Renewal Inspection Report

Date of Inspection: 22 April 2010
Length of inspection: 8 hours
Inspectors: Paula Nolan, Sara Parlett, Andrew Riddle
Operation Audit: Chris Hall, Siobhan Kelly

Inspection details:
The report covers the pre-inspection analysis, the visit and information about the centre received between 24 March 2009 – 1 July 2010.

Date of Executive Licensing Panel: 15 July 2010

Purpose of the Inspection report
The purpose of the inspection is to assess whether centres are complying with the HF&E Act 1990 (as amended), the HF&E Act 2008 and the Code of Practice to ensure that centres are providing a quality service for patients. The report summarises the findings of the 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	Homerton Fertility Centre
Centre Number	0153
Licence Number	L0068/14/b
Centre Address	Homerton University Hospital, Homerton Row, London, E9 6SR.
Telephone Number	0208 510 7660
Person Responsible	Mr Anil Gudi
Licence Holder	Ms Nancy Hallett
Date Licence issued	01/10/2009
Licence expiry date	31/08/2010
Additional conditions applied to this licence	None

Contents

Brief description of the centre and its licensing history:
Homerton Fertility Centre holds a treatment and storage licence. The centre has been licensed for treatment since 1995 and is located on the site of the Homerton University Hospital NHS Trust. On the 15 October 2008, the centre's licence was varied to:

- Re-locate the clinical and some laboratory areas to new premises at the same address,
  Homerton University Hospital, Homerton Row, Hackney London, E9 6SR and
- Change the centre's name to Homerton Fertility Centre (from Homerton Fertility Unit).

Following the move into new premises all administrative, patient consultations and most clinical work is carried out in the new premises. Egg collections are carried out in a designated theatre in the Trust's day surgery unit which is located in the same building. Embryo and sperm storage remain in the original cryo store area covered by this licence.

There is a temporary storage facility in the new laboratories with separate storage tanks for sperm and embryos. Embryos and sperm are frozen in the new laboratories and then transferred to the cryo store on a weekly basis. These tanks are alarmed and monitored by the Facility Monitoring System (FMS) along with the other equipment in the new centre.

The PR explained that the centre plans to pursue new developments over the next year:

- To set up a satellite with Spire Roding hospitals.
- A business plan has been submitted to the Trust to build a new laboratory to enable HIV positive patients to receive IVF treatment. The service will be supported by the HIV service at the Homerton hospital.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period (1/12/2008 – 30/11/2009*)
In Vitro Fertilisation (IVF)	453
Intracytoplasmic sperm injection (ICSI)	269
Frozen embryo transfer (FET)	67
Intra uterine insemination (IUI) (01 Jan 2009 – 31 Dec 2009)	180
Donor insemination (DI)	119

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

*These data were extracted from the HFEA register for the period 1/12/2008 – 30/11/2009. 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 inspectorate considers that it has 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 Person Responsible (PR) is suitable and has discharged his duty under section 17 of the HF & E Act 1990 (as amended). The PR has successfully completed the HFEA Person Responsible Entry Programme (October 2007) and has discharged the responsibilities described in Licence Condition T9;
- On inspection the premises appeared suitable for licensable activity;
- On inspection the practices appeared largely suitable for licensable activity;
- The centre has submitted appropriately completed documentation in support of the application for renewal of its licence and has met the requirements of paragraph 16 of General Directions 0008;
- The centre has paid the required application fee to the HFEA in accordance with requirements.

Recommendation to the Executive Licensing Panel:

Version: 0

Trim:

The inspectorate wishes to make particular note of the following:

The PR and staff have developed and implemented a comprehensive quality management system that encompasses detailed quality objectives, quality indicators and detailed standard operating procedures (SOPs). The audit scheme is comprehensive, rigorously implemented and cross referenced with their quality management programme. Audit outcomes are discussed by the whole team at regular meetings and corrective action implemented, documented and evaluated

The inspectorate considers that, overall there is sufficient information available to recommend the renewal of this centre's licence for a period of 4 years without additional conditions.

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

Outstanding recommendation from the previous inspection report:

- At the time of the inspection two cryopreserved samples from six noted at the time of the previous inspection remained in storage without written consent. In the draft report it was recommended that the PR should, as a matter of urgency, ensure compliance with the requirements of the Human Fertilisation and Embryology Act in relation to the storage of gametes.
  Subsequent to the inspection and review of the draft report the PR provided an update on 20 May 2010 confirming that after successfully contacting both patients these samples have now been discarded.

New recommendations

- The centre has a third party agreement with a courier company for the transporting of gametes and embryos. This third party agreement does not define the transport conditions nor has the requirement for the maintenance of those conditions been documented (Licence Condition T107). The PR should ensure that all transport conditions, such as temperature and time limit are defined and maintained during distribution.

- Where sperm is procured at home the centre must record this in the gamete provider's records.

- The PR should ensure that the centre performs HTLV- 1 antibody testing, prior to storage, for patients living in or originating from high incidence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas.

- The laboratory performs andrology services for GPs and the PCT however the laboratory is not CPA accredited. To comply with Licence Condition T21 the PR must ensure that diagnostic laboratory tests are carried out by a qualified laboratory, which has suitable accreditation (for example by CPA (UK) Ltd or another body accrediting to an equivalent standard.

- The PR should ensure that all critical equipment and technical devices are identified and validated.

Details of Inspection findings

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

Focus

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

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

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

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

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

- **Areas of concern** – The analysis of the centre's self assessment questionnaire and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked during the inspection visit to this centre:
    - There were no areas of concern identified prior to the on site inspection.

