b and T71. The QM confirmed that the PGS and PGD genetic testing methodologies have all been validated by the testing laboratory, as required by Licence Condition T72. PGS is being performed as part of a multi-centre trial, as recommended by the professional bodies.

QIs have been established for PGS and PGD, as required by Licence Condition T35. The SOPs for embryo biopsy, and other PGS and PGD processes, have also been recently reviewed against the regulatory requirements, as required by Licence Condition T36.

Staff participating in the PGS or PGD activities at the centre have all been competency assessed in those areas, as required by Licence Conditions T12 and T15a.

As there has not yet been any licensed treatment activity, the centre can confirm that they have not performed sex selection for social reasons (Licence Condition T88d) or transferred biopsied embryos in the same cycle as non-biopsied embryos (Licence Condition T88a).

The third party agreement between the centre and the testing laboratory is compliant with Licence Conditions T116, requiring the testing laboratory to meet the requirements of the relevant licence conditions and HFEA CoP Guidance. The testing laboratory's ability to do so were assessed by the QM as part of the licence variation application process in April 2010, compliant with Licence Condition T112.

What the centre does well: Nothing noted at inspection

What they could do better.

The testing laboratory provided the Executive in January 2010 with an action plan for gaining accreditation from an appropriate agency. The testing laboratory manager advised the Executive in June 2010 that the action plan has been implemented and the agency will soon be inspecting the laboratory. The testing service is though currently unaccredited, non-compliant with Licence Condition T21.

2. Changes/improvements since the previous inspection on 17 July 2008

Area of practice	PR's response in August 2008 (in italics) and subsequent observations on this inspection
1) The Centre should ensure that there is an organisation chart which clearly defines accountability and reporting relationships as required by COP Standard Licence Condition A.10.1.	*The chart has been corrected and submitted* A detailed, up-to-date and accurate organisational chart was provided at this inspection. This issue was considered by the inspectorate to be now compliant with HFEA requirements.
2) The complaints procedure should be reviewed, revised as required, dated and re-approved promptly by authorised personnel in compliance with the requirements of S.5.2.5 (a).	*The Trust now has an up to date, reviewed complaints policy (attached). However, the Trust is about to implement a new and substantially different procedure, for which the SOP is not yet available.* On inspection, the complaints procedure was provided to the inspectorate and it was seen to have been recently reviewed. The complaints policy was seen to be displayed in the patient waiting area which encourages patients to discuss any complaints with staff so they can be immediately addressed. This issue was considered by the inspectorate to be now compliant with HFEA requirements.
3) The PR should continue to ensure that documents are regularly reviewed, revised as required, dated and re-approved promptly by authorised personnel in compliance with S.5.2.5.	*The SOPs have been reviewed that were due or overdue, and the appropriate copies are confirmed as being on the document management system. The incoming consultant has agreed to review the clinical SOPs (in consultation with existing clinical staff), prior to her arrival.* The Quality Manager (QM) stated that the centre have recently implemented an electronic document control and quality management system, which will ensure compliance with Licence Condition T34. The QM is in the process of transferring documents from the old to the new system, and reviewing them for compliance with HFEA requirements at the same time. This has been delayed due to the QM's other commitments. Some documents have not therefore been reviewed in the last year, since they await transfer to the new system (e.g. the sperm donation SOP). The QM should progress as quickly as possible to review its documentation as it is transferred to the new document management system, to comply with the at least annual review required by CoP Guidance 31.6.

