Inspection Report

Date of Inspection: 31 March 2011
Purpose of inspection: Interim inspection of treatment and storage licence

Length of inspection: 6 hours

Inspectors: Ellie Suthers, Sara Parlett, Paula Nolan.

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 25 November 2008 and 10 June 2011

Date of Executive Licensing Panel: 24 June 2011

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 interim inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Authority's Executive Licensing Panel which makes the decision about the continuation of the centre's licence.

Centre details

Centre Name	Assisted Reproduction and Gynaecology Centre
Centre Number	0157
Licence Number	L0157/23/c
Centre Address	13, Upper Wimpole Street, London, W1G 6LP
Telephone Number	0207 486 1230
Person Responsible	Mr Mohamed Taranissi
Licence Holder	Mr Mohamed Taranissi
Date Licence issued	01/06/2009
Licence expiry date	30/06/2012
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

The Assisted Reproduction and Gynaecology Centre (ARGC) is a privately owned centre and has held an HFEA licence for the provision of various assisted reproductive treatments (ART) since 1995. The present licence is for a three year time period.

The ARGC also has a separately licensed "sister" centre (Reproductive Genetics Institute RGI) located approximately 250 metres from the ARGC premises. Depending on the types of treatment patients and their partners may receive treatment and/or care on both sites. All staff, policies and processes are common to both centres. For example all gametes and embryos are stored at the RGI and the system for administering and maintaining consent for storage is carried out on site at the ARGC.

The patients' pathway will always begin at ARGC with consultations, treatment planning, diagnostic investigations, information provision, counselling and documentation of effective consent occurring at ARGC. Following egg collection, treatment may continue at ARGC or eggs may be transferred to RGI for fertilisation, embryo culture and embryo transfer. Any follow-up care required further to embryo transfer or treatment usually occurs at ARGC.

The Person Responsible (PR) is the Medical Director; has been at the centre since it opened and has successfully completed the HFEA PR Entry Programme (PREP).

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 31/12/2009 – 01/01/2011
In vitro fertilisation (IVF)	327
Intracytoplasmic sperm injection (ICSI)	878
Frozen embryo transfer (FET)	227
Intra uterine insemination (IUI)	No cycles reported to HFEA.
Donor insemination	0

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

Outcomes*
For IVF/ICSI, HFEA held register data for the period 2009 show the centre's success rates are above national averages in all treatment and age groups.

*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 system

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 draw a conclusion on the continuation of the centre's licence.

The Executive Licensing Panel is asked to note that there are a number of areas of practice that require improvement, including five areas of major non-compliance and five other areas of non-compliance or areas of poor practice. Note that there are no areas of critical non compliance.

The Executive Licensing Panel is also asked to note that because of the nature of the administrative and managerial relationship between ARGC and RGI that a number of the non compliances are common to both centres. These commonalities are indicated in the main body of the report.

The Inspection team recommends that the Executive Licensing Panel requires that the Person Responsible complies with recommendations in the following areas of practice within the prescribed timeframes set out in the inspection report:

- Cryopreserved embryos stored beyond consented storage period;
- Validation of critical equipment and processes;
- Multiple births minimisation;
- Documentation of embryo biopsy audit;
- Submission of registry forms and consent to disclosure of information to the HFEA;
- One third party agreement;
- Accuracy of standard operating procedures;
- Documenting competency assessments.

Recommendation to the Executive Licensing Panel

The inspection team considers that, overall there is sufficient information available to recommend the continuation of this centre's licence without additional conditions. In making this recommendation it is noted that the PR has responded to some of the recommendations made in this inspection report and further improvement is required in some areas of practice.

Details of Inspection findings

1. Focus of inspections for 2010-12

Providing information to patients in relation to costed treatment plans and parenthood
What the centre does well. **Costed treatment plans** A comprehensive list of treatment, procedure and investigation costs is displayed on the centre's website. The list also includes the costs for the centres more specialist services including immune blood screening, hormone profiling and embryo testing. Patients are provided with an individualised costed treatment plan following their first consultation. Two plans reviewed by inspectors contained the main elements of the treatment proposed (including investigations and tests), the cost of that treatment and any possible changes to the plan, including their cost implications. The PR explained that the basic costs are displayed on the centre's website however, because of the nature of some of the more complex treatments and medication provided by the centre care and time is taken to explain where any additional costs may be incurred (Guidance 4.3). **Legal Parenthood** The PR explained that the centre carries out very few donor treatments and that no treatments had been carried out using donor gametes since the last inspection in November 2008 or other treatment where the change in legal parenthood status will have a role. No treatments using donor gametes or embryos have been reported to the HFEA register. The PR demonstrated an understanding of the need for documented consent to legal parenthood by a second parent where relevant and explained that each patient/couple would be treated individually during the consent taking process if donor treatment were to be carried out.
What they could do better. Nothing noted at the time of inspection.

