Inspection Report

Date of Inspection: 29 February 2012 and 1 March 2012
Purpose of inspection: Renewal of Treatment & Storage Licence
Length of inspection: 11 hours
Inspectors: Ellie Suthers, Paula Nolan Emer O'Toole, Ricky Gourd

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 31 March 2011 and 4 May 2012.

Date of Executive Licensing Panel: 18 May 2012

Purpose of the Inspection Report
The purpose of the inspection is to assess whether centres are complying with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the Human Fertilisation and Embryology (HF&E) Act 2008 and the Code of Practice, to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence renewal inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Authority's Executive Licensing Panel which makes the decision about the centre's licence renewal application.

Centre details

Centre name	Assisted Reproduction and Gynaecology Centre
Centre number	0157
Licence number	L0157/23/c
Centre address	13, Upper Wimpole Street, London, W1G 6LP
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 with no additional licence conditions.

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, documented procedures and quality management are common to both centres.

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 (T/1075/7).

The Person Responsible for the Assisted Reproduction and Gynaecology Centre is in the process of challenging the application of Licence Condition T123 (*The centre must not exceed the maximum multiple birth rate specified by Directions*) on the clinic's licence. The representations are to be heard by a Licence Committee in due course.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 1 Feb 2011 - 31 Jan 2012
In vitro fertilisation (IVF)	377
Intracytoplasmic sperm injection (ICSI)	1023
Gamete intra fallopian transfer (GIFT)	0
Frozen embryo transfer (FET)	251
Donor insemination (DI)	10
Partner insemination	No reported IUI treatments
Egg share provider (sharer)	0
Egg share recipient	0
Egg donation (non-egg share)	3

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

Outcomes*

From the information that has been submitted and is held on the HFEA register for the time period December 2010 to November 2011 for IVF and ICSI treatment the centre's success rates are in line with national averages with the following exceptions: IVF with fresh embryos age range 16 – 37; ICSI with fresh embryos age ranges 16 – 37 and 38 – 65, which have success rates that are above the national average at a statistically significant level.

However, it should be noted that the PR has not submitted 27% of required outcome information to the HFEA and as a result this analysis may not be accurate.[1]

For the years 2010 and 2011 the centre has not reported any cycles of partner insemination.

*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.

[1] Data extracted from the data warehouse containing Register data as at 27/03/2012

Summary for licensing decision

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

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

The Executive Licensing Panel is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including four major areas of non-compliance.

Since the inspection visit the PR has given a commitment to fully implement the following recommendation:

Major area of non-compliance:

- The PR should continue to carry out their established action plan and "bring forward" system in order to ensure that all embryos and gametes are stored within the consented storage period; continue to provide update information to the inspector and complete the action plan by 1 September 2012.

The Executive Licensing Panel is asked to note that there are a number of areas of practice that still require improvement, including three major areas of non-compliance.

Major areas of non-compliance:

- The PR should submit the centres multiple birth minimisation strategy and practice to external peer review and provide a report and any action plan to the inspector by 1 August 2012.

- The PR should ensure that data provided to the Authority about activities and data, which the Authority is required to hold on its Register of Information, is accurate and provided by dates specified in Directions or in writing. The PR should ensure that all missing outcome information is submitted to the HFEA register by 1 September 2012.

- The PR should audit all patient consent records against the consent decisions which have been submitted to the HFEA via EDI and all discrepancies corrected by 1 September 2012. The PR should provide a report to the inspector by 5 October 2012

Recommendation to the Executive Licensing Panel

The inspection team considers that overall there is sufficient information available to recommend the renewal of the centre's licence for a period of four years without additional conditions subject to compliance with the recommendations made in this report being implemented within the prescribed timescales.

However, in recognition that the PR did not provide evidence of the implementation of all of the recommendations made in the last report it is proposed that the centre is revisited in six months from the date of the ELP meeting if key evidence is not submitted.

If evidence of progress is not made available in relation to any of the recommendations then this will be referred back to the Executive Licensing Panel or Licence Committee as appropriate for further consideration.

Details of Inspection findings

1 Protection of patients and children born following treatment

Focus

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

- conducts all licensed activities with skill and care and in an appropriate environment, in line with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring
- takes into account the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth
- ensures that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose
- reports all adverse incidents (including serious adverse events and reactions) to the HFEA, investigates all adverse incidents and shares lessons learned.

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

What the centre does well.