4) Centre management should continue to make progress in the establishment of documented agreements with third parties when an activity takes place which influences the quality and safety of gametes and embryos in compliance with the requirements of S.4.2.10.	*A third party agreement is with the Trust's procurement department awaiting signature – this covers all outstanding supplies/services.* The centre maintains a list of third party agreements, as required by Licence Condition T115. All have been reviewed within the last year. The PR considers that agreements are in place with all third parties who provide goods or services that influence the quality and safety of gametes and embryos, compliant with T111.These agreements were inspected and their content was considered compliant with the requirements for Licence Conditions T114 and T116. This area of practice was considered by the inspectorate to be now compliant with HFEA requirements.
5) The Person Responsible should review the arrangements for payment of invoices and ensure that there are no barriers to the prompt payment of invoices.	*This has been drawn to the attention of the Trust finance dept, and will be actively monitored by the PR.* The centre in the year to March 2010 took on average 57 days to pay HFEA invoices. The PR explained that all invoices are paid through a finance department which services all the Birmingham NHS Trusts. The PR has spoken recently with the directorate manager regarding the issue and hopes that pressure can be applied to more rapidly pay invoices.
6) It is recommended that the PR ensures that there are effective means for communicating information to staff and that records are kept of meetings and made available to all staff in compliance with COP S.6.2.13. This is considered especially important in relation to the communication of clinical decisions to the nurse led team.	*Records of laboratory meetings are now being kept. Nurses meetings have been scheduled and will be minuted. Nursing staff is back to full establishment. The minutes of all meetings are made available to all staff electronically and in paper copy. No clinical decisions are made at staff/operational meetings. There is a weekly patient meeting at which clinicians, nurses and embryologists are present, and all clinical decisions made here are recorded appropriately in the patient's records.* It was stated by the Laboratory Manager and Lead Nurse that all formal meetings are minuted. Minutes are distributed to relevant staff by email and paper copies are kept on file. Minutes of embryology and nursing staff meetings were provided in evidence and a file of minutes from the all staff meetings was observed in the staff common room. Minutes for the last quality management system review were also provided on request. This area of practice was considered by the inspectorate to be now compliant with HFEA requirements.

7) The Quality Policy should be signed and issued by a person with appropriate authority in line with the requirements of S.4.2.3.	*This has been signed and is displayed in the Unit.* The quality policy was signed by the PR and is on display in the patient waiting area. This issue was considered by the inspectorate to be now compliant with HFEA requirements.
8) The PR should ensure that where equipment or materials affect critical storage parameters they must be the subject of appropriate monitoring, alerts, alarms and corrective action, as required in compliance with S.6.4.2 (b). SOPs for the monitoring of alarms should be developed in line with the requirements of standard licence condition A.11.1 and the SOP should document the appropriate procedures to ensure the welfare of for lone workers in compliance with S.6.3.2.	*These SOPs are currently being drafted in collaboration with the medical physics department and will be submitted on completion.* The required SOP for monitoring the cryostore alarm system and responding to it was provided on inspection. It was reviewed and considered appropriate. This area of practice was considered by the inspectorate to be now compliant with HFEA requirements. .
9) The PR should ensure that personnel are provided with initial and update training, as required. The training programme must ensure and document that each individual has demonstrated competence in the performance of their designed tasks in compliance with standard licence condition A.10.11	*Records inspected were those of new staff who are participating in the Trust annual cycle of induction and health and safety training. This training is not yet completed, and signatures are present against all training that has been completed. Signatures were absent where training was not complete. The induction procedure will be reviewed to include more specific competencies for embryologists and other specific professional groups.* Discussions with staff and documents provided on inspection, indicate that induction, initial training and competency assessment procedures are now in place for all staff groups. Documented records were reviewed for an embryologist and a nurse and were found to be well organised, detailed and good evidence of compliance with Licence Condition T12. Plans for regular re-assessment of competence are in development, but are not yet in place. This non-compliance with Licence Conditions T12 and T15a is discussed below in Section 3, Area of Practice 4.
10) Donor screening	*Donor screening procedures are compliant. In the case cited*