Consent - particularly consent to disclosure to researchers and consent to storage
What the centre does well. **Consent to the disclosure of information held on the HFEA register to researchers** The PR explained that consent to the disclosure of information held on the HFEA register to researchers is discussed with all patients during the first consultation as part of the consent to treatment (and storage) process. Five sets of patient records and consent to disclosure of information to researchers forms were audited at the time of inspection. All consent forms had been completed correctly (Guidance 5.27d). **Consent to storage** The PR provided five sets of patient records that contained relevant completed consent forms for treatment and storage of gametes or embryos. All consent to storage forms stated the maximum storage period. Each consent form was completed to state what should be done with the gametes or embryos if the person giving the consent dies or cannot, because of mental incapacity, withdraw or vary the terms of the consent (HFE Act 1990 (as amended), Schedule 3 2(2) and Standard Licence Condition T57). The PR described the process that staff at the centre would follow if a patient or their partner were to withdraw consent to storage before the expiry of the consented period. Staff at the centre would send the patient and/or partner a withdrawal of consent form which would be stored in the patient's records. The PR demonstrated awareness of the permitted 12 month cooling off period and described the procedure for dealing with any disputes. The PR said that he would personally discuss any issues with both patient and partner and if required they could be referred to the counsellor (Guidance 5.34 and 5.35). The PR provided copies of two standard operating procedures: *Consent to treatment* (Mansop4) and *Completion of consent forms* (Nursop11) that are used at the centre. (Standard Licence Condition T33b).
What they could do better. **Submission of information to the HFEA registry** Five sets of patient records and consent to disclosure of information to researcher's forms were audited at the time of inspection. All consent forms had been completed correctly however, in four instances the information had not been accurately submitted to the HFEA register. The patients and partners had provided consent for their information to be used by researchers however, the centre had reported that the patients and partners had said no. (Standard Licence Condition T9e and Directions 0005) The PR has not provided an annual return to the Authority of any IUI treatments carried out at the centre. (Directions 0005 section 10)

Consent to storage
In response to the self assessment question prior to the inspection visit: *Does the centre have written, effective consent for the storage of all cryo preserved embryos in store?* the PR responded 'no' and reiterated this at the time of inspection (HFE Act 1990 (as amended), Schedule 3 8(2) and Standard Licence Condition T79). At the inspection the PR explained that the embryos in storage where consent has expired are all in storage in the RGI facility. The administration of the "bring forward system", the storage of patient records containing consent forms and the staff who manage the system are located at the ARGC facility.

The embryologist explained that staff at the centre are in the process of contacting the patients to whom the material belongs as described in the centres "bring forward system", however, most of the embryos in storage are from overseas patients and contacting them is proving time consuming.

Following a request by the inspector, after the inspection the PR provided a documented procedure *Action plan for audit of cryopreserved gametes/embryos with expired storage consent.* The procedure describes the steps to be taken to identify patients for whom the consented period has expired and the process to be followed to either extend the consent period or discard any stored material depending on the patient's wishes. The PR provided a copy of a document *consent status of audit of patients for whom the consented storage period for cryopreserved gametes/embryos has expired. April 19th 2011.* This states that an audit of patients for whom consent has expired has been completed and that these patients have been contacted. At the time of the audit 44 patients have returned their consent forms and gametes/embryos have been discarded accordingly. The audit states that patients who have not responded to the reminder will be discussed at a case conference.

The PR has put in place an audit and action plan for addressing the issue of expired consent, however, the centre has embryos in storage beyond the consented storage period (Act, Schedule 3 8(2) and Standard Licence Condition T79).

NB. It should be noted that all staff, policies and processes are common to both centres. All gametes and embryos are stored at the RGI premises and the system for administering and maintaining consent for storage is carried out on site at the ARGC. This major area of non compliance spans both centres and the recommendation is the same for both.

Multiple births

The centre's multiple pregnancy rate for 2008/2009 was 35% with an elective single embryo transfer (eSET) rate of 2.4% for the same time period[1].

What the centre does well.

Background

During discussions the PR and embryologist described the approach taken by staff when reaching a decision as to the number of embryos to be transferred to women. The PR explained that he recognises the potential complications and risks of multiple pregnancies; however, each patient is assessed on an individual clinical basis along with an assessment of embryo development, previous treatment cycles and the woman's age. Further, the PR said that all women are offered monitoring during pregnancy until the time of delivery in order to manage any gestational complications.

The PR explained that 70 – 80% of the women treated at the clinic have received a number of unsuccessful treatment cycles before they present at the ARGC and that the centre treats women in the older age groups (54% of women treated at the ARGC are 38 yrs or over compared with the national average of 35%[2]). The PR added that he treated few women in the under 35 age group who are undergoing their first cycle of treatment where elective single embryo transfer is most successful.