▶ Take account of the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth (Principle 4).

Evidence of how the centre demonstrates compliance with this principle

Welfare of the child: Guidance Note 8
The PR and staff provided verbal and written evidence that before any woman is provided with any treatment services account is taken of any child born as a result of treatment by staff at the centre (Licence Condition T58). If staff have any concerns they will bring them to the monthly management meeting for further discussion. Welfare of the child assessments and the requirement to complete a questionnaire is part of the information provided to patients before any treatment is considered (Code of Practice 8th Edition (CoP) guidance 4.2 (b)).

During interview staff described how they can access further information about the patient and their partner from the general practitioner, social services or other support services (with the patient's consent) including referral to the full time counsellor if thought beneficial. The counsellor is available for both staff and patients/partners to discuss or further explore any issues that may be raised when considering the welfare of any child born as a result of treatment.

At the time of the inspection the HFEA operation audit team reviewed six sets of patient records: all welfare of the child questionnaires were seen to be present, complete and signed as required (Licence Condition T56).

What the centre does well.

What they could do better.

Nothing noted at the time of inspection.

▶ Conduct all licensed activities with skill and care and in an appropriate environment, in line with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring (Principle 7).

Evidence of how the centre demonstrates compliance with this principle

Surrogacy: Guidance Note 14

The centre offers surrogacy treatment and the centre's patient information showed that patients are treated in the same way as other donors, including the requirement for quarantine of donor sperm (Licence Condition T53 (c)).

Donor assisted conception: Guidance Note 20
Staff interviewed explained that it is mandatory for patients having treatment with donor gametes to undergo counselling prior to the treatment. Patient information as well as discussions with staff highlighted the importance of informing children of their donor origins (CoP guidance 20.7 – 20.8).

Quality management system: Guidance Note 23
The PR has implemented a computer based quality management system that reflects the quality improvement requirements of the CoP (Licence Condition T32). As part of the system there is a clearly articulated quality manual along with training and reference manuals that were seen to be readily accessible by all members of staff (Licence Condition T33). Within the quality manual there are SOPs covering all aspects of the centres licensable activities. The quality policy is displayed in the patient waiting area (CoP guidance 23.7 (b)).

The quality manager post is shared between the operational manager and a senior clinician. During the course of inspection the quality managers provided established quality indicators for the centre's licensable activities including indicators for: consent, provision of information, witnessing, gamete and embryo storage, intracytoplasmic sperm injection (ICSI), procurement and processing of gametes, confidentiality, submission of data to the HFEA, adverse incidents, welfare of the child assessment and counselling (Licence Condition T35).

A comprehensive index of the documents was provided prior to inspection and the documents were reviewed as part of this inspection. A documented audit schedule showed that licensed activities are audited for compliance with SOPs and quality indicators (Licence Condition T36). It was seen in meeting minutes that audit results, discrepancies and corrective actions are discussed in management and team meetings and any required action plans implemented. The quality management system is reviewed every two months and minutes of these meetings were provided during the course of the inspection.

Key performance indicators are set for a number of processes, including fertilisation rates, clinical pregnancy rates and live birth rates. Thresholds, under which corrective action is taken are reviewed on a monthly basis and discussed at the relevant team meetings.

What the centre does well.
The PR has put in place a wide ranging quality management system. The quality managers provided detailed evidence of audit outcome, discussion and corrective actions.

The PR and staff have developed and implemented a comprehensive quality management system that encompasses detailed quality objectives and quality indicators. The audit schedule is comprehensive, rigorously implemented and cross referenced with the quality management system. Audit outcomes are discussed by the whole team at regular meetings and corrective action implemented, documented and evaluated.

What they could do better.

Nothing noted at the time of inspection.

▶ Ensure that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose (Principle 8).
Evidence of how the centre demonstrates compliance with this principle **Witnessing: Guidance Note 18** The centre has documented SOPs for the processes to be followed for witnessing laboratory and clinical processes. The SOPs identify where patient identification and all the critical points of the clinical and laboratory processes require double checking (Licence Condition T71). Five sets of patient notes audited on inspection were found to include all required witnessing steps, including the name and signature of the person witnessing the procedure A list of names, titles, signatures and initials of all witnesses are kept on the centre's electronic quality management system (CoP guidance 18.8). Three instances of witnessing were observed during inspection and the embryologist was seen to check the patient's name, date of birth and unique patient number and cross check this information against the patient's notes (CoP guidance 18.5). **Third party agreements: Guidance Note 24** A binder containing written agreements established with those third parties who provide goods and services that influence the quality and safety of gametes is in place (Licence Condition T111, T115).
What the centre does well.
What they could do better. **Third party agreements: Guidance Note 24** The centre has a third party agreement with a courier company for the transportation of gametes and embryos. The third party agreement does not define the critical transport conditions nor has the requirement for the maintenance of those conditions been documented (Licence Condition T114 (e) (f)).
▶ Ensure that all staff engaged in licensed activity are competent and recruited in sufficient numbers to guarantee safe clinical and laboratory practice (Principle 9).
Evidence of how the centre demonstrates compliance with this principle **Staff: Guidance Note 2** An organisational chart defining accountability and reporting relationships for the centre was seen to be appropriate (Licence Condition T11). A review of meeting minutes and discussions with staff provided evidence that there is good communication between staff and that each member of staff has adequate supervision and professional line management. Staff training folders provided evidence of basic, initial and ongoing training. Staff from different disciplines were able to provide evidence of training and appropriate continued professional development (Licence Condition T15) and mandatory training (including fire

and life support training) (Licence Condition T15 (c)). All staff, where appropriate, were seen to be registered in accordance with the relevant professional and/or statutory bodies (Licence Condition T14).