procedures should be reviewed as a matter of urgency to ensure compliance with the relevant standards. Patient information and standard operating procedures should be reviewed to ensure they reflect practice.	*the result was available but had not been filed. All donor files have been audited and results are present in all files.* Issues related to donor screening are discussed in Section 1, Focus of Inspections, 2010-2012: Donation processes, screening, information provision and reimbursements.
11) It is recommended that a plan for validation is drawn up. The plan should take into account the particular needs of the unit and prioritise the validation of those processes considered to be most likely to impact on the quality of the service.	*Plans for validation were discussed. It is intended to use validation of the electronic witnessing system as a pilot, and this will be submitted when complete.* Issues related to validation of processes and equipment are discussed in Section 1, Focus of Inspections, 2010-2012: Validation of critical processes and equipment.
12) The PR should review and update the transportation procedure to ensure compliance with the requirements of Alert 21 and relevant aspects of S.7.7.	*Procedure being reviewed and will be submitted when complete (by 17th October 2008)* This procedure was reviewed and seen to be compliant with CoP requirements. This issue was considered by the inspectorate to be now compliant with HFEA requirements.
13) The content of third party agreements should be reviewed in consideration of the guidance.	*Working to compliance* As discussed in item 4 in this section, a sample of third party agreements was inspected and their content was considered compliant with the requirements of Licence Condition T114. This issue was considered by the inspectorate to be now compliant with HFEA requirements.
14) The PR should review the provision of clinical input in consideration of guidance note.1.2.1 of the COP which requires that the individual with overall clinical responsibility for treatment services involving IVF should be on the General Medical Council Specialist Register	*New Acc Consultant appointed who will review all clinical procedures* The new nominated medical practitioner was interviewed on inspection. She is a consultant gynaecologist and trained fertility specialist, listed on the GMC specialist register. This issue was considered by the inspectorate to be now compliant with HFEA requirements.

and have completed training recognised by the Royal College of Obstetricians and Gynaecologists.	
15) The PR should review the standard operating procedures for screening of prospective donors after consideration of the BFS guidelines. The PR should also ensure that staff are aware of screening requirements and that all relevant screening tests are carried out on prospective egg donors. Alternatively, the rationale for non compliance with the guidelines should be documented. If screening procedures are changed, patient information should be updated to include all of the screening tests carried out.	*Working to compliance* Issues related to donor screening are discussed in Section 1, Focus of Inspections, 2010-2012: Donation processes, screening, information provision and reimbursements.
16) The centre should maintain a separate record of the name, job title and signature of every person who carries out or is a witness to laboratory and clinical procedures. In compliance with G.13.2.2 and that an induction programme is in place for new staff to ensure that the principles of witnessing are fully understood and that centre specific protocols are followed in line with the requirements of G.13.6.1.	*No response from PR in June 2008* On inspection it was stated by the Laboratory Manager that a list of witnesses used at the centre is now maintained, which details their name, job title and signature. It was available if required but was not inspected. This area of practice was considered by the inspectorate to be now compliant with HFEA requirements.

3. Areas of concern

The analysis of the centre's self assessment questionnaire (SAQ) 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-1	Inspection findings	Assessment of whether the action taken meets requirements or whether any further action is required
In the SAQ, the PR assessed the centre as being less than fully compliant with Licence Condition T12, in that the centre was not operating with a full staff compliment.	The PR explained that a nurse had resigned and the centre was attempting to recruit a replacement. The PR supplied an activity-resource assessment after this inspection as evidence that activity is controlled to fit the resources available. No complaints have been made which would indicate that patients are being affected by staffing problems.	The inspectorate has no regulatory concerns regarding the nurse shortage as this is a temporary issue and an appointment will soon be made. Treatment activity is also controlled to ensure it is appropriate for the available staffing resources. The delays in document review and implementing the electronic document management system, suggest the QM may not have enough time to devote to the role. The PR should assess whether further staffing resources are needed in this area to ensure the centre's quality management system is compliant with HFEA requirements.

Area of concern-2	Inspection findings	Assessment of whether the action taken meets requirements or whether any further action is required
In the SAQ, the PR stated that all staff working in the embryology laboratory were not registered with the Health Professionals Council (HPC), potentially non-compliant with Licence Condition T14.	The Laboratory Manager has a relevant degree or equivalent and many years experience of embryology, and in the management of embryology laboratories. He is not however registered with the Health Professional's Council (HPC). Thus he complies with the requirements of CoP guidance note 2.19 a and b, but	The Laboratory Manager is currently not qualified to the requirements of CoP guidance note 2.19c however appropriate actions have been taken to correct this. The inspectorate note the PR can cover for the Laboratory Manager if needed, given her qualifications, experience and HPC registration. The other embryology staff are moving toward HPC registration, where required, at an appropriate pace.