The embryologist explained that the benefits of eSET, where appropriate, along with the risks of multiple pregnancies and multiple births are discussed with patients during their treatment cycle.

What they could do better.

The centre's multiple pregnancy rate of 35% is above the 2008/2009 multiple pregnancy rate target of 30%[2] at a statistically significant level[3]. This is non compliant with the target set by the Authority.

The PR has developed a multiple birth minimisation strategy however the strategy does not appear to be effective in reducing the number of multiple pregnancies and ensuing multiple births resulting from IVF treatment at the centre in line with the Authorities' target.

Staff at the centre have audited their clinical pregnancy rates and live birth rates and the processes supporting these outcomes. However, the staff do not continually review the efficacy of the multiple birth minimisation strategy.

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[1] *This data was extracted from the HFEA's Register data as at 23/06/2010. At this time the HFEA had performed a preliminary validation process in which centres were asked to confirm the accuracy of information on treatment cycles carried out up to and including 30/06/2009 for pregnancy outcomes and 30/06/2008 for live birth outcomes. Some of the information used in this analysis may be subject to change.*

[2] *Age split of patients undergoing fertility treatments and average length of infertility HFEA website 2010*

[3] *This data was extracted from the HFEA's Register data as at 23/06/2010. At this time the HFEA had performed a preliminary validation process in which centres were asked to confirm the accuracy of information on treatment cycles carried out up to and including 30/06/2009 for pregnancy outcomes and 30/06/2008 for live birth outcomes. Some of the information used in this analysis may be subject to change.*

The embryologist and PR explained that the transfer of double and triple embryos is recorded on the centre's own database, in patient records and the number reported to the HFEA. At the time of inspection a summary log containing the reasons for multiple transfer as required by Directions 0003 3c is not maintained. The embryologist said that there are plans to develop and maintain a summary log.

The PR is not compliant with the requirements of Directions 0003. The PR has not met the 2008/2009 multiple pregnancy rate and appears unlikely to meet the Authorities multiple live birth rate target.

Validation of critical equipment and processes

What the centre does well.

The embryologist provided a number of equipment and process validation records derived from the Association of Clinical Embryologist (ACE) template/guidance explaining that the validation of critical procurement and processing procedures is ongoing and almost complete.

Equipment Validation
The centre's *Validation* (labsop67) SOP describes the centre's approach to equipment validation including the requirement for: keeping a history of maintenance; services and repair; calibration against traceable standards and the requirement to use CE marked consumables when available. The embryologist explained that all consumables used at the centre are CE marked, including petri dishes which have recently been awarded CE marking. (Standard Licence Condition T24).

Completed equipment qualification reviews were provided for some laboratory equipment including several incubators. The embryologist explained that any repaired equipment would be revalidated prior to use as and would be recorded in the relevant piece of equipments validation documentation. (Standard Licence Condition T25).

Process Validation
Staff at the centre have made steady progress on the implementation of the process validation plan since the last inspection in December 2010.The embryologist provided the inspector with a process validation folder containing validation documents describing the procedure and test method for a number of processes including preparation of culture dishes, IVF, sperm and embryo freeze and the embryo thaw procedure (Standard Licence Condition T72).

The embryologist provided evidence to show that laboratory key performance indicators such as overall fertilisation rates, pregnancy rates, ICSI fertilisation rates and embryo cleavage rates are monitored quarterly. (Standard Licence Condition T35 and T36).

What they could do better.

The embryologist provided documented evidence to show that the validation of all critical equipment and processes is ongoing , however, is not complete. (Standard Licence Condition T72).

NB. It should be noted that all validation policies and processes are common to the equipment and processes in both centres and are carried out by the same staff. This major area of non compliance spans both centres and the recommendation is the same for both.

Witnessing and assuring patient and donor identification

What the centre does well.

The PR and embryologists interviewed at the time of the inspection provided evidence to demonstrate that staff at the centre double check 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, ensuring patients receive treatment using the correct gametes and embryos (Standard Licence Condition T71).

Patients and partners are asked to provide photographic identification prior to treatment to confirm their identity. An audit of five patient records was seen to contain copies of the patient's passports as a record of identity (Guidance 18.17).

The inspector observed an embryo transfer, all required witnessing steps were carried out at the time of the procedure and documented contemporaneously. The signature of the person performing the procedure and the signature of the person witnessing the procedure is documented in the patient notes. A separate list of the name, status and signature of all staff is maintained.

The PR also provided five sets of patient records from patients in treatment for review as an example of practice by staff. All witnessing records were seen to be correctly completed (Standard Licence Condition T71).

The PR provided an SOP *witnessing* (labsop45) used by staff at the centre that describes the requirements for the witnessing, by two people, at all critical points of the clinical and laboratory process along with the requirement for recording the witnessing in the patients records (Standard Licence Condition T71).