The PR undertakes an annual workforce assessment. This has recently enabled the centre to recruit two more embryologists and one doctor. The PR explained that the centre intends to increase the number of treatment cycles provided by two hundred over the next 12 months (up to 800 cycles). Therefore a further workforce assessment will be carried out to ensure that the centre has an adequate number of staff to accommodate the increase of cycles.

It appeared at the time of inspection that personnel in the centre are available in sufficient number for the present activity and work load and are qualified and competent for the tasks they perform (Licence Condition T12).

What the centre does well.

The PR explained that when a doctor comes to the end of his or her contract they overlap for one month with the next doctor employed. The newly employed doctor is supernumerary for that month allowing him or her to observe clinical procedures such as embryo transfer as well as sitting in on patient counselling sessions, familiarising themselves with the Code of Practice and the centre's SOPs and policies.

What they could do better.

Nothing noted at the time of inspection.

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

Evidence of how the centre demonstrates compliance with this principle

Adverse incidents: Guidance Note 27

The PR has reported a small number of adverse incidents to the HFEA including 4 diagnoses of Ovarian Hyper-Stimulation Syndrome (OHSS) since the last inspection. All reporting has been done in a timely manner in compliance with Licence Conditions T118, T120, T121 and Direction 0011.

Evidence was provided to the inspectorate that the centre has established and implemented a documented SOP to report, investigate, register and report information about adverse incidents (Licence Condition T118).

A review of the minutes from team and management meetings at the centre showed that incidents had been discussed in some detail and corrective actions planned and implemented.

Complaints: Guidance Note 28

The centre has, and adheres to, a complaints procedure. There is a designated nominated member of staff identified as a first point of contact to deal with complaints (CoP guidance 28.4). The centre also participates in the Homerton University Hospital NHS Foundation Trust complaints process. If a complaint cannot be resolved informally it will be escalated through to the complaints office and Chief Executive of the Trust for investigation and resolution (guidance 28.6).

A complaints information notice is displayed in the main waiting area detailing the complaints procedure and who to contact. Staff at the centre maintain a log of all complaints and their resolution. A review of complaints and any remedial actions are reviewed as part of the quality management system and documented in meeting minutes.

What the centre does well.

Following the recent reporting of OHSS incidents the PR carried out an audit of the centre's practice and revised the associated protocol. A copy of the audit, action plan and revised protocol was submitted to the HFEA prior to the inspection.

What they could do better.

Nothing noted at the time of inspection.

2. Patient Experience

Focus

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

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

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

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

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

    - Not all samples currently stored at the centre have valid written consent.

▶ Treat prospective and current patients and donors fairly, and ensure that all licensed activities are conducted in a non-discriminatory way (Principle 1).
Evidence of how the centre demonstrates compliance with this principle **Treating people fairly: Guidance Note 29** The centre has developed and implemented eligibility criteria for treatment based on clinical/scientific standards and professional guidance. Each commissioning body (PCT)) has its own funding eligibility criteria that the centre follows. The PR provided evidence that all patients/partners are provided with treatment carried out in licensed premises by staff trained and competent to perform their jobs. All patients/partners are provided with treatment using the same SOPs, follow the same patient pathway and are treated by the same members of staff. The centre provides all patients/partners with information leaflets that detail very clearly the types of treatment funded by the different commissioning PCTs and who is eligible for NHS funded treatment. Patient/partner literature is primary available in English and the PR explained that leaflets can be provided in different languages/formats upon request. A translation/advocacy service is also readily available from the Trust. As part of the Trust's mandatory induction programme all staff undergo equality and diversity training that is updated annually.
What the centre does well.
What they could do better. Nothing noted at the time of inspection.

▶ Have respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors (Principle 2).
Evidence of how the centre demonstrates compliance with this principle **Counselling: Guidance Note 3** The availability of counselling is described in the initial information pack sent to patients (Licence Condition T58 (f)) and patients are encouraged to make an appointment with the counsellor. It is mandatory for patients undergoing treatment with donated gametes to undergo counselling prior to treatment. Contact details and promotional materials are also available for patients/partners in the waiting area. The counsellor can be contacted via a referral from centre staff or a telephone number is available for self referral if the patient prefers. The centre employs a full time, suitably qualified counsellor who has worked at the centre for six years. She holds a recognised counselling qualification; is accredited by the British Association for Counselling and Psychotherapy and is currently applying for accreditation from the British Infertility Counselling Association (Licence Condition T14). **Confidentiality and privacy: Guidance Note 30** A tour of the centre confirmed that patients are provided with an acceptable level of privacy and comfort and patient records are stored in an appropriately secure location. All treatment, scanning, consultation and counselling rooms appeared to be suitable for the purpose for which they are used including confidential discussions and personal physical examination and treatment. The PR stated that new members of staff have training in the confidentiality requirements and this was evidenced in the staff training records. All computer terminals in the centre are password protected to prevent unauthorised access (Licence Condition T45). The PR provided a SOP describing how information is kept confidential and how access is controlled to health data and records (Licence Condition T43).
What the centre does well.
What they could do better. Nothing noted at the time of inspection.