Continued	not with 2.19c. The Laboratory Manager has however recently applied for HPC registration. He expects to be interviewed for registration in July 2010. The PR is also an experienced HPC registered embryologist with managerial experience, so can cover for the Laboratory Manager if required. Three other embryologists were seen to be working towards HPC registration in an appropriate manner.	The inspectorate considers the non-compliance with guidance note 2.19c is of very low risk to patients, gametes and embryos. The PR should ensure these actions progress and that the Executive is advised when the Laboratory Manager and staff attain their HPC registrations.

Area of concern-3	**Inspection findings**	**Assessment of whether the action taken meets requirement or whether any further action is required**
In the SAQ, the PR stated that the centre's counsellor was not accredited by the British Infertility Counselling Association (BICA) but was working towards accreditation.	Evidence that the counsellor is working towards accreditation with BICA was provided on inspection.	The inspectorate considers there are no regulatory issues associated with this SAQ response.

Area of concern-4	**Inspection findings**	**Assessment of whether the action taken meets requirement or whether any further action is required**
In the SAQ, the PR assessed the centre as being less than fully compliant regarding training and/or the assessment of staff competence to perform:	Discussions with staff and documents provided on inspection, indicate that induction and initial training and competency assessment programmes are established. Re-assessment of	The centre is currently non-compliant with Licence Conditions T12 and T15a in that documented evidence of the re-assessment of key competencies can not be provided for each staff member. Documented competency frameworks and methodologies for their re-assessment are
Continued:		

a) consent taking b) WoC assessment c) selecting/recruiting donors d) witnessing e) maintaining confidentiality f) submitting data to the HFEA Thus the centre was considered at risk of being non-compliant with Licence Conditions T12 and T15a	key competencies at appropriate frequencies is not generally performed, contrary to Licence Conditions T12 and T15a. It is noted however that the review of quality indicators for laboratory processes, is used to monitor the embryologists' competence. Competency frameworks and methodologies for their re-assessment were seen to be in preparation for each staff group. These documented frameworks should include consent taking, WoC assessment, selecting donors, witnessing, maintaining confidentiality and data submission to the HFEA, where relevant to staff activities. They should also state the frequency of re-assessment of competence for each activity.	being developed by the centre.

Area of concern-5	**Inspection findings**	**Assessment of whether the action taken meets requirement or whether any further action is required**
The PR stated in the SAQ that the centre was less than compliant in ensuring training and reference manuals are present, non-compliant with Licence Condition T33	The Lead Scientist provided documentary evidence that training and reference manuals are now present, as part of the validation pack for each item of equipment.	The inspectorate considers there are no regulatory issues associated with this SAQ response.

Area of concern-6	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
In the SAQ, the PR stated that the centre was less than fully compliant in ensuring that it was a condition of all third party agreements, that the third party will meet the requirements of the relevant licence conditions and the guidance set out in the HFEA Code of Practice, as required by Licence Condition T116	The centre's third party agreements were also discussed in Section 2, item 13. Recently established third party agreements were inspected and their content was considered compliant with the requirements of Licence Conditions T114 and T116. Older third party agreements do not however state that they require the third party to comply with relevant Licence Conditions and CoP Guidance, and are thus non-compliant with Licence Condition T116. Centre staff said that this requirement will be introduced as third party agreements come up for renewal with the third parties.	Some of the centre's third party agreements are non-compliant with Licence Condition T116. The centre plans to review third party agreements to determine which are non-compliant with Licence Condition T116, and correct them as they come up for renewal in an on-going manner. The inspectorate considers that this is a proportionate action which will bring the centre to compliance with Licence Condition T116 within a year.

Area of concern-7	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
In the SAQ, the PR indicated the centre was less than fully compliant with Licence Condition T22. This requires that it is possible to track all the equipment and materials used in the procurement and processing of gametes and/or embryos intended for human application	The Lead Scientist described that all laboratory and clinical consumables are recorded in a batch log with the dates of use. Some equipment used in processing is recorded on the laboratory sheets but some items of equipment are not recorded, non-compliant with Licence Condition T22.	The inspectorate considers that the centre are currently non-compliant with Licence Condition T22 in that the use of some equipment in processing, is not recorded in the patient record or a retained log of some kind.