Staff interviewed at the time of the inspection provided documented 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. (SLC T71)

The embryologists provided all laboratory records for the year 2011. An audit of a sample of twenty records demonstrated that all witnessing records were correctly completed, accurate and included signatures and the date and time of the witnessing event. (SLC T71) It is noted that the centre does not keep the record of witnessing in the patient records as required by SLC T71, however, this is not considered a risk as there are comprehensive records that can be linked to each individual patient treatments.

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

Staff provided a Standard Operating Procedure (SOP) *Witnessing Protocols for Laboratory Procedures* (*labsop35*) used by staff 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 (SLC T71).

The embryologist explained that the witnessing records are audited for completeness at each step of the patient journey and a final check is conducted at the time that patient information is uploaded to the HFEA EDI system.

Staff explained that they are trained in the witnessing process and each member of the laboratory staffs practice is audited against individual laboratory SOPs during their competence assessments. Each SOP includes the required witnessing steps of each procedure.

What the centre could do better.

Nothing noted at this inspection.

Patient selection criteria and laboratory tests

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

What the centre does well.

Laboratory staff provided up to date and document controlled SOPs for all critical and processing procedures. (T33b)

Prior to the processing of patient gametes or embryos intended for use in treatment or storage staff provided evidence to demonstrate that the required biological screening tests are carried out. An audit of five sets of patient records demonstrated that all had undergone the required screening. The screening tests are carried out by a CPA (UK) accredited laboratory. (SLC T50)

Staff demonstrated an understanding of the requirement for additional Hepatitis B Core antigen testing and a poster in the patient's waiting room provides information about the additional requirement.

The centre's laboratory is not CPA accredited as required by SLC T50, however, staff at the centre participate in the United Kingdom National External Quality Assessment Service (NEQAS) for andrology/semen analysis, have fully validated their semen analysis and diagnostic procedures and provided documented evidence of their competency in semen analysis. This is considered by the inspection to team to be sufficient to ensure the quality of service.

An audit of five patient records on the day of inspection demonstrated that records are kept of the patients medical history, reason for treatment, the services provided to them, a welfare of the child assessment, consent to treatment and storage and clinical and laboratory data and the results of tests carried out. (SLC T49)

Counselling:
The counsellor was not available for interview on the day of inspection, however, the quality manager was able to explain that all patients are offered the opportunity of counselling and that patients who are be treated with donor gametes are required to undertake counselling prior to starting treatment (HF&E Act (as amended) Schedule 3, S(1)(a) and SLC T60). The offer of counselling is recorded on the patient/donor treatment checklist which was seen to be completed in ten patient/donor records.

For patients who are undergoing donor treatment the counsellor always writes a full report which is filed in the patient's record prior to the start of treatment. An audit of five records of patients treated with donor gametes showed that they had all undertaken counselling and a report filed in their record. (SLC T60)

The counsellor is suitably qualified and experienced and is accredited by the British Infertility Counselling Association. (Guidance 2.12a)

What the centre could do better.

Nothing noted at this inspection.

Donor recruitment, assessment and screening (Guidance Note 11)
Payments for Donors (Guidance Note 13)
Donor assisted conception (Guidance Note 20)
Only applicable to centres licensed to carry out treatment using donor gametes and / or embryos

What the centre does well.

The centre does not actively recruit sperm, egg or embryo donors. Patients who require donor assisted treatment are required to select their own donors from a donor bank and staff at the centre will then transfer or support gamete/embryo importation for treatment. The donor coordinator explained that infrequently patients are treated with gametes from known donors. No reimbursement or payments are made by the centre to donors.

An audit of five donor (import) files on the day of inspection demonstrated that the records contained: a medical history of the donor; laboratory test results demonstrating screening has been carried out as required by SLC T52; evidence that the screening has been conducted in an accredited laboratory and had been quarantined for the requisite time period before release and use in treatment. (SLC T53a and c)

An audit of two known-donor records demonstrated that the donor had provided health and medical information on a questionnaire, had been interview by a qualified and trained healthcare professional and had been screened in accordance with SLC T52. The centre has an SOP that describes the requirements for donor assessment and screening. (SLC T33)

Women are not provided with treatment with donor gametes unless they have participated in counselling, which is stated in patient information literature and recorded as being offered and undertaken in patient records. The donor coordinator explained that the counsellor always writes a full report which is filed in the patient's record prior to the start of treatment. An audit of five records of patients treated with donor gametes showed that they had all undertaken counselling and a report filed in their record. (SLC T60)

What the centre could do better.

Nothing noted at this inspection

Good clinical practice

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

What the centre does well.

