Inspection Report

Date of Inspection: 13 and 14 June 2012
Purpose of inspection: Renewal of Treatment (with embryo biopsy) and Storage Licence
Length of inspection: 13 hours
Inspectors: Gill Walsh, Susan Jolliffe, Chris O'Toole
Chris Hall and Cathy Hodgson (Operational Audit)
Jenny Clifford (Observer)

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 16 June 2010 and 24 August 2012.

Date of Executive Licensing Panel: 21 September 2012

Purpose of the Inspection Report
The purpose of the inspection is to assess whether centres are complying with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the Human Fertilisation and Embryology (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 Executive Licensing Panel which makes the decision about the centre's licence renewal application.

Centre details

Centre name	Assisted Conception Unit, Birmingham Women's Hospital
Centre number	0119
Licence number	L0119/15/c
Centre address	Birmingham Women's Hospital NHS Foundation Trust Edgbaston Birmingham B15 2TG
Person Responsible	Dr Sue Avery
Licence Holder	Dr Rosemary Keeton

Date licence issued	1 December 2007
Licence expiry date	30 November 2012
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

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.

A full range of licenced assisted conception therapies are offered. The centre has additionally been licenced to provide embryo testing since May 2010. Treatment is provided to both NHS commissioned and self-funding patients.

The centre recruits egg and sperm donors, has an egg share programme and occasionally treats couples requiring surrogacy. The centre also provides a facility for the storage of gametes and/ or embryos for the preservation of fertility.

The centre currently holds a research licence with expires on 30 September 2014.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 01 May 2011 – 30 April 2012*
In vitro fertilisation (IVF) including frozen embryo transfer (FET) after IVF	461
Intracytoplasmic sperm injection (ICSI) FET after ICSI	379
Gamete intrafallopian transfer (GIFT)	0
Donor insemination (DI)	49
Partner insemination	163 (2011 total)
Egg share provider (sharer)	7
Egg share recipient	3
Egg donation (non-egg share)	4

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

Outcomes*
For IVF/ICSI, HFEA held register data for the period December 2011 to November 2012 show the centre's success rates are in line with national averages.

For the year 2011 the centre reported 163 cycles of partner insemination with 14 pregnancies. This equates to a 15% pregnancy rate which is in line with the national average.

*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 inspection team 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 is suitable and has discharged her duty under section 17 of the HF&E Act 1990 (as amended)
- the premises are suitable
- the practices are suitable
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, in application for renewal of their licence
- the centre has an application fee to the HFEA in accordance with requirements

The Executive Licensing Panel is asked to note that at the time of the inspection there were a number of areas of practice that required improvement: there were no critical areas of non-compliance two major areas of non-compliance and four other areas of non-compliance or areas of poor practice.

Since the inspection visit the PR has confirmed and/or provided evidence that the following recommendations have been fully implemented –

Major areas of non-compliance:

- The PR must ensure that data which the Authority is required to hold on its Register is provided within the timeframe specified in Directions. The process for submitting licensed treatment data to the authority should be reviewed and where appropriate enhanced to ensure licensed treatment activity is reported to the Authority and compliance with submission timeframes detailed in Direction 005 is achieved.

Other areas of practice that require improvement:

- The PR should establish a third party agreement with each of the organisations identified. In so doing it should be ensured that the agreement with the surgical unit within another Trust where surgical sperm recovery is conducted is compliant with SLC T117 and that the agreement with the separate histology department is compliant with SLC T114(f) specifically.
- Donor selection and recruitment procedures should be audited against approved protocols, quality indicators or regulatory requirements.
- All personnel involved in the donor selection and recruitment process should have their competence to perform these tasks assessed by a suitably qualified and experienced person and the outcome of that assessment documented.
- The PR must ensure that going forward the centre develops a process to identify when there is a need to submit disclosure consent variation form data to the Authority and to ensure it is submitted in such circumstances.

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

Major areas of non compliance:

- Whilst it is recognised that the PR has periodically updated the HFEA regarding the status of the testing laboratory's application for CPA (UK) Ltd accreditation, it remains

the responsibility of the PR to ensure that diagnostic testing is conducted in an appropriately accredited laboratory. The PR is to update the HFEA when information is received regarding progress with accreditation and if any further barriers to the anticipated assessment process occur.

Recommendation to the Executive Licensing Panel

The inspection team 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. In making this recommendation it is noted that the PR has responded to all recommendations made in this inspection report.

Details of inspection findings

1. Protection of patients and children born following treatment

Focus

The purpose of the inspection was to assess whether the centre:

- conducts 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
- takes into account the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth
- ensures that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose
- reports all adverse incidents (including serious adverse events and reactions) to the HFEA, investigates all adverse incidents and shares lessons learned.

▶ Witnessing and assuring patient and donor identification (Guidance Note 18)

What the centre does well.

All samples and the patients to whom they relate are identified and witnessed contemporaneously and a record of the witnessing checks is kept in the patient / donor's medical record, as confirmed by witnessing procedures observed and by a review of patient records seen on inspection. (Standard licence condition (SLC) T71)

The centre uses an electronic witnessing system to ensure the identification of gametes and embryos and the patient or donor to whom they relate at all critical points of the clinical and laboratory process and to ensure that patients receive treatment using the correct gametes or embryos.

Comprehensive standard operating procedures (SOP) for witnessing, electronic and manual, were seen on inspection in addition to quality indicators (QI) which are monitored against on a rolling monthly basis to form part of the witnessing audit. (SLC T36)

Staff competencies for witnessing are documented (electronic and manual) (SLC T15 (a))

The following laboratory activities were observed in the course of the inspection: preparation for embryo transfer, (including active identification of the patient against patient records and the electronic system), fertilisation check and ICSI, including sperm to egg witnessing. All of the procedures observed were witnessed in accordance with HFEA requirements using an electronic witnessing system and manually witnessed steps where required.

A review nine patient records on inspection confirmed that records of both manual and electronic witnessing are maintained.