Area of concern-8	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
In the SAQ, the PR indicated the centre was less than fully compliant with Licence Condition T23. This requires that documented evidence be available of the maintenance and regular inspection of equipment in accordance with the manufacturer's instructions.	This was discussed with the Lead Scientist who provided evidence that all equipment is serviced and maintained appropriately.	The inspectorate found no evidence that the centre was non-compliant with Licence Condition T23.

Area of concern-9	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
In the SAQ, the PR indicated the centre was less than fully compliant with Licence Condition T27, in that while documented procedures for the operation of all critical equipment are available, those procedures do not outline what to do if the equipment malfunctions or fails.	This was discussed with the Lead Scientist who stated that the equipment SOPs have been updated and now state that all malfunctions and non-conformities should be reported to the Laboratory Manager or to the Lead Scientist so that appropriate actions can be decided upon and implemented.	The inspectorate found no evidence that the centre was non-compliant with Licence Condition T27.

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	Reference	Action required	Timescale for action	PR Response	Executive Review
None noted at the time of inspection.					

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-1	Action required/timescale	PR Response	Executive Review
Elements of the witnessing practices (those used during sperm preparation) have been assessed for compliance with witnessing SOPs and CoP Guidance Note 18. The remainder of the witnessing practices have not however been assessed, non-compliant with Licence Conditions T33b and T36.	The remainder of the witnessing practices must also be assessed against the SOPs and CoP guidance note 18, to comply with Licence Conditions T33b and T36. This assessment should be completed by 1 November 2010	All aspects of witnessing have now been assessed against the Code of Practice and against SOPs. The sperm preparation procedures have been the subject of a highly detailed audit, as a pilot prior to auditing the rest of the procedures. A modified version of this audit will be applied to the rest of the procedures	The Lead Inspector is satisfied with the PR's statement that the witnessing practices have now all been reviewed against the SOPs and CoP requirements. There is therefore no remaining regulatory concern associated with this matter.

Area of practice-2	Action required/timescale	PR Response	Executive Review
QIs have not been established for witnessing, contrary to Licence Condition T35.	QIs for witnessing should be documented, including the methods and frequency of monitoring and review. This actions should be completed by 1 November 2010	Quality indicators for witnessing have been agreed with the Quality Manager. A six monthly audit will be carried out to establish compliance with SOPs in terms of completion of paperwork, complete electronic records, along with a process audit. Details will be supplied.	The Lead Inspector is satisfied with the PR's statement that QIs have been established for witnessing. There is therefore no remaining regulatory concern associated with this matter.

Area of practice-3	Action required/timescale	PR Response	Executive Review
The competence of staff to perform manual and electronic witnessing is not re-assessed and documented at a specified frequency, contrary to Licence Conditions T12 and T15a.	The PR should ensure that all staff who perform manual and electronic witnessing, have their competence to do so regularly re-assessed and documented at a frequency specified in procedures, to comply with Licence Conditions T12 and T15a. This action should be completed by 1 November 2010.	An assessment of competency will be carried out annually or in response to any change in procedure, for all existing staff. Details to be supplied.	The Lead Inspector is satisfied with the PR's statement that an assessment of competence for witnessing will be performed annually, or when the SOP is changed. There is therefore no remaining regulatory concern associated with this matter.

Area of practice-4	Action required/timescale	PR Response	Executive Review
Inaccurate entry of data through the EDI system was noted regarding consents for disclosure for registry research. This puts the PR at risk of non-compliance with Direction 0005.	The PR will need to audit the consent for disclosure for registry research decisions in the patient records against the decisions which have been submitted to the HFEA Register via the EDI system. Discrepancies will need to be investigated and corrected. This audit will need to encompass all patients for whom consent for disclosure for registry research decisions have been submitted over the EDI system. This action should be completed by 1 November 2010 and a report provided to the Executive. 2010. The PR must ensure that in the future, all data submitted through the EDI system regarding consents for disclosure for registry research is entered accurately and supported by the patient record.	This issue has been drawn to the attention of those recording the data for entry on to EDI. An audit has been initiated, results to be supplied. An investigation to establish the cause of any discrepancies has been initiated with a view to making any necessary changes to procedures.	The Lead Inspector is satisfied that the PR has taken appropriate actions to prevent further non-compliance in this area. The results of the audit will be supplied when completed. The issue will be monitored by the Compliance Team.