The embryologist explained that although there are no documented quality indicators related to witnessing, the completeness of witnessing documentation is checked by a member of staff when they are uploading patient information to the HFEA via EDI. Each member of the laboratory staff is audited against laboratory SOPs which also includes the witnessing steps of each procedure.

During the process of egg collection, follicular fluid (containing eggs) is transferred into an unlabeled petri dish; any eggs in the fluid are identified and transferred by the embryologist to a labelled patient tube. The petri dish is then immediately discarded. Not labelling the

petri dish is non compliant with Standard Licence Condition T101. During discussion the embryologist explained that he has carried out an assessment of any risks that may present where eggs are placed in an unlabelled dish under these circumstances. He explained that only one sample is ever in the critical working area at any one time and the petri dish is always immediately discarded. The critical work area is always completely cleared prior to the next egg collection procedure. Although this is not compliant with Standard Licence Condition T101 the embryologist has described a series of mitigating actions to avoid risk related to eggs being placed in an unlabeled petri dish at this specific part of the process.

What they could do better.

Standard Operating Procedure
The requirement for witnessing the disposal of cryopreserved gametes/embryos is described in the SOP *witnessing* (labsop45). The embryologist explained the process for the disposal of fresh gametes/embryos including the requirement for witnessing of the disposal, however, this process is not documented in the witnessing SOP (Standard Licence Condition T33b).

In practice staff document the date and time of each witnessing step. This was seen to be recorded in five patient records and also observed during an embryo transfer procedure. The requirement for completing the date and time is not described in the witnessing SOP (Standard Licence Condition T33b).

Gamete and embryo donation – reimbursement, information provision and screening

What the centre does well.

The PR explained that the centre does not actively recruit gamete or embryo donors and it is not the centres policy to pay expenses, reimburse or issue compensation for any donation event.

The PR explained that the only donor treatments provided are when patients have their own 'known ovum donors' and that this is very rarely carried out at the centre. No donor treatments have been reported to the HFEA since the last inspection.

There is a SOP *Ovum Donation* (*NURSOP35*) that describes the process to be followed when evaluating potential ovum donors. The requirements in the SOP include the need for counselling by a registered infertility counsellor, that all the listed consent forms are completed and all required screening requirements are completed. (Standard Licence Condition T52). The laboratory that would be used for carrying out the screening tests for donors is CPA accredited. (Standard Licence Condition T53a).

As no donor treatments have been carried out no audit of patient/donor records was carried out at the time of inspection.

What they could do better.

Nothing noted at the time of inspection

Embryo testing (if applicable)

What the centre does well.

The embryologist explained that the centre does employ a dedicated, trained embryologist in embryo biopsy but that the centre carries out few embryo biopsies. During a biopsy process this embryologist is always observed by another member of the embryologist team for the whole biopsy procedure to ensure that double witnessing is carried out at critical steps. Biopsy procedures are audited for pregnancy rates although, the embryologist explained, this can be difficult as there have been very few biopsies carried out recently. During interview the biopsy practitioner confirmed that biopsied embryos are not transferred in the same cycle as non biopsied embryos (Standard Licence Condition T88a) and that the centre has not carried out sex selection for social reasons (Standard Licence Condition T88d).

The embryologist provided copies of two SOPs Pre Implantation Genetic Screening (PGS) *lapsop 23* and Pre Implantation Diagnosis (PGD) *lapsop 24.* Both SOPs describe the criteria for embryo biopsy, equipment requirements, preparation procedure and the need for witnessing at all stages (Standard Licence Condition T33b).

Blastomeres are sent for analysis to a third party laboratory. This laboratory is accredited by the College of American Pathologists (LAP No 7026301 Exp 29/11/2011). A certificate was accepted by the HFEA as part of a previous PGD/HLA application (Standard Licence Condition T21)

The embryo biopsy practitioner explained that he had initially been trained at the laboratory where biopsy analysis takes place in the USA, that in the past he has been assessed by the HFEA, that regularly attends conferences and biopsy workshops e.g. ESHRE 2010 and is regularly supervised by colleagues and the PR.

What they could do better.

During biopsy one embryologist observes the biopsy practitioner for the whole biopsy procedure and any variation from expected outcomes is analysed at the time; an informal audit is thus carried out at the time of the procedure, however, this is not documented. (Standard Licence Condition T36).

A third party agreement between the centre and testing laboratory was not available at the time of inspection. (Standard Licence Condition T111)

Following embryo biopsy the blastomere is transferred to a glass slide for transport to the testing laboratory and the biopsied embryo is transferred to a culture dish and transferred to an incubator. The embryologist described that in practice the witnessing of these steps

includes double checking of patient name, unique identifier and allocated ‘embryo number’ on each label. The double checking of each ‘embryo number’ is performed but is not recorded as an individual witness step per embryo. Both embryo biopsy practitioners agreed that the witness sheet for PGD is best practice and the witness sheet will be modified to capture each individual witness step.