What the centre could do better.
Nothing noted

Patient selection criteria and laboratory tests

- Procuring, processing and transporting gametes and embryos (Guidance Note 15)
- Counselling (Guidance Note 3)

What the centre does well.

Procuring, processing and transporting gametes and embryos

An audit of nine patient records on inspection demonstrated that records are kept which include the patient's medical history, the indication for treatment, the services provided, welfare of the child assessment, consent to treatment (and storage where applicable), clinical and laboratory data and the results of tests carried out. (SLC T49 and T46)

There are SOPs in place to direct all critical procurement and processing procedures (SLC T33(b))

Critical procurement and processing procedures were seen to have been audited against approved protocols, regulatory requirements and the centre's own quality indicators within the last two years (SLC T35 and T36). Quality indicators are monitored quarterly and the results documented and discussed at the multidisciplinary team meeting. Where required, corrective actions and the implementation of those actions was seen to have been documented in audit reports (SLC T36).

An SOP is in place detailing the circumstances, responsibilities and procedures for the release of stored material before distribution (SLC (T33b)).

Validation documentation is in place for containers and packages used for the transportation of gametes and embryos. (SLC(T108)).

The Person Responsible (PR) stated that she is confident that staff are competent to conduct their assigned tasks. Evidence of induction, training, continuing professional development and competence assessment was available for all staff members (SLCs T12, and T15(a)).

Patients generally produce their sperm sample on site but may, on occasion, produce their sample at home or elsewhere within the hospital if they are oncology patients or other patients wishing to store sperm for the preservation of fertility. Staff asked confirmed that if a sample is produced away from the centre, this is recorded in the gamete provider's medical record (SLC T68).

Prior to processing, all gamete providers are screened in accordance with standard licence condition by a CPA (UK) Ltd accredited laboratory T50 as confirmed by review of results recorded in medical records seen on inspection.

Counselling

Independent counselling is offered to all patients and their partners before they provide consent for treatment. (SLC T60) Counselling is available throughout the treatment

process and following its conclusion, if required. Counselling is also offered to those providing consent to donation, agreed legal fatherhood and legal parenthood where donor gametes are used. Where treatment with a surrogate is proposed, alongside the commissioning couple, the surrogate and her partner, where she has one, are counselled as to the implications of such an arrangement.

The counsellor was able to demonstrate competence to perform her role, having practised in the field for many years and anticipates gaining accreditation with the British Infertility Counselling Association within the next four to six months. (SLCs T14 and 15(a)) The counsellor described that she has been supported in her clinical professional development by the centre and participates in monthly independent clinical supervision sessions (SLC T15).

There is a comprehensive counselling SOP in place to guide the process and was seen to have been updated in April 2012. Quality indicators have been established and are monitored to assess performance and user satisfaction with the counselling service. Results from service user feedback are evaluated and feed into the overall centre quality appraisal (SLC (T35).

The counselling service is audited annually; the audit for 2011/12 was available to see on inspection. No corrective active actions were required. (SLC T36).

The counsellor is able to refer individuals or couples for more specialist counselling, if required, including that for oncology or therapeutic counselling. Specific genetic counselling is also provided separately where required.

What the centre could do better.
Nothing noted.

Donor recruitment, assessment and screening (Guidance Note 11)
Payments for Donors (Guidance Note 13)
Donor assisted conception (Guidance Note 20)

What the centre does well.
Donor recruitment, assessment and screening
There is an SOP in place which includes quality indicators, to be followed when selecting and recruiting donors. (SLC T33(b) and T35)

From discussions with staff, a review of documentation and six egg donor / sharer and six sperm donor records, the inspection team concludes that donors are selected in accordance with professional body guidelines on the basis of their age, health and medical history by appropriately trained and qualified staff. (SLC T52(a). All donors are screened appropriately in compliance with standard licence condition T52(b) by a CPA (UK) Ltd. accredited laboratory.

Donated sperm or embryos are quarantined for a minimum of 180 days prior to repeat screening before being released for use. (SLC T53(c))

Payment of Donors

The centre was able to provide evidence that where expenses have been paid this is done in accordance with Directions 0001. The centre has not imported any donated gametes.

Donor Assisted Conception
Evidence was provided that those who are to receive treatment with donated gametes or embryos are provided with information on the importance of informing any resulting child at an early age of their donor origins and how best parent may do this. (SLC T63(a,b))

Confirmation was provided that where the provider of gametes donated prior to April 2005 has not consented to being identifiable, these gametes and any embryos created with those gametes, will only be used in treatment to achieve a sibling pregnancy. (SLC T54)

What the centre could do better.
Procedures for selecting and recruiting donors have not been audited against compliance with approved protocols, regulatory requirements and quality indicators in the last two years. (SLC T36)

Some relevant staff could not provide documented evidence of the assessment of their competence to perform donor recruitment, assessment and screening procedures. (SLC T15(a))

Good clinical practice

- Quality management system (Guidance Note 23)
- Traceability (Guidance Note 19)
- Validation (Guidance Note 15)
- Equipment and materials (Guidance Note 26)
- Premises – suitability of the premises and air quality (Guidance Note 25)
- Adverse incidents (Guidance Notes 27)
- Third party agreements (Guidance Note 24)
- Intracytoplasmic sperm injection (ICSI) (Guidance Note 21)

What the centre does well.
There is a quality management system in place which includes a quality manual and training and reference materials. (SLC T33)

From discussions with staff, observation and a review of documentation at inspection, the inspection team conclude that there are SOPs in place (SLC T33(b)) to direct all activities to be provided in the course of providing treatment services and where relevant specify any critical materials and reagents used in the procedure described. (SLC T31) Quality indicators have been established for the centre's activities (SLC T 35) and audits have been conducted within the last two years for the majority of the centre's activities. (SLC T36)

Evidence was provided to demonstrate that there are measures in place for reviewing the centre's overall performance, user satisfaction and efficacy of the quality management system to ensure continuous and systematic improvement. The most recent quality management and resource review was submitted with the centre's renewal application.