Area of practice-5	Action required/timescale	PR Response	Executive Review
In the sperm donation SOP, the screening tests listed at page 6 ('confidential screening checklist'), at page 2 ('Logistics Recruitment of Sperm Donors') and at page 3 ('Issues discussed in addition to separate information/counselling') are inconsistent with each other. This may cause confusion or the omission of some of the screening tests required by Licence Condition T52 and COP Guidance 11.16.	The sperm donation SOP should be reviewed so that the screening tests listed are consistent. This action should be completed by 1 November 2010.	These SOPs have been reviewed and are now consistent.	The Lead Inspector is satisfied with the PR's assurance that the SOPs have been reviewed and are now consistent. There is therefore no remaining regulatory concern associated with this matter.

Area of practice-6	Action required/timescale	PR Response	Executive Review
It does not state in the sperm donor SOPs and checklist that patient identity is verified using photographic identity documents. This leaves the centre at risk of non-compliance with CoP Guidance 11.6.	The sperm donor SOP and checklists should state and ensure that patient identity is verified using photographic identity documents. This action should be completed by 1 November 2010.	These SOPs and checklists have now been amended.	The Lead Inspector is satisfied with the PR's assurance that the SOPs and checklist have been reviewed and amended to ensure patient identification is verified with photographic identity documents. There is therefore no remaining regulatory concern associated with this matter.

Area of practice-7	Action required/timescale	PR Response	Executive Review
Documented evidence of the assessment of staff competence in selecting and recruiting donors was not available, non-compliant with Licence Conditions T12 and T15a.	Staff stated that a competency assessment framework for nursing staff at the centre is in development which will include assessment regarding selecting and recruiting donors. The PR should ensure this is implemented as quickly as possible to ensure compliance with Licence Conditions T12 and T15a. This action should be completed by 1 November 2010.	Details of this framework will be submitted by the 1st of November.	The Lead Inspector is satisfied with the PR's assurance that the recommended action will be taken by 1 November 2010. The issue will be monitored by the Compliance Team.

Area of practice-8	Action required/timescale	PR Response	Executive Review
The centre is currently non-compliant with Licence Conditions T12 and T15a in that documented evidence of the re-assessment of key competencies can not be provided for each staff member. Documented competency frameworks and methodologies for competence re-assessment are being developed.	The PR should ensure the frameworks and methods for on-going re-assessment of staff competencies are developed and implemented as quickly as possible, to comply with Licence Conditions T12 and T15a. This action should be completed by 1 February 2011 and the Executive updated at regular intervals regarding progress on this issue.	These frameworks are currently in development and will be implemented prior to the deadline.	The Lead Inspector is satisfied with the PR's assurance that the recommended action will be taken by 1 November 2010. The issue will be monitored by the Compliance Team.

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from good practice.

Area of practice-A	Action required/timescale	PR Response	Executive Review
Practice at the centre is to select donors on the basis of the age limits stated in professional body guidelines. The egg and sperm donor recruitment SOPs and checklists do not however make clear that age is a criteria for donor selection, leaving the centre at risk of non-compliance with T52a	The SOPs and checklists should be modified to include an assessment of the donor's age, as happens in practice at the centre.	These SOPs and checklists have now been updated.	The Lead Inspector is satisfied with the PR's assurance that the SOP and checklist have been reviewed and updated. There is therefore no remaining regulatory concern associated with this matter.

Area of practice-B	Action required/timescale	PR Response	Executive Review
The egg and sperm donor screening SOPs and checklists were non-compliant with professional body guidelines and thus CoP Guidance 11.15, in that they did not include a physical examination of the donor or an assessment of the risk of prion disease. Egg but not sperm donors are however physically examined in practice.	Donor screening procedures and/or practices at the centre should be revised to include a physical examination of the donor and an assessment of their risk of prion disease, to comply with professional body guidelines and thus CoP Guidance 11.15. This action should be completed by 1 November 2010.	These SOPs have been updated. Negotiations are underway to ensure the appropriate availability of a clinician to carry out physical examinations of the sperm donors in line with the escalation of our sperm donor recruitment programme.	The Lead Inspector is satisfied that the PR has taken appropriate actions to prevent further non-compliance in this area. Assuming the plan to ensure a clinician is available is implemented, there are no remaining regulatory concerns associated with this matter. The implementation of the plan will be monitored by the Compliance Team.