2. Changes / improvements since the previous inspection on 25 November 2008

Breach	Action required	Inspection 31/03/2011
The average payment time for treatment fees is 73 days. The PR has been reminded of outstanding invoices on a number of occasions. The HFEA payment terms are 28 days. Payment outside these terms is a breach of standard licence condition A.13.3 which states that in consideration of the grant of the licence (or its variation to designate the individual named in this licence as Person Responsible), the Person Responsible agrees that s/he will pay to the Authority any additional fee, as defined in section 16(6) of the Act, within 28 days of the date of the notice of such additional fee.	The PR should pay any amounts still outstanding immediately and take steps to ensure that in future fees are paid within 28 days in compliance with A.13.3 Licence Condition T9(d) 2010	This non compliance was noted but not discussed at the time of this inspection as the PR and the HFEA Finance department are in discussions to find a resolution. Further action and the outcome will be monitored as part of the compliance cycle and reported at the next inspection. Further action required
Different versions of the same document were seen to be available. The index of SOPs and references to these also needs updating and reconciling. Also some document reviews appeared to be overdue. This is a breach of standard S.5.2.5.	Care should be taken to ensure that only the current version of documents is made available. If a protocol is updated within the review cycle a mechanism for updating the hard copy folder should be developed to ensure consistency between hard and electronic records and all reference to documents. The maximum interval between document reviews should be 12 months.	At the time of this inspection all SOPs were seen to be document controlled and within review periods. The PR provided a comprehensive list of laboratory, clinical and administrative SOPs which is part of the quality management system. No further action required
Appropriate consent was seen in all records except one that had incomplete MT and WT forms.	Centre staff should ensure that fully complete consent forms are always present to ensure compliance with S.7.5.4 and A.12.2.	At the time of this inspection an audit of five patient records showed consent forms to be correctly complete. No further action required

Breach	Action required	Inspection 31/03/2011
The HFEA QA department reports that there are recurrent problems with the submission of certain forms. These are predominantly due to forms being submitted outside the timescales in directions D2007/7 and the subsequent directions D.2008/6.	The PR should ensure that forms are submitted to the Authority within the timescales listed in directions D.2008/6.	Registry forms are being submitted outside the timescales laid out in Directions 0005. See page 22 of this report 'recommendations' for further detail. Further action required
No application on the current version of the application form was received for this inspection within 28 days of the information being requested. According to the HF&E Act (1990) section 16, in order for a licence to be granted an application must be made to the Authority in a form approved for the purpose by it. This is also a breach of standard licence condition A.13.2, which states that in support of an inspection the Authority shall be provided, within 28 days of a request in writing being made, with such information as specified in the written request or in Directions. The previous application received is dated 3 May 2007. If the PR wishes to proceed with this application then the centre cannot be licensed for insemination with partner sperm, processing of gametes and/or embryos, treatment with donor embryos, zona drilling or procurement and distribution of gametes and embryos.	An application on the current version of the application form should be submitted.	No retrospective application form has been submitted. This inspection was an interim inspection so no application forms are required. On the day of this inspection the centre submitted a completed Self Assessment Questionnaire (SAQ) on line via the HFEA Portal. The centre is currently licensed for • Storage of eggs • Storage of sperm • Storage of embryos • Insemination • GIFT • In Vitro Fertilisation IVF • Treatment with donor gametes or donor embryos • Pre implantation Genetic Diagnosis PGD • Pre implantation Genetic Screening PGS • Intra Cytoplasmic Sperm Injection ICSI • Procurement and distribution of gametes and embryos • Processing of gametes and embryos • Donor insemination • Use of Embryos in training No further action required

Breach	Action required	Inspection 31/03/2011
There are no formal documented competencies for staff. This is a breach of A.10.9 and S.6.2.9.	The competency of the personnel must be evaluated at appropriate intervals specified in the quality system.	The embryologist provided documented evidence of competency assessments for some laboratory staff. One training folder for a newly appointed embryologist showed documented competency assessments for each critical process as described by the ACE process validation document. The centre participates in NEQAS scheme which is described in an SOP *Inter and intra lab comparisons* (labsop59) and this includes the requirement for feedback and discussion with staff about their results. SOP *induction and training (*labsop61) describes the process of induction, shadowing, working under supervision before working independently. The PR described a process for assessing competence for both clinical and scientific staff in some detail. The process was seen to be recorded on one training folder reviewed on inspection. Further action required