▶ Give prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions (Principle 5).
Evidence of how the centre demonstrates compliance with this principle **Information to be provided prior to consent: Guidance Note 4** The PR provided fifty three patient information leaflets prior to inspection, most of which are easily available from the centre's website (CoP guidance 4.2 and 4.4). Leaflets were available in the main waiting area and distributed by staff when required. The centre holds an information evening for prospective patients on the first Wednesday of the month. The information provided contains details of the natures of the treatments available, consequences and risks, analytical tests, confidentiality, consent and the availability of counselling (Licence Condition T58). Patient questionnaires are used to assess the feedback from patients/partners about the quality of information given to them. Audits are carried out, against quality indicators, of patient records to check that there is a record of the information provided and that the record is consistent with the consent forms signed (Licence Condition T35 & T36). **Costed treatment plans** A "schedule of fees" is given to self funding patients in the information pack prior to their first appointment and gives comprehensive details of charges. This information is also available on the centre's website. The cost of treatment is discussed with self funding patients following their initial consultation and once a specific treatment plan has been drawn up, a personalised costed treatment plan is discussed and provided during their second consultation at the centre (CoP guidance 4.3).
What the centre does well.
What they could do better. Nothing noted at the time of inspection.

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

Evidence of how the centre demonstrates compliance with this principle

Consent to treatment, storage, donation and disclosure of information: Guidance Note 5

The PR provided evidence that written consent is obtained from patients/partners and donors before any form of treatment or donation is provided (Licence Condition T57). The operational manager provided a copy of the SOP for the process to be followed when obtaining consent (Licence Condition T33b). Training files for medical and nursing staff indicated that competencies for taking consent are updated annually (Licence Condition T12). The PR has established quality indicators relevant to consent procedures and audits to assess the accuracy of consent taking are scheduled to take place this year.

Five sets of patient notes were examined during the inspection and found to contain effective consent including consent for the disclosure of information to researchers. Copies of patient photo identification were observed in the patient notes and staff confirmed that ID is checked when consent is provided (CoP 5.10).

Legal parenthood: Guidance Note 6

Legal parenthood requirements are documented in the centre's "consent" SOP (Licence Condition T60). The PR explained the procedures to be followed when a patient or their partner withdraws their consent to parenthood (Licence Condition T64 and T65).

The PR showed the inspectorate a power point presentation from a meeting that all staff attended regarding legal parenthood and the new consent forms.

What the centre does well.

What they could do better.

Consent to treatment, storage, donation and disclosure of information: Guidance Note 5

Samples for two patients (gametes) are being stored without written consent. The Human Fertilisation and Embryology (HFE) Act 1990 (as amended) states in Schedule 3, section 8 (1) A person's gametes must not be kept in storage unless there is an effective consent by that person to their storage and they are stored in accordance with the consent.

At the time of inspection the PR was aware of this issue as it was also an area of non compliance raised at the previous inspection (six samples being stored without written consent). The laboratory director had provided a copy of the centre's annual gamete and embryology storage audit (January 2010) prior to the inspection that also highlighted the two samples being stored without written consent.

The PR should, as a matter of urgency, ensure compliance with the requirements of the Human Fertilisation and Embryology Act in relation to the storage of gametes. The PR explained that he was in the process of obtaining both legal advice and advice from the Trust's Caldecott Guardian in relation to obtaining written consent for the samples.

Relative success rates from the HFEA held register data 1 January 2006 to 31 December 2009 show the centre's success rates are in line with national averages.

Evidence of how the centre improves its live birth rates and reduces the number of multiple births

Multiple births (Guidance note 7)

The PR has complied with HFEA Directions 0003. A Multiple Birth Minimisation Strategy (MBMS) was submitted to the HFEA by the date required and includes all requirements in Directions 0003. The MBMS, SOP and outcomes have been audited and a report presented to the inspectorate prior to the onsite inspection.

Information about the risks associated with multiple pregnancy are fully discussed with the patient and evidence of this is recorded in the patient's notes. Patient information about single embryo transfer is present in the initial patient information pack and on the centre's website.

A log is kept for patients who request a double embryo transfer when they fit the criteria for a single embryo transfer. The PR confirmed that the risks associated with multiple pregnancy are fully discussed with the patient and evidence of this is recorded in the patient's notes.

A spreadsheet detailing all three embryo transfers was seen at inspection, compliant with Directions 0003. It was observed that no three embryo transfers were performed on patients under the age of 40 (CoP guidance 7.4).

What the centre does well

What the centre could do better

Nothing noted at the time of inspection.

3. Protection of embryos

Focus

- **Safe procurement, processing, storage, application and disposal of gametes and embryos** – gametes and embryos must only be procured, processed, used, stored and disposed off in accordance with the law
- **Areas of concern** – The analysis of the centre's self assessment questionnaire and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked during the inspection visit to this centre:
    - Where sperm is procured at home, the centre must record this in the gamete provider's records.
    - Validation of critical equipment.
    - The laboratory carries out andrology analysis although it is not accredited by the CPA (UK) Ltd or an alternative body accrediting to an equivalent standard.
    - HTLV-1 antibody testing for patients.

▶ Have respect for the special status of the embryo when conducting licensed activities (Principle 3).

Evidence of how the centre demonstrates compliance with this principle

Procuring, processing and transporting gametes and embryos: Guidance Note 15

The laboratory director and senior embryologist confirmed that validation of critical processing procedures has been carried out. A master list of all SOPs was submitted, and covers all critical procedures conducted at the centre: these included sperm preparation, IVF and witnessing (Licence Condition T33b).

Quality indicators relevant to procurement and processing have been developed and audited each month. Outcomes and any corrective actions are discussed and documented at management meetings (Licence Condition T35).