Area of practice-C	Action required/timescale	PR Response	Executive Review
The egg donor information on page 1 uses the term 'anonymous volunteer donors' which may give donors the erroneous impression they can remain anonymous to donor-conceived offspring.	The egg donor information should be revised to remove any reference to anonymous donors. This action should be completed by 1 November 2010.	This information has now been revised.	The Lead Inspector is satisfied with the PR's assurance that the donor information has been revised according to the recommendation. There is therefore no remaining regulatory concern associated with this matter.

Area of practice-D	Action required/timescale	PR Response	Executive Review
A letter is sent by the centre to the egg donor's General Practitioner (GP), if the donor so consents to disclosure. This letter refers to Section 4.5 of the HFEA CoP, which is not found in the HFEA CoP 8th edition.	The PR should review the letter's content against the HFEA CoP 8th edition and update the letter accordingly. This action should be completed by 1 November 2010.	This letter has now been revised. In accordance with the current Code.	The Lead Inspector is satisfied with the PR's assurance that the letter has been revised according to the recommendation. There is therefore no remaining regulatory concern associated with this matter.

Area of practice-E	Action required/timescale	PR Response	Executive Review
The egg and sperm donor information sheets indicate that donors can be paid reasonable expenses and compensation for loss of earnings, up to a total of £250. They indicate that this payment will occur in two	The PR should ensure that the compliant reimbursement practices at the centre, which were discussed on inspection, are documented in procedures and reflected in patient/donor information. This action should be completed by 1 November 2010.	These information sheets are now consistent with compliant practice.	The Lead Inspector is satisfied with the PR's assurance that the donor information has been revised according to the recommendation. There is therefore no remaining regulatory concern associated with this matter.
Continued stages, each of £125. These			

arrangements are non-compliant with Direction 0001. They are also at odds with the compliant reimbursement practices at the centre, which were discussed on inspection.			

Area of practice-F	Action required/timescale	PR Response	Executive Review
In the SAQ, the PR indicated that the centre was not fully compliant with Licence Condition T21; i.e. that all diagnostic services used in support of patient treatment are appropriately accredited. This relates to the genetic testing laboratory which supports the PGD service, which is preparing for an imminent accreditation inspection but is currently unaccredited.	The PR should advise the manager of the PGD service that the centre must use a PGD service which is appropriately accredited. The PGD service should therefore gain appropriate accreditation as rapidly as possible. The PR should advise the Executive when this will be. This action should be completed by 1 February 2011.	The service provider has been reminded of this condition and we will continue to monitor the situation.	The Lead Inspector is satisfied with the PR's assurance that the PGD service has been advised regarding this issue. Indeed, an update on progress towards CPA accreditation has been provided by that service lead to the Lead Inspector which indicates that accreditation will soon be in place. There is therefore no remaining regulatory concern associated with this matter.

Area of practice-G	Action required/timescale	PR Response	Executive Review
Some documents have not been reviewed in the last year, non-compliant with CoP Guidance 31.6, since they await transfer to the new electronic document control system (e.g. the sperm donation SOP).	The PR should ensure the QM reviews the centre's documentation as it is transferred to the new document management system, to comply with the, at least, annual review required by CoP Guidance 31.6. This action should be completed by 1 November 2010	This action will be completed by the deadline.	The Lead Inspector is satisfied with the PR's assurance that the recommended action will be taken by 1 November 2010. The issue will be monitored by the Compliance Team.

Area of practice-H	Action required/timescale	PR Response	Executive Review

HFEA Finance reported before inspection that invoices in the year to 6th March 2010 had been paid in an average of 57 days. The PR should note that Chair's Letter CH(10)02 requires payment of HFEA invoices within 28 days of their issue	The PR is obliged under Licence Condition T9d to ensure fees are paid within the written specified timescale. The PR should therefore take appropriate actions to meet the 28 day payment deadline and monitor payment times. This action should be completed by 1 November 2010.	Work is continuing with the finance department to ensure robust procedures are in place to allow timely payment of invoices.	The Lead Inspector is satisfied that the PR has taken appropriate actions to minimise the risk of further non-compliance in this area. The issue will be monitored by the Compliance Team. There is therefore no remaining regulatory concern associated with this matter.