Traceability
From discussions with staff, a review of patient / donor records seen and practice

observed, the inspection team conclude that all gametes, equipment and materials coming into contact with gametes used in treatment which may affect their quality and safety are traceable throughout from procurement to treatment or disposal and there is an SOP to direct these processes. (SLC T22, T33 (b) and T99)

All tubes/dishes are labelled with patient / donor name and a unique identifier (electronic or manual). This was confirmed during the inspection by the observation of two separate witnessing procedures in the laboratory which demonstrated the identification and labelling of tubes and dishes containing patient gametes and embryos.

Quality indicators relevant to traceability have been established and procedures audited. Staff competence to perform traceability procedures has been documented (SLC T35, T36, T15(a)).

Provision is in place to ensure that the data necessary to ensure continued traceability is stored securely for at least 30 years (and such longer period as may be specified in Directions). (SLC T103)

Process validation
Critical procurement and processing procedures and all equipment used in these processes have been validated. Documents were available to view on inspection (SLC T24 and T72).

Equipment and materials
Documented evidence was available to see on inspection which demonstrated all critical equipment (including that for new cryo storage vessels commissioned in May 2012) used in patient treatment or the storage of gametes and embryos have been validated and will not render the gametes or embryos clinically ineffective or harmful to the recipient. (SLC T24) An example of revalidation of equipment following repair and re-commissioning was also seen for an oxygen monitor. (SLC T25)

Manuals and documented procedures for the operation of all critical equipment were seen to be readily available to staff in the work areas which included the actions to be taken in the event of equipment malfunction or failure. (SLC T27) Key equipment or materials that affect the critical processing or storage parameters where observed to be calibrated to traceable standards and subject to appropriate monitoring and alarms. (SLC T24) Documented evidence of regular cleaning, decontamination (SLCT26) and preventative maintenance and servicing was also seen. (SLC T28)

Premises
A tour of the centre confirmed that the centre's premises are suitable for the licensed activities and that all activities to which the centre's licence applies are conducted in the licensed premises (SLC T1). Evidence was provided that the processing of gametes takes place in an environment of the appropriate air quality (SLC T20), and that air quality is regularly monitored, most recently in May 2012.

Adverse incidents
There is a SOP in place to direct the reporting of adverse incidents or near miss events to the HFEA. Staff were able to describe the process to be followed for reporting and the investigation of an incident or untoward event and demonstrated a good understanding of

the nature of events or incidents that should be reported to the HFEA (SLC T118). An audit of incidents reported to the HFEA since the last inspection against the centre's own incident reporting records demonstrated no non-compliances. All incidents were seen to have been appropriately investigated and follow up actions documented and implemented.

Third party agreements
The centre has written agreements with most of the third parties who provide goods or services that influence the quality and safety of gametes (SLC T111). Evidence was seen that confirmed that the centre has evaluated the ability of third parties to meet the required standards (SLC T112) and that the content of the agreements is compliant with SLC T113 and T114 where applicable. A list of all third party agreements is maintained by the centre (SLC T115). Two third party agreements were audited on inspection (one of which is an over arching agreement with the Trust procurement department though which the centre is required to channel all consumables and equipment purchases used in licensed treatments), both were considered to be compliant with CoP requirements. No non-conformities were noted.

ICSI
There is a prescriptive SOP in place to direct ICSI practice (SLC T33(b)) which has been validated based on professional body guidelines and published studies. (SLC T72). All staff conducting ICSI procedures were able to provided documented evidence of the assessment of the competence in this procedure. (SLC T15(a)) Quality indicators for performance have been established and are monitored. (SLC T35) Results for all ICSI practitioners are discussed at monthly team meetings and practice reviewed periodically as part of their audit of practice. (SLC T36)

What the centre could do better.
The laboratories with whom the centre has a third party agreement for pre-implantation genetic screening (PGS) and pre- implantation genetic diagnosis (PGD) in not CPA (UK) Ltd accredited.

There are no third party agreements in place with:

- a neighbouring hospital (different Trust) which now conducts surgical recovery of sperm for the preservation of fertility
- the specialist courier service
- the histology laboratory used for testing sperm samples for a specific group of patients who have undergone surgical sperm retrieval at the neighbouring hospital

Multiple Births (Guidance Note 7)

In 2010/11 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 19% : this represented performance that was not likely to be statistically

different from the 20% live birth rate target.

For the time period April 2011 to March 2012 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 16 %: this also represents performance that is not likely to be statistically different from 15% live birth rate target

What the centre does well

Ongoing monitoring of the centres multiple clinical pregnancy rate suggests that the centre is not likely to exceed the 2011/12 multiple birth rate target of 15% (SLC T123)

The PR has provided sufficient evidence to demonstrate compliance with HFEA Directions 0003 in that:

- staff were able to describe their progress towards reducing their multiple pregnancy rates and subsequent multiple birth rates;
- staff at the centre have audited their strategy and protocols as part of the quality management audit programme;
- staff have maintained a log of women receiving double and triple embryo transfers who meet the criteria for single embryo transfer;
- staff have maintained a log which indicates the reasons for variation from the single embryo transfer policy and outcomes which are also recorded in the patients records.

What the centre could better
Nothing noted.

Staff engaged in licensed activity

- Person Responsible (Guidance Note 1)
- Staff (Guidance Note 2)

What the centre does well.

The PR is a consultant embryologist and has academic qualifications in the field of biological sciences as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii). She has many years of practical experience which is directly relevant to the activity to be authorised by the licence.

The PR has successfully completed the HFEA Person Responsible Entry Programme (PREP number T/1065/7).

From discussions with staff, observation on inspection and from documentation reviewed, the inspection team conclude that:

- the PR has carried out her duties appropriately and has provided assurance that;
- staff are suitably qualified and are available in sufficient numbers to carry out all the services offered and workforce requirements have been reviewed within the last year;
- medical practitioners are registered with the General Medical Council (GMC);
- nursing staff are registered with the Nursing and Midwifery Council (NMC);
- eligible scientific staff are registered with the Health Professionals Council (HPC);

- all staff can show evidence that they are trained to carry out their designated tasks;
- all staff can show evidence of their competence to carry out their designated tasks (with one exception noted where the assessment was not documented);
- staff have access to continued professional development (CPD);
- all medical activities are overseen by a medical practitioner – the medical director;
- the centre's patients, their partners and donors have access to a suitably qualified counsellor.