The centre has a sperm production room. The laboratory director explained that sperm can also be produced by the male partner at home and when this occurs an "off site production of semen samples form" is completed.

Storage of gametes and embryos: Guidance Note 17

The cryoroom containing dewars of stored samples was seen at inspection and the dewars were seen to be secure and alarmed (Licence Condition T24) and relevant safety notices were on display (CoP guidance 25.14).

The centre stores sperm, oocytes and embryos, and the centre's semen freezing and embryo freezing SOPs and operating policy for the dewar room were seen at inspection. Prior to storage the providers of gametes and embryos are screened for HIV, Hepatitis B and Hepatitis C (Licence Condition T50).

Patients are written to six months before the expiry of their consent to storage of gametes and embryos as part of the "bring forward" system. This ensures advance notice of the end of the statutory storage period for gametes and embryos in storage (CoP guidance 17.17).

What the centre does well.

What they could do better.

Procuring, processing and transporting gametes and embryos: Guidance Note 15
The centre keeps a copy of the “off site production of semen samples form” in the laboratory. To comply with Licence Condition T68 where sperm is procured at home, the centre must record this in the gamete provider’s records.

Storage of gametes and embryos: Guidance Note 17
To comply with Licence Condition T50 the PR must ensure that the centre performs HTLV-1 antibody testing, prior to storage, for patients living in or originating from high incidence areas or with sexual partners originating from those areas or where the donor’s parents originate from those areas.

Ensure that all premises, equipment, processes and procedures used in the conduct

of licensed activities are safe, secure and suitable for the purpose (Principle 8).

Evidence of how the centre demonstrates compliance with this principle

Imports and exports: Guidance Note 16

The laboratory director confirmed that the requirements of Directions 0006 are complied with for import and export of embryos and gametes. A gamete movement report extracted from the Registry data showed that no imports or exports between 1 October 2009 and 20 April 2010 occurred under general directions, where the destination would indicate that special directions were required.

Traceability: Guidance Note 19

The centre's "Traceability SOP" was submitted to the HFEA (Licence Condition T33 (b)). The laboratory traceability system was discussed at inspection (Licence Condition T99). Evidence was provided that all containers (dishes, vials, ampoules, tubes etc) used at all stages of the procurement, processing and storage process are labelled with the patient's full name and further identifier (Licence Condition T101).

Data on traceability was seen to be recorded and kept for the required length of time (Licence Condition T103) on the centre's commercial software programme (IDEAS). This ensures that relevant data relating to anything coming into contact (including equipment) with gametes or embryos is traceable and can be easily identified from the software programme (Licence Conditions T22 & T99).

ICSI: Guidance Note 21

The centre's "ICSI" SOP was seen at inspection to describe the ICIS process in detail. The laboratory director confirmed that ICSI rates are reviewed per embryologist on a monthly basis.

Premises and facilities: Guidance Note 25

The activities authorised by the licence are carried out in the premises specified in the licence (Licence Condition T1). A copy of the Certificate of Licence was displayed in the patient waiting area (Licence Condition T5). Documented air quality test reports and discussions with the laboratory director showed that the environment where gametes and embryos are processed achieves Grade A air quality, with a background of Grade B air quality (Licence Condition T20).

Equipments and materials: Guidance Note 26

At the time of inspection staff at the centre provided documented evidence of regular cleaning and disinfection of equipment, the maintenance and regular inspection of equipment in accordance with manufacturer's instructions and that all equipment that effects critical processing or storage parameters are subject to monitoring, alerts and alarms (Licence condition T23, T24 and T26). The centre has an on call rota for response to alerts or alarms including, dewars and incubator alarms, out of opening hours. All medical devices used are CE marked, where possible (Licence Condition T30).

What the centre does well.

What they could do better.

Premises and facilities: Guidance Note 25

The laboratory director explained that the centre performs andrology services for GPs and the PCT however the laboratory is not CPA accredited. To comply with Licence Condition T21 the PR should ensure that laboratories that undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, must obtain accreditation by CPA (UK) LTD or another body accrediting to the equivalent standard. The PR should keep the inspectorate informed of progress in the diagnostic laboratory gaining CPA accreditation.

Equipments and materials: Guidance Note 26

Some but not all critical equipment has been validated (Licence Condition T24). At the time of the inspection the PR was aware of this non compliance and had completed the pre inspection self assessment questionnaire accordingly. To comply with Licence Condition T24 the PR should ensure that all critical equipment and technical devices have been validated.

4. Good governance and record keeping

Focus

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

- **Areas of concern** – The analysis of the centre's self assessment questionnaire and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked during the inspection visit to this centre:
  - There were no areas of concern identified prior to the inspection.

Maintain accurate records and information about all licensed activities (Principle 10).

Evidence of how the centre demonstrates compliance with this principle

Record keeping and document control: Guidance Note 31
The PR has developed a SOP to be followed when submitting data to the HFEA in compliance with the requirements of Directions 0005 (Licence Condition T33a).

Quality indicators for record keeping have been established and activity audited against SOPs. The HFEA quality assurance officer confirmed that any errors in submission are discussed with centre staff and corrected promptly.

All patient/partner records reviewed at the time of inspection were seen to be clear, legible, very well organised and complete. Each record reviewed was seen to include: patient's first name, surname, date of birth, age and sex. Details were seen of how the patient has 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 (Licence Condition T46).

The centre's traceability SOP details that records are maintained for 30 years after clinical use (Licence Condition T48).