Area of practice-I	Action required/timescale	PR Response	Executive Review
The inspectorate considers that the centre are currently non-compliant with Licence Condition T22 in that the use of some equipment in processing, is not recorded in the patient record or a retained log of some kind.	The PR should ensure that traceability data for all equipment used in processing is documented in the patient records or a retained log of some kind, to comply with Licence Condition T22. This action should be completed by 1 November 2010.	Records formats are being reviewed to allow recording of this data appropriately.	The Lead Inspector is satisfied that the PR has taken appropriate actions to prevent further non-compliance in this area. The issue will be monitored by the Compliance Team.

Area of practice-J	Action required/timescale	PR Response	Executive Review
Some older third party agreements are non-compliant with Licence Condition T116. The centre plans to review third party agreements for compliance and to correct them as they come up for renewal.	The PR should ensure that the review of third party agreements for compliance with Licence Condition T116, is performed as they come up for renewal. This action should be completed by 1 August 2011.	TPAs will be reviewed and amended on a rolling renewal basis such that all will have been reviewed by 01/08/2011.	The Lead Inspector is satisfied that the PR has taken appropriate actions to prevent further non-compliance in this area. The issue will be monitored by the Compliance Team.

Area of practice-K	Action required/timescale	PR Response	Executive Review

The Laboratory Manager is currently not qualified to the requirements of CoP guidance note 2.19c, however HPC registration has been applied for which will correct this situation. Given the experience of the Laboratory Manager and the PR, the inspectorate considers the non-compliance with guidance note 2.18c is of very low risk to patients, gametes and embryos.	The PR should ensure that Laboratory Manager progresses with his application for HPC registration and should inform the Executive when HPC registration is attained. Registration should be attained by the time of the next scheduled inspection.	The Laboratory Manager has submitted his application. We await the outcome.	The Lead Inspector is satisfied that the PR has taken appropriate actions to prevent further non-compliance in this area. The issue will be monitored by the Compliance Team.

Additional Information from the Person Responsible

HFEA Executive Licence Panel Meeting

10 September 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 1

Centre 0119 (Birmingham Women's Hospital) - Interim Inspection Report (Treatment and Storage)

Members of the Panel:	Committee Secretary:
Mark Bennett, Director of Finance & Facilities (Chair) Nick Jones, Director of Compliance Hannah Darby, 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:

- Interim inspection report, 16 June 2010
- Licence Committee Minutes 14 February 2007, renewal inspection report
- Licence Committee Minutes 2 May 2007, EUTCD variation to treatment and storage licence at centre 0119
- Licence Committee Minutes 15 October 2008, Interim Inspection Report
- Licence Committee Minutes 12 August 2009, Change of NL
- ELP Minutes 21 April 2009, Embryo testing, PGD and PGS variation to treatment and storage licence at centre 0119

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 Centre's first licence was granted in 1992. It has a good history of regulatory compliance and the current licence, active until 30 November 2012, has no additional conditions placed upon it. The Centre conducted 700 treatment cycles from 1 March 2009 – 28 February 2010.

2. The Panel noted that the Person Responsible (PR) is a Consultant embryologist and has completed the PR Entry Programme (PREP).

3. The Panel considered the Interim Inspection Report and was satisfied that the Centre was broadly compliant. The Panel noted that the Centre had corrected five of eight major non-compliances and six of eleven other non-compliances. However, it was satisfied that the PR has committed to implement all remaining recommendations within the required deadlines.

4. The Panel discussed concerns regarding recording consent to research and was now satisfied that this had been addressed .

5. The Panel commended the Centre's multiple birth strategy which has been fully implemented and works.

Decision

6. The Panel agreed to the continuation of the Centre's licence without any conditions placed upon it. The Panel endorsed the Inspectorate's recommendations and associated timeframes for the PR to meet these recommendations.

Signed:  Date: 21/9/10

Mark Bennett (Chair)