Non compliance

Areas for improvement	Action required	Inspection 31/03/2011
The witnessing SOP does not mention that the date and time of the procedure should be recorded in order to ensure that practice is in compliance with G.13.2.1. It was also noted that this SOP does not specifically mention that egg collection tubes/dishes are labelled with patient ID or checked against patient notes as required by G.13.1.1.	The SOP should be amended to ensure compliance with G.13.2.1 and G.13.1.1.	See page 11 of this report 'Witnessing' for further detail. No further action required
In three sets of witnessing records, the date or time was missing on the witness sheet. In two sets of records there were signatures missing (total of 3 signatures missing).	Witnessing should always be fully documented to ensure compliance with G.13.2.1.	See page 11 of this report 'Witnessing' for further detail. No further action required
Two patients who had PGS treatment had three embryos transferred. This is non-compliance with G.8.5.3.	Where embryos have been screened for aneuploidy, no more than two embryos should be transferred.	No longer an non compliance under the 8th Edition Code of Practice No further action required
The discarding of gametes is not currently witnessed. This is non-compliance with G.13.1.1 (j).	Discarding of gametes should be witnessed.	See page 11 of this report 'Witnessing' for further detail. No further action required

Recommendations

Area for improvement	Time scale
The inspection team were informed that the performance against a number of key performance indicators is assessed, but this is not formally recorded. S.9.2.5 requires that records of audits are kept and the main elements of the quality management system should be subject to internal audit once every 24 months.	The embryologist provided evidence to show that laboratory key performance indicators such as overall fertilisation rates, pregnancy rates, ICSI fertilisation rates and embryo cleavage rates are monitored quarterly but are not recorded. (Standard Licence Condition T35 and T36) Further action required
The protocol for assessing air quality was not being followed. The most recent air quality result was from March 2007. Centre staff should ensure that the frequency of air quality testing is sufficient to ensure that A.10.19 and G.9.4.3 are complied with at all times.	At the time of inspection the embryologist provided a copy of a SOP *Monitoring and maintenance of lab air quality* (labsop 50) that states the requirement for air quality of grade D background and grade C in the flow hood. It also describes the requirement for air filter changes and particle counts six monthly. It also states that any corrective actions should be discussed and implemented where required. The embryologist provided documented evidence that the laboratory environment achieves a grade C air quality tested at several positions in the laboratory and grade A is achieved in the flow hoods (25/11/2010 and 14/10/10 respectively). These are compliant with the requirements of Standard Licence Condition T20. No further action required

3. Areas of concern

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

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
The PR indicated in the centres Self Assessment Questionnaire that the centre has embryos in storage beyond the consented storage period HFE Act, Schedule 3 8(2) and Standard Licence Condition T79.	The centre has embryos in storage beyond the consented storage period.	Further action is required: See page 21 major area of non compliance

Areas of practice that require the attention of the Person Responsible

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

Critical area of non compliance

A critical area of non compliance is an area of practice which poses a significant direct 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
No areas of critical non compliance were identified at this inspection			

Major area of non compliance

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

- which poses an indirect risk to the safety of a patient, donor, 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 reference	Action required and timescale for action	PR Response	Executive Review
The PR has put in place an audit and action plan for addressing the issue of expired consent and provided this to the inspector, however, the centre has gametes and embryos in storage beyond the consented storage period (Act, Schedule 3 8(2) and Standard Licence Condition T79). HFE Act, Schedule 3 8(2) and Standard Licence Condition T79	The PR should ensure that all cryo preserved embryos and gametes are stored within the consented storage period. The PR should provide the inspector with an action plan documenting the number of embryos stored without consent and the number of patients affected. The plan should show the anticipated timeline for contacting the patients and any actions should contact not be established. The action plan and update on progress should be submitted to the inspector by 1 October 2011 **NB:** Please note that this is the same recommendation made for the centres "sister" centre RGI.	The PR has submitted a documented process to be followed by staff to resolve this non compliance. *Verbal response* *The PR said that staff are contacting patients where consent to storage has expired but that this is taking time. It is also difficult to contact some patients and not all are responding quickly.*	Further action required. This will be monitored via the compliance cycle

Area of practice reference	Action required and timescale for action	PR Response	Executive Review
	The PR should conduct a root cause analysis (or similar type of investigation) of the centres "bring forward" procedures in order that they are sufficiently robust to ensure that embryos do not remain in storage beyond the consented storage period. To be completed and submitted to the inspector by 1 October 2011.	No written or verbal response has been received from the PR	Further action required. This will be monitored via the compliance cycle
The embryologist provided documented evidence to show that the validation of all critical equipment and processes is ongoing, however is not complete. Standard Licence Condition T72.	The PR should ensure that all critical equipment and processes are validated. The PR should provide the inspector with an action plan listing the critical equipment for which validation is outstanding and the anticipated timeline for completion of the validation of this equipment. The plan should be submitted to the HFEA by 1 October 2011. Validation of all critical equipment and processes should be completed by January 1 2012. **NB:** Please note that this is the same recommendation made for the centres "sister" centre RGI.	No written or verbal response has been received from the PR	Further action required. This will be monitored via the compliance cycle