Operational Audit Summary
To determine whether all licensed treatments are reported to the Authority as required by Directions 0005, a sample of treatments undertaken between 01/01/09 and 31/12/09 were reviewed. The sample was drawn from the centre's IDEAS system. An attempt was made to match each treatment in the audit sample to data held on the statutory register.

We found all 231 licensed treatments in the audit sample (inc. 125 IVF and 106 DI treatments) had been reported to the Authority by the audit date.

Of our sample of 231 treatments only 6 (circa 5%) of the 125 IVF sample treatments and 41 (ca. 39%) of the 106 DI sample treatments had been notified to the Authority within five working days as required by Directions 0005.

To ascertain the quality of the data submitted by the centre for inclusion on the statutory register, 81 sets of assorted form data submitted to the Authority between 01/01/09 and 31/12/09 were reviewed. Data included on the register was reviewed against source documentation held on site (i.e. principally patient and donor records). 18 (22%) sets of form data contained an error or omission. None of the errors/omissions were in critical fields and none were indicative of significant systemic or systematic error/omission.

What the centre does well.

What they could do better.

Nothing noted at the time of inspection.

▶ Conduct all licensed activities with regard for the regulatory framework governing treatment and research involving gametes or embryos within the UK, including: maintaining up-to-date awareness and understanding of legal obligations responding promptly to requests for information and documents from the HFEA, co-operating fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare (Principle 13).
Evidence of how the centre demonstrates compliance with this principle 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 responded to the recommendations from the previous inspection with one exception. However the PR has provided an update regarding the steps he has taken to try and resolve this issue.
What the centre does well.
What they could do better. Nothing noted at the time of inspection.

5. Changes / improvements since the last inspection on 24 March 2009

Area for improvement	Action required	Action taken as evidenced during this inspection
The centre has a few errors that need to be corrected to comply with Direction 2008/6 Collection, conformation and publication of Register data - 1/10/08.	The PR should resolve any issues that lead to errors in data reporting to the HFEA.	The PR explained that the centre has now employed an additional administrator for data reporting. The HFEA quality assurance officer confirmed that there are no outstanding data submissions.
As at the time of this inspection, during the demonstration of the bring forward system, it was observed that the centre was storing cryopreserved material for six patients without written consent. Section 3(3)(c) of the Human Fertilisation and Embryology Act 1990, as amended, states that "A licence cannot authorise keeping or using an embryo in any circumstances which regulations prohibit its keeping or use"; Schedule 3 prohibits keeping embryos without written, 'effective', consent. Section 41(1) (b) states that "A person who – does anything which, by virtue of section 3(3) of this Act, cannot be authorised by a licence is guilty of an offence and liable on conviction on indictment to imprisonment for a term not exceeding ten years or a fine or both."	The PR should, as a matter of urgency, ensure compliance with the requirements of the Human Fertilisation and Embryology Act in relation to the storage of gametes and embryos and 1. notify the lead inspector of the date of the monthly audit and 2. submit to the inspectorate, until the date of the next inspection: a) the results of the monthly audit of expired consents within seven days of the audit being conducted, and b) all documentary evidence of the steps taken to obtain the written consent to satisfy the requirements of the HFE Act, 1990, and c) an action plan of how the PR will assure that this breach is avoided from now on.	The PR has provided regular updates including six monthly audits regarding progress on contacting the six patients. At the time of this inspection sperm samples for two patients are being stored without written consent. The PR explained that he has developed an action plan and will provide an update in the “areas of practice that require the attention of the Person Responsible” section of this report.
It was noted at inspection that not all staff working at the centre have: initial basic	The PR should review the requirement of licence condition A.10.11 to ensure	The PR explained that this referred to one member of staff. A general administration

and update training or competence assessments. This does not meet the requirements of licence condition A.10.11.	that this condition is met for all staff.	officer was drafted in to cover an unexpected absence. The PR provided evidence that all members of staff have initial, basic and updated training and annual competency assessments.
The PR may also wish to consider the guidance in G.13.4.4 as to auditing the witnessing procedure to ensure compliance with regulations. At inspection, a review of the IVF witnessing procedure, identified a need to add and/or clarify steps in the freezing/thawing process.	It is recommended that the PR reviews the template witnessing records and updates it to include the steps missing in the current procedure.	The PR explained he has reviewed the practice and included steps to witness every aspect of the freezing and thawing process. These changes have already been made for witnessing these specific areas. The laboratory sheets have also been changed. On inspection the witnessing SOPs were reviewed and found to be compliant with Licence Condition T71.

Assessment of compliance with statutory requirements

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

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

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

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

Licence Condition	Assessment
Equipment and Materials	
T22	Fully Compliant
T23	Fully Compliant
T24	Not Compliant
T25	Fully Compliant
T26	Fully Compliant
T27	Fully Compliant
T28	Fully Compliant
T29	Fully Compliant
T30	Fully Compliant
T31	Fully Compliant
Quality Management	
T32	Fully Compliant
T33	Fully Compliant
T34	Fully Compliant
T35	Fully Compliant
T36	Fully Compliant
Records and Information	
T37	Fully Compliant
T38	Fully Compliant
T39	Fully Compliant
T40	Fully Compliant
T41	Fully Compliant
T42	Fully Compliant
Data protection and Confidentiality	
T43	Fully Compliant
T44	Fully Compliant
T45	Fully Compliant
Patient Records	
T46	Fully Compliant
T47	Fully Compliant
T48	Fully Compliant
Patient Selection Criteria and Laboratory Tests	
T49	Fully Compliant
T50	Not Compliant
T51	Fully Compliant
Donor Selection Criteria and Laboratory Tests	
T52	Fully Compliant
T53	Fully Compliant
T54	Fully Compliant
T55	Fully Compliant