What the centre could do better.
Nothing noted

Welfare of the Child (Guidance Note 8)

What the centre does well.
Documented evidence was available to show that patients are not provided with treatment until account has been taken of the welfare of any child who may be born as a result and of any other child who may be affected by the birth (SLC T56).

An audit of five patient records showed that both patient and partner had completed welfare of the child assessment questionnaires and that the forms had been reviewed by a member of the nursing team prior to treatment. Staff described that any indication of further information being required to inform the assessment would be documented and concerns discussed within the multidisciplinary team. There is an SOP in place to guide the assessment process (SLC T33(b)).

The centre has audited their WoC procedures (SLC T36) and a copy of the audit was seen on inspection.

Assessment of staff competencies in WoC assessment were documented and staff interviewed were able to demonstrate a full understanding of WoC requirements (SLC T15(a)).

What the centre could do better.
Nothing noted.

Embryo Testing – *only applicable to centres licensed to carry out Pre-implantation genetic diagnosis and screening)*

- Pre-implantation genetic screening (Guidance Note 9)
- Embryo testing and sex selection (Guidance Note 10)

What the centre does well.

The centre conducts embryo biopsy for pre-implantation genetic screening (PGS) which is analysed by a genetics laboratory with whom the centre has a third party agreement. (SLC T111)

There is an SOP to direct embryo testing procedures(SLC T33) which has been validated

against professional body guidance and published studies (SLC T72). Staff performing embryo biopsy procedures were able to provided evidence of training and the assessment of their competence to conduct this procedure (SLC T15(b)). Quality indicators relevant to embryo testing procedures have been established (SLC T35) and the results are regularly audited. (SLC T36)

The PR was able to provided assurance that:

- no embryo is transferred to a woman where that embryo or material removed from it, or the gametes that produced it, has been subject to genetic testing unless expressed authorised by the HFEA (SLC T88) and;
- no information derived from tests conducted has been used to select embryos of a particular sex for social reasons (SLC T89)
- biopsied embryos are not transferred biopsied embryos into a woman in the same cycle of treatment as non-biopsied embryos (SLC T77).

The third party agreement in place with a genetics testing laboratory was reviewed on inspection and considered to be compliant with SLC T114.

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

10 PGS/D patient records were reviewed on inspection as part of a thematic review, there were no non-compliances noted.

What the centre could do better.
The third party genetics laboratory which conducts the analysis of embryo biopsies is working towards accreditation with CPA (UK) Ltd.

2. Patient Experience

Focus

The purpose of the inspection visit was to assess whether the centre:

- treats prospective and current patients and donors fairly, and ensures that all licensed activities are conducted in a non-discriminatory way
- has respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions
- ensures that patients and donors have provided all relevant consents before carrying out any licensed activity

Treating patients fairly

- Treating patients fairly (Guidance Note 29)
- Confidentiality and privacy (Guidance Note 30)
- Complaints (Guidance Note 28)
- Provision of costed treatment plans (Guidance Note 4)
- Egg sharing arrangements (Guidance Note 12) – *if applicable*
- Surrogacy (Guidance Note 14) – *if applicable*

What the centre does well.

Treating patients fairly

From the information provided, observations made and discussion with staff, the inspection team were assured that all licensed activities are conducted in a non-discriminatory manner with proper respect for the privacy, confidentiality, dignity, comfort and well-being of all prospective and current patients and their partners and that information is kept confidential and only disclosed in circumstances permitted by law (SLC T43).

Confidentiality and privacy

Access to confidential records and the areas where confidential information may be seen, obtained or stored was demonstrated to be restricted to licensed centre personnel authorised by the PR. (SLC T45)

SOPs direct how the confidentiality of patients, partners and donors is maintained and incorporate measures to ensure no unauthorised disclosure of information is possible. (SLC T44(c)) There is also an SOP governing access to patient / donor records which includes measures for considering and responding to requests for access to confidential records. (SLC T44 (b,c,d,e)).

Complaints

Information on how to make a complaint was available in the patient waiting area, the PR is the nominated person to contact in case of complaint. The centre's complaints log was reviewed on inspection. Evidence of response, investigation and resolution was seen in each case.

Staff at the centre actively seeks patient feedback through monitoring of patient satisfaction questionnaires. All patients are offered a questionnaire and the results are collated and discussed for action at team meetings. The HFEA patient questionnaire

showed high levels of satisfaction with the service.

Provision of costed treatment plans
Before treatment, storage or both are offered, a personalised costed treatment plan is provided to the patient and her partner (where applicable) and the proposed plan is discussed prior to treatment commencing. A copy of the costed treatment plan provided was seen in medical records reviewed where treatment was self funded.

Egg sharing arrangements
The centre has an egg sharing scheme. All egg sharers are screened in accordance with HFEA requirements and are registered with the HFEA as donors.The centre has appropriate agreements with both the egg sharers and the patients receiving treatment with the donated eggs.

Patient records reviewed on inspection included patients who had been in the egg sharing programme. The records documented the screening tests conducted, that counselling was offered and contained relevant consents.

Records reviewed and discussions with staff confirmed that treatment is only provided to the egg sharer in the course of the donation cycle unless there is a documented medical reason as to why treatment cannot be provided at that time. (Directions 0001)

Surrogacy

The centre has a surrogacy programme and the patient records of a commissioning couple and host were reviewed on inspection.

All parties had been assessed for welfare of the child and received counselling. All appropriate consents and agreements were in place.

The commissioning couple had been screened and registered as donors (SCL(T53c and Directions 0003)) and the surrogate had been screened prior to being treated.

What the centre could do better.
Nothing noted.