Area of practice reference	Action required and timescale for action	PR Response	Executive Review
The PR has developed a multiple birth minimisation strategy, however, the strategy does not appear to be effective in reducing the number of multiple pregnancies and ensuing multiple births resulting from IVF treatment at the centre in line with the Authorities' target. Staff at the centre have audited their clinical pregnancy rates and live birth rates and the processes supporting these outcomes. However, the staff do not continually review the efficacy of the multiple birth minimisation strategy. Directions 0003 3b Standard Licence Condition T36	The PR should audit and review the efficacy of their multiple birth minimisation strategy in reducing the number of multiple pregnancies and ensuing multiple births and consider and address any barriers that may be preventing the centre from achieving the Authorities multiple birth rate target. To be completed and submitted to the inspector by 1 October 2011.	*Verbal response* *The PR reiterated his position as stated previously in this report.*	Further action required. This will be monitored via the compliance cycle

Area of practice reference	Action required and timescale for action	PR Response	Executive Review
During biopsy one embryologist observes the biopsy practitioner for the whole biopsy procedure and any variation from expected outcomes analysed at the time; an informal audit is carried out at the time of the procedure, however, this is not documented. Standard Licence Condition T36	The PR should ensure that the audit carried out at the time of the embryo biopsy is documented. From the date/time of the next embryo biopsy	No written or verbal response has been received from the PR	Further action required. This will be monitored via the compliance cycle
Registry forms are being submitted to the HFEA outside the timescales laid out in Directions 0005 Collecting and recording information for the HFEA. Standard Licence Condition T9 (e). The PR has not provided an annual return to the Authority of any IUI treatments carried out at the centre for 2010/2011(Directions 0005 section 10)	The PR should ensure that data provided to the Authority about activities and data required to be held on the HFEA register of information is accurate and provided within the timescales set out in Directions. The PR should ensure that the centre submits an annual return to the Authority of IUI treatments no later than 28 February in each calendar year. The PR should submit an annual return for IUI treatments or confirm a null return for 2010/2011 by the next verification period 1 October 2011.	No written or verbal response has been received from the PR	Further action required. This will be monitored via the compliance cycle

Other areas of practice that require improvement

Other areas of practice that require 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
Five sets of patient records and consent to disclosure of information to researchers forms were audited at the time of inspection. All consent forms had been completed correctly however, in four instances the information had not been accurately submitted to the HFEA register. Standard Licence Condition T9e and Directions 0005.	The PR should ensure that there are suitable processes in place to ensure that this information is correctly submitted to the HFEA register. To be completed by 1 July 2011. The PR should ensure that all inaccuracies in the centres submissions relating to consent to disclosure of information to researchers to the HFEA are corrected. To be completed by 1 October 2011.	*Verbal response:* *The PR said that his staff would review the process.*	Further action required. This will be monitored via the compliance cycle.
At the time of inspection a summary log containing the reasons for multiple embryo transfer is not maintained. Directions 0003 3c	The PR should ensure that the centre maintains a summary log recording the reasons for multiple embryo transfer as described in Directions. To be completed and a copy submitted to the inspector by 1 October 2011.	No written or verbal response has been received from the PR.	Further action required. This will be monitored via the compliance cycle.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Three areas of witnessing practice were seen to be carried out in practice but are not described in the witnessing SOP. • The disposal of fresh gametes/embryos • Recording the date and time of the witnessing step • The transfer of eggs into a petri dish following egg collection. Standard Licence Condition T33b	The PR should review the SOP *witnessing* (labsop45) and ensure that it reflects actual practice. To be completed by 1 October 2011.	No written or verbal response has been received from the PR.	Further action required. This will be monitored via the compliance cycle.
The PR and embryologist described training, supervision and continued professional development for members of staff, however, competency assessments are not documented for all staff Standard Licence Condition T15a	The PR should ensure that all members of staff have documented competency assessments. By the time of the next inspection.	No written or verbal response has been received from the PR.	Further action required. This will be monitored via the compliance cycle.
A third party agreement between the centre and embryo testing laboratory was not available at the time of inspection. Standard Licence Condition T111.	The PR should ensure that any third party agreement the centre has with the embryo testing laboratory is provided to the inspector. To be completed by 1 October 2011.	No written or verbal response has been received from the PR.	Further action required. This will be monitored via the compliance cycle.

Additional information from the Person Responsible
The inspector met with the PR on 26 May 2011. Verbal comments at this meeting have been added to the PR Response column. There have been no written comments received from the PR or his staff.