On the basis of discussion with staff and documented evidence provided at the time of inspection it is concluded that: staff at the centre follow good clinical practice; premises and equipment for the treatment services offered are suitable and there is a quality management system to continually improve the quality and effectiveness of the service provided in accordance with good practice.

Quality Management System
The quality manager provided evidence of a quality management system (QMS), including a quality manual, a signed quality policy, a suite of document controlled and up-to-date standard operating procedures, clinical and laboratory audit of practice, quality indicators for licensable activity, and responses and actions from patient surveys. (SLC T32, T33 and T35).

The centre has an adverse incident and near miss reporting system. The adverse incident SOP details centre specific reporting requirements and the requirement for reporting incidents to the HFEA within the mandatory timeframe (SLC T118 and T119). The quality manager explained that there had been no adverse incidents since the last inspection. There were a small number of "near misses" recorded along with their investigation and documented corrective actions.

Staff at the centre actively seek patient feedback through a patient questionnaire provided to patients after their treatment. The quality manager provided evidence to show that patient comments are regularly reviewed and audited. The quality manager provided as an example of responding to patient comments that a small number of patients had commented that the standard of décor in the main patient areas could be improved. In response the centre is in the process of being redecorated and refurbished.

Traceability
Staff provided evidence to demonstrate that they record information about all the media, consumables and equipment that comes into contact with gametes and embryos, from the time they were created until the time the embryos are used in patient treatment or disposal. (SLC T99)

Staff provided evidence to demonstrate that all the containers at all stages of procurement, processing use and storage of gametes and embryos are labelled with the patient's full name, unique patient number and date. (SLC T101)

The PR provided an SOP (*Laboratory Monitoring Traceability labsop57*) describing the requirements for traceability of equipment, consumables and media used in the procurement, processing and storage of gametes and embryos. (SLC T33b) Records of equipment, batch numbers and the date used are recorded in a traceability folder.

An audit of five patient records demonstrated that all equipment, consumables and media can be identified for those patients. (SLC T101) The embryology staff audit their traceability practice during the patients treatment cycle and would correct any omissions before the patient moves to the next stage in their treatment. The audits are documented and reviewed quarterly. (SLC T36)

The embryologist explained that the information required for traceability will be stored for 30 years; however, the centre does not have any material in storage for that period of time. (SLC T103)

Premises and facilities:
The centre has suitable premises and facilities for licensed activity and maintains records of regular cleaning and disinfection of the premises. (SLC T17 and SLC T26)

The embryologist provided documented evidence to demonstrate that the processing of gametes and embryos takes place in an environment of grade A air quality, (laminar flow hood) with a background environment of grade C. (SLC T20) The background environment air quality is tested regularly by an external contractor by a process described in a service level agreement and the air quality in the flow hoods is tested through the laminar flow hood servicing contract. An SOP describes the process for the monitoring of air quality. *(Air Quality Monitoring Labsop 50)*

The laboratories that undertake diagnostic investigations are accredited by Clinical Pathology Accreditation (UK) Ltd. (SLC T20)

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

The centre's SOP *Validation (labsop67)* 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. The embryologist explained that all consumables used at the centre are CE marked, including petri dishes which have recently been awarded CE marking. (SLC T24). Completed equipment qualification reviews were provided for a sample of 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 equipment validation documentation. (SLC T25).

The embryologist provided the inspector with a process validation folder containing validation documents describing the procedure and test method for a sample of processes including preparation of culture dishes, IVF, sperm and embryo freeze and the embryo thaw procedure (SLC T72).

The embryologist provided evidence to show that laboratory quality indicators such as overall fertilisation rates, pregnancy rates, ICSI fertilisation rates and embryo cleavage rates are monitored quarterly. (SLC T35 and T36) This process also includes comparing the results of each practitioner.

Equipment and materials:
Documented evidence of the maintenance and regular inspection of equipment in accordance with manufacturers was provided for inspection including a sample of up-to-date servicing and maintenance records for five pieces of equipment. (SLC T23)

An SOP *(Labsop 34)* describes the actions to be taken in the case of equipment failure.