Information

- Information to be provided prior to consent (Guidance Note 4)
- Information about storage of embryos (including cooling off periods)
- Information about Intracytoplasmic sperm injection (Guidance Note 21)
- Information about preimplantation genetic testing (Guidance Notes 9 & 10) – Information about legal parenthood (Guidance Note 6)

What the centre does well.
From discussions with staff, documents reviewed and feedback given by patients during the inspection and from questionnaires submitted to the HFEA, the inspection team conclude that proper information about the nature of the treatment, consequences and risks, tests, confidentiality, consent, and the availability of counselling is given to patients consenting to treatment or donation or donation to research and that those giving consent are given adequate opportunity to discuss the implications of their consent before treatment or donation commences.

There is an SOP in place to guide this process. (SLC T33(b))

Patients and their partners are invited to a fortnightly information evening which is attended by members of the multidisciplinary team. Generic treatment information packs are given out at these meetings and more specific information relevant to the individual is discussed and reinforced with further written information at subsequent consultation appointments when the treatment pathway is agreed.

The centre submitted a suite of patient information prior to the inspection which was reviewed. The information provided was considered to meet the requirements of the Code of Practice and was clear to the reader. Information provided to patients includes that regarding the proposed treatment pathway, information about the implications and responsibilities around the storage of gametes and embryos, including variation to consent and actions in the event of a dispute regarding the continued storage of embryos (cooling off period). Specific information about ISCI and pre implantation genetic testing is also provided.

Three patients interviewed on inspection were complimentary about the centre staff and care received. They expressed satisfaction with the level of information received and communication and contact with the centre.

The centre provides treatment with donor gametes to women and couples who may or may not be married or in a civil partnership. Those affected by legal parenthood legislation are informed of how the nomination of a second legal parent affects them and of the consent process prior to treatment being offered. (SLC T60) The are measures in place to ensure treatment is not provided to a woman where there is consent to parenthood is withdrawn or varied until all parties are informed of the change and agreement reached. (SLC T60 and T64(b))

Staff were able to provided documented evidence of training and the assessment of their competence to provide information to patients consenting to treatment, donation or donation to research. (SLC T15(b))

An audit of information giving procedures against the centres SOP and competence matrix has been conducted this year and the results documented. No corrective actions were noted to be required. Staff stated that in the event that actions were required they would be discussed at the multidisciplinary meeting and action logged. (SLCT36)

The centre's website directs the reader to a link to the HFEA website data on success rates for reference without separate comment is therefore considered compliant with the requirements of Chairs letter CH(11)

What the centre could do better.
Staff asked described that they measure the effectiveness of their information giving process against the SOP and monitor patient feedback but quality indicators relevant to the information given prior to consent being sought have not formally been established. (SLC T35)

Consent

- Consent to treatment, storage, donation, training and disclosure of information (Guidance Note 5)
- Consent to legal parenthood (Guidance Note 6)

What the centre does well.

Centre staff provided evidence that written consent is obtained from patients prior to treatment and the centre has a documented SOP for obtaining consent (SLC T33 (b)).

Centre staff explained that photographic evidence is used to verify patient/partner identity and is cross referenced with primary documentation prior to treatment being given. Copies of photographic identification were seen in the patient notes reviewed on inspection (CoP Guidance 5.10).

Ten sets of patient records were reviewed on inspection. All had appropriately completed consent forms.

Quality indicators relevant to consent procedures are measured against the centre's SOP and staff competence matrix documents (SLC T35) which form part of their audit process which was last conducted this year. No non-conformities were noted. (SLC T36)

Consent to legal parenthood:

SOP's were seen to be in place to obtain the relevant written records of consent to parenthood (SLC T33(b)). Staff interviewed on inspection confirmed that information regarding legal parenthood is given. Staff demonstrated an understanding of the process for consenting and the need to ensure that should a nominated second parent withdraw their consent the named woman would not be treated until she was informed (SLCT64(b))

Eight sets of records of patients who had undergone treatment using donor sperm were reviewed. Consent to legal parenthood was obtained appropriately in all cases.

What the centre could do better.
Nothing noted.

3. Protection of gametes and embryos

Focus

The purpose of the inspection was to assess whether the centre has respect for the special status of the embryo when conducting licensed activities

Legal Requirements [Human Fertilisation and Embryology Act 1990 (as amended)]

- Licensed activities only take place on licensed premises
- Only permitted embryos are used in the provision of treatment services
- Embryos are not selected for use in treatment for social reasons
- Embryos are not created by embryo splitting
- Embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman
- Embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies
- Embryos which are or have been stored are not given to a person, other than in the course of providing treatment services, unless that person is a person to whom a licence applies
- No money or other benefit is given or received in respect of the supply of gametes or embryos unless authorised by the Authority

What the centre does well.

Discussions with the PR and a tour of the centre demonstrated that the activities authorised by the centre's licence are carried out at the premises specified in the licence or that of a third party (SLC T1).

All staff at the centre has respect for the special status of the embryo when carrying out assisted conception treatment services and only permitted embryos are used in the provision of treatment services.

Donor compensation
The centre keeps a record of all reimbursements made to donors, and has adapted their SOPs in consideration of the changes introduced from 1 April 2012 in Directions 0001, evidence was provided that no money or benefit is given or received for the supply of gametes or embryos in contravention of Directions 0001.

What the centre could do better.
Nothing noted.

Storage of gametes and embryos

- Storage of gametes and embryos (Guidance Note 17)

What the centre does well.
The is an SOP for the storing of gametes and embryos (SLC T33(b)) and procedures for storage have been validated using professional body guidance and published studies. (SLC T72) Evidence was provided that all material currently in storage is within the

gamete providers consent and statutory storage periods and that gamete providers are screened in accordance with standard licence condition T50 prior to storage of their gametes or embryos created with their gametes and there are mechanisms in place to identify when additional screening may be required.

Quality indicators relevant to storage procedures are in place (SLC T35) and have been audited against. No non-conformities were noted. (SLC T36)

The centre operates a 'bring forward' system to ensure gamete providers have sufficient notice of the end of their consented storage period.

What the centre could do better.
Nothing noted.