HFEA Executive Licence Panel Meeting

24 June 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 2

Centre 0157 (Assisted Reproduction and Gynaecology Centre) – Interim Inspection Report (Treatment and Storage)

Members of the Panel:	Committee Secretary:
Mark Bennett, Director of Finance & Facilities (Chair) Nick Jones, Director of Compliance Juliet Tizzard, Head of Policy	Joanne McAlpine

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

The Panel also had before it:

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

Consideration of Application

1. The Panel noted that this is a privately owned centre and has held an HFEA licence for provision of assisted reproductive treatments (ART) since1995.

2. The Panel noted that this centre has a separately licensed "sister" centre (Reproductive Genetics Institute, RGI) located a short distance from this centre.

3. The Panel noted that, depending on the types of treatment, patients and their partners may receive treatment and/or care at both sites, and all staff, policies and processes are common to both centres.

4. The Panel noted the Inspectorate's observation that because of the nature of the administrative and managerial relationship between this centre and RGI, there are a number of non-compliances common to both centres.

5. The Panel noted the reasons given on the cover page of the report for not providing the usual three previous licensing-related minutes and that such exception would not impact consideration of this item.

6. The Panel noted that this is a large centre that carried out 327 in vitro fertilisation (IVF) treatment cycles, 878 intracytoplasmic sperm injections (ICSI) and 227 frozen embryo transfers (FET) in 2010.

7. The Panel noted that the success rates held on the HFEA register for 2009 show that this centre is above the national average in all treatment age groups for IVF/ICSI.

8. The Panel noted that the Person Responsible (PR) is the Medical Director, has been at the centre since it opened and has successfully completed the HFEA PR Entry Programme.

9. The Panel noted that, at the time of the inspection, the Inspectorate identified a number of areas that required improvement, including five areas of major non-compliance and five other areas of non-compliance or for improvement.

10. The Panel noted there were no critical areas of non-compliance identified.

11. The Panel noted that the HFEA is discussing issues relating to the payment of fees with the centre. This is recorded in the report and the Panel considered this had no significant bearing on its consideration of the report or its findings.

12. The Panel noted that the PR has submitted a documented process to be followed by staff at the centre, to ensure that consent is obtained for all patients gametes and embryos that remain in storage beyond the storage period (Act, Schedule 3 8(2) and Standard Licence Condition

T79. The Panel endorsed the recommendation by the Inspectorate and encouraged the PR to ensure it is fully implemented.

13. The Panel noted that the centre had provided evidence to show that the validation of all critical equipment and processes is ongoing. However, it is not complete in accordance with standard licence condition T72. The Panel endorsed this recommendation and urged the PR to ensure it is implemented.

14. The Panel noted that the centre has a Multiple Birth Minimisation Strategy in place and a post-treatment patient care regime. The Panel also noted the PR's comments relating to patient characteristics. The report identified the centre's multiple pregnancy rate in 2008/09 was significantly higher than the rate to achieve the multiple birth target set by the Authority and that the strategy does not appear to be effective in reducing the number of multiple births. Further, the centre does not keep a summary log of all cases in which multiple embryos have been transferred to patients who meet the criteria for SET, as required by Direction 0003 3c, although it is stated there are plans to do so.

15. There are well-established health risks associated with multiple births and the Authority has set a maximum multiple births rate of 20% for each centre in 2010/2011, decreasing further in 2011/12. The Panel noted the risk reported that the centre may not meet the target live multiple births rate and urged the PR to pay particular attention to addressing this. The Panel endorsed the Inspectorate's recommendation together with the timescale attached to the action.

16. The Panel endorsed the Inspectorate's recommendations for improvements to documenting biopsy audits and in reducing delay in submitting forms and annual returns and urged the PR to ensure implementation.

17. The Panel noted the PR's comments provided verbally as reported on some of the recommendations within the report. It noted the report showed the PR had not commented on or committed to implement seven recommendations identified, three of which were classified as major. The Panel observed it was unusual to have such a limited response to recommendations from a PR.

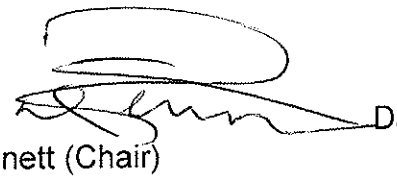
18. The Panel noted the Inspectorate's recommendation that it is satisfied there is sufficient information available to recommend the continuation of the centre's licence with no additional conditions.

Decision

19. The Panel agreed with the Inspectorate's recommendation to continue the centre's licence, with no additional conditions.

20. The Panel encouraged the PR to respond to and implement the outstanding recommendations in the report, in particular action relating to minimising multiple births, within the timescales specified.

21. The Panel requested the Inspectorate to work with the PR to ensure recommendations are implemented. Given the incomplete or lack of response by the PR to some of the recommendations, if the Inspectorate is not satisfied with progress then it should use its discretion in dealing with insufficient progress, for example by conducting a management review or reporting back to the Panel.

Signed:  Date: 6 July 2011

Mark Bennett (Chair)