Calibration certificates were provided for two pieces of equipment with critical measuring functions, (a particle counter and thermometers). (SLC T24)

Records were provided to demonstrate that equipment and materials that effect critical processing or storage parameters are subject to monitoring, alerts and alarms. (SLC T24) Evidence was provided to demonstrate that sterile instruments and devices are used for the procurement of gametes and embryos and that instruments or devices are of good quality, validated and regularly maintained. (SLC T28)

The maintenance, servicing, cleaning, disinfection and sanitation of all critical equipment and premises is performed regularly and recorded accordingly. (SLC T26) Only one piece of reusable equipment is used during patient treatment which and this is sterilised at a local specialist centre. (SLC T29)

Third Party Agreements:
The quality manager provided documented evidence to demonstrate that agreements have been established with third parties who provide goods and services that influence the quality and safety of gametes and embryos a list of which was provided at the time of inspection. (SLC T111 and T115) Staff at the centre evaluate the agreements annually (SLC 112) and an audit of four agreements demonstrated that they specify the terms of the relationship and responsibilities as well as the protocols to be followed to meet the required performance specification. (T113)

What the centre could do better.

Nothing noted at this inspection.

Multiple Births (Guidance Note 7)

The Authority introduced a multiple birth policy in 2009, a component of which was establishing an annual multiple birth rate which centres should not exceed. The first, 'year one', target for 2009 (January 2009-March 2010) was that no more than 24% of births for all IVF, ICSI and FET cycles for all age groups in a licensed centre should be multiple births. The second, 'year two' target for April 2010-March 2011 was 20%.

The centre's multiple clinical *pregnancy* rate for all IVF, ICSI and FET cycles for all age groups in 2009-10 was 35%. In 2010-11 the centre's multiple clinical *pregnancy* rate for all IVF, ICSI and FET cycles for all age groups was 32%.

There is always a time 'lag' in information being available to verify all centres' performance as regards multiple *birth* outcomes. At the time of inspection this information was not available for performance relating to multiple birth outcomes for 2009-2010. In order to provide an indication of likely birth outcomes the HFEA applies a 'correction factor' as regards multiple *pregnancy* rate performance (that is the proportion of clinical pregnancies reported which have more than one gestational sac present). For 2009-10 a multiple pregnancy rate no greater than 30% would be necessary to achieve the multiple birth rate target of 24%, and for 2010-11 a multiple pregnancy rate no greater than 25% would be necessary to achieve the multiple birth rate target of 20%.

The performance of the centre for 2009-2010 and 2010-2011 pregnancy outcomes represent a statistically significant under performance (unlikely to be due to random variation) as regards multiple *birth* rate performance. [2]

The Authority's third, 'year three' target for April 2011- October 2012 is that no more than 15% of births for all IVF, ICSI and FET cycles for all age groups in a licensed centre should be multiple births. From October 2012 a 'year four' target of 10% will be introduced. For 2011-12 a multiple pregnancy rate no greater than 19% would be necessary to achieve the multiple birth rate target of 15%, and from October 2012 a multiple pregnancy rate no greater than 13% would be necessary to achieve the multiple birth rate target of 10%.

At the time of inspection the centre had not submitted all information required to report on performance regarding multiple pregnancy rates for the period 2011-2012. Based on information submitted to date the centre's multiple clinical *pregnancy* rate is likely to be between 18% (if all outstanding outcomes reported are singleton pregnancies) and 31% (if all outstanding outcomes reported are multiple pregnancies).

Background

The centre has developed a multiple birth minimisation strategy which states that *multiple pregnancy is associated with higher maternal and perinatal morbidity and mortality compared with singleton pregnancies* and that the aim of the strategy is to *reduce the incidence of IVF-related multiple births and comply with the HFEA policy of phased reduction in multiple births after IVF.*

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. They explained that they recognise the potential complications and risks of multiple pregnancies; however,

[2] The HFEA wrote to all UK fertility centres in November with detail of the centre's performance, and published information relating to performance regarding multiple pregnancy rates of all centres. http://www.hfea.gov.uk/6195.html

each patient is assessed on an individual clinical basis along with an assessment of embryo development, previous treatment cycles and the woman's age.

What the centre could do better

The centre did not meet the Authority's multiple birth rate target for 2009-10 and 2010-11.

From the incomplete data submitted by the centre for 2011/12, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups is likely to be between a range of 18% to 31%, and is unlikely to meet the required pregnancy rate necessary to meet the Authority's multiple birth rate target for that year. Until the missing data is submitted and birth outcomes are subsequently verified this performance cannot be confirmed.

The centre did not provide an audit or review of its multiple births' minimisation strategy in November 2011, as required.

The centre does not comply with Direction 0003.

Staff engaged in licensed activity

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

What the centre does well.

The PR is registered with the General Medical Council, has academic qualifications in the field of medicine as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii) and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA Person Responsible Entry Programme (T/1075/7).