Distribution and / or receipt of gametes and embryos

- Distribution of gametes and embryos (Guidance Note 15) – *only applicable for centres that has distributed or exported gametes and / or embryos*
- Export of gametes and embryos (Guidance Note 16) – *only applicable for centres that has exported gametes and / or embryos*
- Receipt of gametes and embryos (Guidance Note 15) – *only applicable for centres that has received gametes and / or embryos*
- Import of gametes and embryos (Guidance Note 16) – *only applicable for centres that has imported gametes and / or embryos*

What the centre does well.

An SOP was seen to be in place detailing the circumstances, responsibilities and procedures for the release of stored material before distribution. (SLC T33b)

A checklist was seen detailing information provided when distributing material (SLC T110) and the required transport conditions are specified.

The centre is currently considering implementing a system of continuous temperature monitoring for gametes and embryos in transit. Containers and packages used for the transport of gametes and embryos are validated as fit for purpose before use (SLC T108) and packaged in such a manner as to minimise the risk of damage or contamination. (SLC T105) Containers are labelled and accompanied by the required documentation. (SLC T107)

What the centre could do better.
Recall of gametes an embryos
The centre does not have a procedure in place that defines the responsibilities and actions required when a distribution is recalled, for handling returned gametes and embryos or the investigation of any recall as an adverse incident. (CoP mandatory requirements 15B)

Whilst it is recognised that the centre does not currently initiate the transport of gametes to or from the centre, this being done by the centre to provide or receive the gametes or embryos, it was noted that there was no third party agreement in place with the specialist courier should it be necessary to use them.

Use of embryos for training staff (Guidance Note 22)
What the centre does well. The centre does not currently use embryos in the training of staff.
What the centre could do better.

4. Good governance and record keeping

Focus

The purpose of the inspection was to assess whether the centre:

- maintains accurate records and information about all licensed activities
- conducts all licensed activities with regard for the regulatory framework governing treatment involving gametes and 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-operates fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare

Record keeping

- Record keeping and document control (Guidance Note 31)

What the centre does well.

All patient/partner and donor records seen at the time of inspection were seen to be clear, legible and well organised. Each record was seen to include: patient/donor first name, surname, date of birth, age, sex, details of how the patient/donor had been identified (passport/driving licence), the treatment provided; a medical history; welfare of the child assessment; relevant documented consents and clinical and laboratory data and the results of tests carried out (SLC T46). Procedures are in place to ensure records are protected from unauthorised amendment; are retained and can be retrieved throughout the designated retention period (SLC T47).

Documents submitted to the HFEA as part of the renewal application and viewed on inspection were seen to be controlled, recording the history of document reviews and systems are in place to ensure that only the current version is in use and accessible to staff (SLC T34).

What the centre could do better.
Nothing noted.

Legal requirements [Human Fertilisation and Embryology Authority 1990 (as amended)]

- Obligations and reporting requirements of centres (Guidance Note 32)

What the centre does well
The PR provided all information as required by the application process prior to inspection. All members of staff cooperated fully with the inspection team and all further information requested at the time of and post inspection was provided in a timely manner.

The PR has fully implemented the recommendations from previous inspections with no outstanding issues.

Data submission SOPs are in place ('Completion of HFEA data forms' and Entering HFEA

data into EDI') and were supplied in advance of the inspection (SLC T33b).

HFEA form submission error rates are used as quality indicators (SLC T35) and a regular periodic programme of audit has been established and copy reports were provided prior to inspection (SLC T36).

Relevant staff were able to provide evidence of having received training in submitting data to the HFEA (T15(a)).

What the centre could do better

To determine whether all licenced treatment activity is reported to the HFEA within required timescales, a sample of treatments recorded within the centres laboratory records ('Red Books') was compared to data submitted by the centre for inclusion on the register.

Some licenced treatment data that the HFEA is required to hold on its register had not been provided by the centre at the time of inspection. In two instances this involved treatments in which donor gametes were used and which potentially affects the Authority's ability to fulfil statutory duties to donors and the donor- conceived.

1 (circa 1%) of the123 IVF and 2 (circa 4%) of the 51 DI treatments within the sample had not been reported to the Authority. Less than 10% of the treatments were reported within 5 working days as required.

Disclosure of information

- Confidentiality and privacy (Guidance Note 30)
- Disclosure of information, held on the HFEA Register, for use in research

What the centre does well.

Confidentiality and privacy

A tour of the centre confirmed that access to all confidential information is restricted to authorised personnel (SLC T43). Access to the centre is restricted and key pad locks provide additional restriction to sensitive areas. A tour of the centre confirmed that patient records are stored securely.

The centre ensures that information about people having treatment, donors and children born as a result of assisted conception is not disclosed unless authorised to do so.

Consent to treatment, storage, donation and disclosure of information

The centre is seeking consent to the disclosure of information, held on the HFEA register of information to medical or other researchers.

To determine whether the register properly reflects the consent given by patients and their

partners for the use of register information for research purposes, a sample of 16 completed patient and partner disclosure consents was reviewed against disclosure consent data supplied by the centre with other patient and partner registration data for inclusion on the register. Except for the two instances detailed below all patient and partner disclosure consents were found to be accurately reflected on the HFEA Register.
What the centre could do better. A discrepancy was found between two of the 16 patient and partner consent disclosure consents reviewed against consent data submitted to the HFEA for inclusion on the register. In both instances the patient and partner appear to have initially ticked ‘No’ to the ‘Generic Research’ and then crossed this through on the form and then selected ‘Yes’. Both forms record consent as being given for both the ‘Generic’ and ‘Contact’ research categories, though the consent data submitted to the register records that consent has been withheld.