Licence Condition	Assessment
Welfare of the Child, Provision of Information, Counselling and Consent	
T56	Fully compliant
T57	Fully Compliant
T58	Fully Compliant
T59	Fully Compliant
T60	Fully Compliant
T61	Fully Compliant
T62	Fully Compliant
T63	Fully Compliant
T64	Fully Compliant
T65	Fully Compliant
Procurement of Gametes and Embryos	
T66	Fully Compliant
T67	Fully Compliant
T68	Not Compliant
T69	N/A
T70	Fully Compliant
Processing and Use of Gametes and Embryos	
T71	Fully Compliant
T72	Fully Compliant
T73	Fully Compliant
T74	Fully Compliant
Storage of Gametes and Embryos	
T55	Fully Compliant
T76	Fully Compliant
T77	Fully Compliant
T78	Fully Compliant
T79	Fully Compliant
T80	Fully Compliant
T81	Fully Compliant
T82	Fully Compliant
T83	Fully Compliant
T84	Fully Compliant
T85	Fully Compliant
Embryo Testing	
T86	N/A
T87	N/A
T88	N/A
T89	N/A
T90	N/A
T91	N/A

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

HFEA Directions	
HFEA Directions	**Assessment**
0001 Gamete and embryo donation	Compliant
0003 multiple births	Compliant
0005 Collecting and recording information for the HFEA	Compliant
0006 Import and export of gametes and embryos	Compliant
0007 Consent	Compliant
0008 Form and content of applications	Compliant
0009 Keeping gametes and embryos in the course of carriage between premises	Compliant
0010 Satellite and transport IVF	n/a
0011 Reporting adverse incidents and near misses	Compliant
0012 Time periods for retention of records	Compliant

Areas of practice that require the attention of the Person Responsible

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

Critical area of non compliance

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

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
At the time of the inspection two sperm samples were being stored without written consent. This non compliance was also noted at the previous inspection.	The Human Fertilisation and Embryology (HFE) Act 1990 (as amended) states in Schedule 3, section 8 (1) A person's gametes must not be kept in storage unless there is an effective consent by that person to their storage and they are stored in accordance with the consent.	The PR should, as a matter of urgency, ensure compliance with the requirements of the Human Fertilisation and Embryology Act in relation to the storage of gametes. The PR should provide the lead inspector with all documentary evidence of the steps taken to obtain the written consent to satisfy the requirements of the HFE Act 1990 (as amended).	By the time this report is presented to the Executive Licensing Panel (15 July 2010)	See additional information from the PR at the end of the report.	The PR provided an update on 20 May 2010 explaining that he has made contact with both patients and the samples have now been discarded. Therefore this is no longer an area of non-compliance.

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	Reference	Action required	Timescale for action	PR Response	Executive Review
The centre has a third party agreement with a courier company for the transportation of gametes and embryos. The	Licence Condition T114 (e) (f)	The PR should ensure that the third party agreement defines the critical transport conditions and the requirement for maintenance of those conditions.	3 months	A new TPA that includes all the necessary conditions to comply with the CoP has been drafted by the Laboratory Director and been sent to the	It is recommended that the Executive continues to monitor progress. Evidence of compliance to be submitted within the prescribed timeframe.

third party agreement does not define the critical transport conditions nor has the requirement for the maintenance of those conditions been documented.				Courier company for acceptance or for any amendment if that is necessary. A final version will be signed before the end of June 2010.	
Where sperm is procured at home, the centre must record this in the gamete provider's records. This information is currently held in the laboratory.	Licence Condition T68	The PR should ensure that a record is kept in the gamete provider's records.	immediately	This information is currently recorded on the laboratory treatment sheet, and a copy of this is filed in the patient notes at the end of treatment. The appropriate protocols have been modified accordingly.	This response is considered to be satisfactory. This area of practice will be reviewed at the next inspection.
At present the centre does not performs HTLV- 1 antibody testing, prior to storage, for patients living in or originating from high incidence areas or with sexual	Licence Condition T50	The PR should ensure that HTLV- 1 antibody testing for patients living in or originating from high incidence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas is	immediately	I have written an information sheet and instructed the team to perform HTLV-1 antibody testing on all patients coming for treatment. Due to the varied ethnic mix of our population, we plan to carry out this test on all our patients for IVF/ICSI treatment and for all	It is recommended that the PR provides the Executive with a copy of the information sheet and updated checklist. This area of practice will be reviewed at

partners originating from those areas or where the donor's parents originate from those areas.		performed.		known sperm donors. We have asked for some more information from the consultant virologist regarding the advice about testing in our group of patients. The checklists have been changed so that patients coming for treatment will have the test checked. We are also awaiting advice about the referral pathway for patients who test positive. Following the recommendation we may change the testing protocol. At present I have asked the test to be done on all patients coming for treatment.	the next inspection.
The centre performs andrology services for GPs and the PCT although the laboratory is not CPA (UK) accredited.	Licence Condition T21	The PR must ensure that diagnostic laboratory tests are carried out by a qualified laboratory, which has suitable accreditation (for example by CPA (UK) Ltd or another body accrediting to an equivalent standard.	The PR should provide an action plan by the time this report is presented to the Executive Licensing Panel (15 July 2010)	The Laboratory Director has contacted the CPA (UK) and exploring the various options of an application. The CPA advised us that either we send in a joint application with our Pathology department or to apply on our own. While we consider these options the formal application	The PR should provide quarterly reports to the inspectorate on the accreditation process until full accreditation is achieved.

				forms are being prepared and we intend to send them before the end of July 2010.	
Some but not all critical equipment has been validated.	Licence Condition T24	The PR should ensure that all critical equipment and technical devices have been validated.	3 months	We are currently in the process of validating all our laboratory equipment. The most critical equipment such as incubators, class II cabinets, heated stages and microscopes has been validated at this point. The validation of the remaining equipment to be completed by the end of July 2010.	The PR should provide a report to the inspectorate on the progress of the remaining critical equipment that requires validation by 31 July 2010. This area of practice will be reviewed at the next inspection.