5 Changes / improvements since the previous inspection on 16 June 2010

Area for improvement	Action required	Action taken as evidenced during this inspection
Some elements of the centre's witnessing practice had not been audited for compliance with approved protocols. SLC T36	Audit for compliance to be completed by 1 November 2010	An audit was completed by the due date and a more recent rolling audit was available for review on inspection. No further action required.
Quality indicators relevant to witnessing procedures had not been established. SLC T35	Quality indicators to be agreed by 1 November 2012 and monitored against going forward.	Quality indicators were established and incorporated into a revised witnessing SOP by 6 October 2010. Evidence was available on inspection demonstrating that quality indicators are monitored and a biennial audit is conducted of compliance with SOPs and required record keeping. No further action required.
Continued competence to perform manual and electronic witnessing procedures had not been assessed at a specific frequency. SLC T12 and T15(a)	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 to have been completed by 1 November 2010.	Annual re-evaluation (or sooner if a change is made to the SOP) of competence to witness is conducted for all staff performing this task. An SOP has been developed to direct annual competence assessment for all critical tasks, including witnessing and was provided to the HFEA in October 2010. Evidence of continued competence assessment having been conducted was recorded in the staff skills and competencies matrix seen on inspection. No further action is required.
It was noted that there were a number of discrepancies between the consent to disclosure to research recorded in patient records held by the centre and that	The PR was recommended to conduct an audit of consent to disclosure decisions recorded in patient records against the decision registered with the HFEA and any discrepancies	The results of the audit for required period and subsequent corrective actions were provided to the HFEA in October 2010.

recorded through the electronic data interface (EDI) for submission of information to the HFEA and consequently recorded on the HFEA register. Direction 0005.	identified to be reconciled accordingly by 1 November 2010 and the cause of the errors be rectified.	A review of further sample number of consent to disclosure consent decision record in patient records against the decision recorded on the HFEA register conducted on inspection revealed a number of discrepancies. Further action is required.
The centre's sperm donor SOP and checklist did not direct that the donor's identity should be verified in accordance with the centre's SOP for patient identification. 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 was to have been completed by 1 November 2010.	A revised SOP was provided to the HFEA in October 2010. The active identification of patients / donors using verified photo ID was seen in practice during procedures observed on inspection. No further action is required.
The centre's SOP for the recruitment of donors did not specify the age criteria for selection though in practice age criteria is enforced.	The SOPs and checklists should be modified to include an assessment of the donor's age, as happens in practice at the centre. Action to have been completed by 1 November 2010.	The SOPs for the recruitment of donors has been update to reflect the relevant age criteria as per HFEA and professional body guidelines and were provided to the HFEA in October 2010 and were seen to have been reviewed and updated on inspection. No further action required.
The donor screening SOPs and checklists did not fully comply with professional body guidelines and CoP guidance 11.5 in that they did not specify the requirement for the potential donor to undergo a physical examination or for the assessment of the risk of prion disease.	Donor screening SOPs 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.	The SOP has been revised several times since the last inspection and was reviewed prior to this inspection. No further action is required.
The third party laboratory which conducts the analysis of embryo biopsies for pre-implantation screening is not CPA (UK) Ltd accredited.	The PR was to advise PGD service that the centre must use a PGD service which is appropriately accredited. The PGD service should therefore	The PGD laboratory service in question provides a service to a number of licensed treatment centres nationally. The PR has communicated

	gain appropriate accreditation as rapidly as possible. The PR should advise the Executive when this will be. This action to have been completed by 1 February 2011.	with the service provider and updated the HFEA on the current position. The update from the service provider as of 25 June is that final submission of documentation is currently being made to the CPA and they await and assessment date. Further action required.
Not all equipment used in the processing of gametes and embryos were recorded in the patient record or other log retained to ensure traceability. SLC T2	The PR should ensure all equipment and materials used in the critical work area for the processing of gametes and embryos which might affect their quality should be traceable. Action to have been complete by 1 November 2010.	The PR gave assurance that traceability record templates have been amended to ensure all relevant equipment and materials used are traceable. Practice observed on inspection supported this. No further action required.
At the time of inspection the laboratory manager was awaiting registration with the Health Professionals Council. (HPC) Guidance 2.18(c)	The PR was to inform the centre's inspection when his registration was complete or in the event that there was some obstacle in achieving this.	Information confirming the laboratory manager's HPC registration has been received. No further action is required.

Areas of practice that require the attention of the Person Responsible

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

Critical area of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

Major area of non compliance

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

- which poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several “other” areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
The laboratories with whom the centre as a third party agreement for pre-implantation genetic screening (PGS) and pre-implantation genetic diagnosis (PGD) in not CPA (UK) Ltd accredited.	Whilst it is recognised that the PR has periodically updated the HFEA regarding the status of the testing laboratory's application for CPA (UK) Ltd accreditation, it is remains the responsibility of the PR to ensure that diagnostic testing is conducted in an appropriately accredited laboratory. The PR is to update the HFEA when information is received regarding progress with accreditation and if any further barriers to the anticipated assessment process occur. As this service is provided to a number of licensed centres the HFEA will also monitor progress with the accreditation of this laboratory separately. The PR is to update the HFEA as to progress reported to the centre by the service provider quarterly and by 14 December 2012 in the first instance.	We have been informed that the laboratory concerned is currently awaiting inspection by the CPA, and will up date us as soon as they have a date for the inspection. In the meantime we are exploring other options should there be further issues with this, in order to ensure an uninterrupted service.	The Executive notes and is satisfied with the PR's response to this recommendation. Progress with the awaited CPA accreditation will be monitored. The PR is to notify the centre's inspector if any changes to the third party providing genetic screening and diagnostic services are planned. No further action is required at this time.

1 (circa 1%) of the123 IVF and 2 (circa 4%) of the 51 DI treatments audited had not been reported to the Authority. Less than 10% of the treatments were reported within 5 working days as required. SLC T9(e) & T41 and Direction 0005	The PR must ensure that data which the Authority is required to hold on its Register is provided within the timeframe specified in Directions. The process for submitting licensed treatment data to the authority should be reviewed and where appropriate enhanced to ensure licensed treatment activity is reported to the Authority and compliance with submission timeframes detailed in Direction 005 is achieved (immediately). It is recommended that the centre's internal audits include a sample check process to ensure the authority has been notified of all licensed treatment activity recorded in laboratory records, and that notification occurs within the required timeframe required by Direction 0005 To be completed by 14 September 2012)	The pathway for completion and submission of these forms has been altered and we will be monitoring the effect. We have are also preparing a business case for additional admin staff to help with this. There is an ongoing audit process to ensure that all forms have been submitted, and we will be monitoring the progress with improving the timeframe (see above).	The registry department of the HFEA report that the all absent donor registrations have been submitted and few reporting errors remain outstanding. No further action required.

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
There are no third party agreements in place with: • the neighbouring hospital for the surgical procurement of sperm • the specialist courier service • the histology laboratory used for testing sperm samples for a specific group of patients who have undergone surgical sperm recovery in a separate unit SLC T111	The PR should establish a third party agreement with each of the organisations described. In so doing it should be ensured that the agreement with the surgical unit within another Trust where surgical sperm recovery is conducted is compliant with SLC T117 and that the agreement with the separate histology department is compliant with SLC T114(f) specifically. To be completed by 14 September 2012	The third party agreement with the Genetics and laboratories Directorate, which provides histology and other pathology services, as well as genetic screening, is now signed and in place. We do have third party agreements in place with UHB for both normal surgical sperm retrieval and trauma banking (separate agreements) – apologies for the confusion. These were checked by our inspector at that time and approved prior to sign off. However, these were signed in 2010 and we are currently reviewing them (although we do not foresee and issues or changes. Agreements have been drafted and sent to the two courier companies that we have had contact with. We are currently awaiting comments	The Executive notes the PR response to this recommendation. No further action is required.

		prior to the final sign off.	
Donor selection and recruitment procedures have not been audited against approved protocols, quality indicators or regulatory requirements within the last two years. SLC T36	An audit of these processes should be completed and the results documented by 14 December 2012.	These have been audited and amended several times in the last two years, and were seen to have been updated at the recent inspection.	The PR's response to this recommendation is noted. A copy of the relevant audit was provided. No further action is required.
Staff were not able to provide documented evidence of the assessment of their competence to conduct donor recruitment and assessment procedures. SLC T15(b)	All personnel involved in this process should have their competence to perform these tasks assessed by a suitably qualified and experienced person and the outcome of that assessment documented. To be completed by 14 December 2012	These are now all in place.	No further action required.
A discrepancy was found between two of the 16 patient and partner consent disclosure consents reviewed against consent data submitted to the HFEA for inclusion on the register. These discrepancies could mean that the consent	The PR must ensure that going forward the centre develops a process to identify when there is a need to submit disclosure consent variation form data to the Authority and to ensure it is submitted in such circumstances (immediately).	We have identified the source of these errors as timing for entering this information on the relevant forms, and this should be addressed by the new procedures as mentioned above.	The registry department report good progress with the correction of these errors and that only a very small number remain. No further action is required.

expressly given by a patient and/or partner is frustrated and the pool of data available to researchers is reduced. Chair's Letter CH(10)05 Guidance supplementary to Chair's Letter CH(10)05 and amended Directions 0005 and 0007	*(NB. The Centre's designated HFEA Form Returnee has been provided with the relevant patient number to facilitate the submission of consent variation data).*		

Additional information from the Person Responsible

HFEA Executive Licensing Panel Meeting

21 September 2012

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

Minutes – Item 1

Centre 0119 – (Birmingham Women's Hospital) – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Mark Bennett, Director of Finance & Facilities (Chair) Rachel Hopkins, Head of Human Resources Paula Robinson, Head of Business Planning	Joanne McAlpine

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

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that this centre has been licensed by the HFEA since 1992, and provides a full range of regulated assisted fertility services to both NHS and self-funding patients.

2. The Panel noted that the centre has additionally been licensed to perform embryo testing since May 2010.

3. The Panel noted that the centre recruits egg and sperm donors, has an egg share programme and occasionally treats couples requiring surrogacy. The centre also provides a facility for the storage of gametes and/ or embryos for the preservation of fertility.

4. The Panel noted that between 1 May 2011 and 30 April 2012, the centre conducted 461 cycles of in vitro fertilisation (IVF) and 379 cycles of intracytoplasmic sperm injection (ICSI).

5. The Panel noted that the centre's IVF/ICSI data for the period of December 2011 to November 2012 show the centre's success rates are in line with national averages.

6. The Panel noted that for 2011 the centre reported 163 cycles of partner insemination with 14 pregnancies. This equates to a 15% pregnancy rate, which is in line with the national average.

7. The Panel noted that, at the time of the inspection, there were a number of areas of practice that required improvement including two major and four other areas of non-compliance or poor practice that required improvement.

8. The Panel noted that, since the inspection, the Person Responsible (PR) has provided evidence to the Inspectorate that one major and four other areas of non-compliance have been addressed.

9. The Panel noted that the PR has given a commitment to implement the further major area of non-compliance within the timeframes highlighted in the report.

10. The Panel noted that the Inspectorate recommended that the centre's licence is renewed for four years with no additional conditions.

11. The Panel noted that the centre had implemented the majority of the recommendations made from the previous inspection, except for the CPA accreditation of the testing laboratory. The PR has given a commitment to implement this recommendation within the described timeframe.

Decision

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

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

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

15. The Panel was satisfied that the premises to be licensed were suitable for the conduct of licensed activities based on the evidence provided within the report.

16. The Panel noted that the centre does not currently use embryos for training purposes.

17. The Panel had regard to 'Guidance on periods for which new or renewed licences can be granted'. The Panel took into account matters set out in paragraph 4.3 and noted paragraph 4.4 of the guidance which states that the Executive Licensing Panel will normally grant a renewal licence for treatment/storage/non-medical fertility services licences for a period of up to four years where the evidence before it reveals no concerns in the matters specified in paragraph 4.3.

18. The Panel agreed it had no major concerns. However, it noted there were two areas with outstanding or incomplete actions from the previous inspection, and urged the PR to complete these as indicated in the report.

19. The Panel endorsed the Inspectorate's recommendations. The Panel agreed to renew the centre's licence for a period of four years with no additional conditions.

Signed: Date: 2 Oct 2012
Mark Bennett (Chair)