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

Additional information from the Person Responsible

Page 3 – About brief description
The entire laboratory and the Andrology laboratory was moved into new premises while the Embryo and sperm storage continued to be stored in the old premises with modifications.

Procuring, processing and transportation of gametes and embryos
We have 1 procurement room. Think it has been mentioned as 2 on the report[1].

Storage of 2 sperm samples
Following the previous inspection we took significant steps to change the system of discarding gametes and embryos. The new team of embryologists and PR in the past 2 years has changed the system to allow for the compliance with the code of practice.
During this process few samples of Oncology patients remained, and the task of finding these patients took a long time. We had informed the HFEA about these 2 samples in the past and were asked to try and contact the patients. Being oncology patients we were worried of discarding the samples, since all our search suggested that the patients were alive. Our fear was that by discarding these samples we would cause harm to these patients. One of the oncology patients made repeated appeals to continue freezing of his samples, but eventually declined to send the consent form. We eventually managed to track the 2nd patient's details and confirmed that both patients had received letters informing them about discarding of the samples and the samples were then discarded following their failure to respond.

[1] Changed from 2 to 1 in relevant section of the report.

HFEA Executive Licensing Panel Meeting

15 July 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – item 1

Homerton Fertility Centre (0153) Renewal Report

Members of the Panel:	
Peter Thompson, Director of Strategy & Information (Chair)	Committee Administrator: Joanne McAlpine
Mark Bennett, Director of Finance & Facilities	
Carmel Dodson-Brown, Head of Clinical Governance and Patient Safety	

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:

- Papers for Executive Licensing Panel (72 pages)
- Supplementary Bundle in accordance with Direction 0008

The Panel also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings of the Authority's Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Direction 0008 (where relevant), and any other relevant Directions issued by the Authority;
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- Indicative applications guidance on the time period for which licences should be granted approved by the Authority on 21 October 2009
- Indicative sanctions guidance approved by the Authority on 18 March 2009
- Licence application and any relevant documentation

1. The Panel considered the papers for this item, which included a renewal inspection report, a renewal application form and Licence Committee minutes from the previous three years.

2. The Panel noted that the renewal inspection took place on 22 April 2010 and lasted eight hours.

3. The Panel noted that this is a large treatment and storage centre that has been licensed since 1995 and is located on the site of the Homerton University NHS Trust.

4. The Panel noted that in 2008 the licence was varied in order to re-locate some of the clinical and laboratory areas to new premises at the same address, and to change the centre's name to Homerton Fertility Centre.

5. The Panel noted that, following the variation of the licence in 2008, egg collections are carried out in a designated theatre in the Trust's day surgery unit located in the same building. Embryo and sperm storage remains in the original cryo store area covered by this licence.

6. The Panel noted that there is a separate storage facility in the new laboratories with separate tanks for sperm and embryos, and the embryos and sperm are then transferred across to the cryo store on a weekly basis.

7. The Panel noted that the Person Responsible (PR) intends to put a plan in place next year to set up a satellite with Spire Roding hospitals. In addition, a business plan has been submitted to the Trust to build a new laboratory to enable HIV positive patients to receive IVF treatment. The service will be supported by the HIV service at the Homerton hospital.

8. The Panel noted the Inspectorate's recommendation to renew the centre's licence for a period of four years with no additional conditions.

9. The Panel noted that the centre has addressed most of the recommendations identified by the Inspectorate, and noted that the PR has developed and implemented a comprehensive quality management system.

10. The Panel noted that the storage of two patients samples without consent had been identified by the Inspectorate as outstanding. The Panel noted that the PR has contacted both sets of patients and the samples have now been discarded.

11. The Panel noted that the centre has implemented its Multiple Births Minimisation Strategy, has complied with Direction 0003 and commended the PR for the centre's efforts in this.

<u>The Panel's Decision</u>

12. The Panel referred to the decision tree for granting and renewing licences, and noted that the application fee had been paid.

13. The Panel noted that the Person Responsible had completed the PR Entry Programme (October 2007) and there were no issues regarding the character, qualifications or experience of the PR or his ability to discharge his duties under Section 17 of the HFEA Act 1990 (as amended).

14. The Panel noted the premises and equipment and agreed that they were suitable based on the evidence in the report.

15. The Panel referred to the indicative sanctions guidance and the regulatory principles for granting and renewing of licences.

16. The Panel agreed that there is evidence to suggest a good compliance and licensing history the PR is co-operative and has responded well to the areas identified in the report and has either addressed these areas or is in the process of addressing them.

17. The Panel agreed to renew the centre's licence for a period of four years with no additional conditions and endorsed the recommendations of the Inspectorate highlighted within the report and the relevant timescales.

Signed.....Date.....26/07/10.
Peter Thompson (Chair)