A number of training files were reviewed (nurse, doctor and embryologist). All contained sections for job description, signed employment contract, curriculum vitae, record of induction, health and safety training, record of professional registration and continued professional development and training records (SLC T15). Staff provided documented and verbal evidence that they are trained to carry out their role and have access to continued professional development including attendance at a number of recent professional conferences. The quality manager explained that all nursing staff are registered with the nursing and midwifery council (NMC) assessed at regular intervals and that all staff undergo regular appraisal.

Up to date documented competency assessments for four members of the laboratory team were provide showing assessment of their competency for the last two years in a number of laboratory procedures including: insemination of oocytes, assessment of embryo development; embryo transfer and cryopreservation. (SLC T15a)

The embryologist explained that all relevant laboratory staff are registered with the Health Professions Council (SLC T14) and provided evidence of Association of Clinical Embryology (ACE) training and professional development and explained that two members of the laboratory staff have completed the Royal College of Pathologist (RC Path) training and five member of staff are working towards completion.

Prior to inspection the PR provided an organisational chart which clearly defines accountability and reporting relationships for staff. (SLC T11).

What the centre could do better.

Nothing noted at this inspection.

Welfare of the Child (Guidance Note 8)

What the centre does well.

Before providing treatment services staff at the centre provided evidence to demonstrate that they take into account the welfare of the 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. (SLC T56)

An audit of ten patient records demonstrated that all had undergone a welfare of the child assessment, had completed a questionnaire and the doctor has agreed to provide treatment following the assessment. A checklist, *(Starting Treatment Checklist IdARGC65)* filed in the patient's record was seen to record the fact that the doctor has discussed welfare of the child issues and an assessment has been completed.

The quality manager explained that all patients are referred by their own general practitioner or family doctor that enables staff to contact them if there are issues or concerns about the welfare of any child born as a result of treatment. Staff conduct quarterly audits of the completeness and presence of welfare of the child assessment documents in a sample of patient records. (SLC T36) The quality manager explained that the minimum standard is 100% accuracy and completeness of assessment forms. The last audit did not highlight any non-conformity.

An SOP describes the process to be followed when conducting a welfare of the child assessment (SLCT33b)

What the centre could do better.

Nothing noted at this inspection.

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

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

What the centre does well.

Staff at the centre have carried out 10 treatment cycles involving pre-implantation genetic diagnosis (PGD) and two treatment cycles involving pre-implantation screening (PGS) between March 31 2011 and 1 March 2012. Two conditions received HFEA approval following applications on 18 March 2011 and 4 November 20011, all other genetic conditions tested for had been previously approved by the HFEA.

An audit of 12 sets of patient records showed that the centre had recorded reasons why treatment was provided for individual patients.

The embryologist explained that the centre has a dedicated, trained embryologist in embryo biopsy. During a biopsy process this embryologist is always observed by a second member of the embryologist team for the whole biopsy procedure to ensure that double witnessing is carried out at critical steps. The embryologist explained that biopsy procedures are audited and that no corrective actions have been required from the twelve biopsies carried out this year. (SLC T36)

During interview the biopsy practitioner confirmed that biopsied embryos are not transferred in the same cycle as non-biopsied embryos (SLC T88a) and that the centre has not carried out sex selection for social reasons (SLC 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 (SLC T33b).

Blastomeres are sent for analysis to a third party laboratory which is accredited by the College of American Pathologists). A certificate of accreditation was accepted by the HFEA as part of a previous PGD/HLA application (SLC T21)
The embryo biopsy practitioner explained that he had initially been trained at the American laboratory; he has been assessed by the HFEA; regularly attends conferences and biopsy workshops e.g. ESHRE 2010 and is regularly supervised by colleagues and the PR.

What the centre could do better.

Nothing noted at this inspection

2. Patient Experience

Focus

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

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

Treating patients fairly

- Treating patients fairly (Guidance Note 29)
- Confidentiality and privacy (Guidance Note 30)
- Complaints (Guidance Note 28)
- Provision of a costed treatment plans (Guidance Note 4)
- Surrogacy (Guidance Note 14)

What the centre does well.

From discussion with staff and evidence provided at the time of inspection staff at the centre ensure that all licensed activities are conducted in a non-discriminatory way and with proper respect for the privacy, confidentiality, dignity, comfort and wellbeing of all prospective and current patients and donors.

Complaints:

The centre has a complaints' procedure that is available to all patients. The *Patients guide to the Assisted Reproduction and Gynaecology Centre* is describes who to contact along with contact details. The information also includes contact details for the Care Quality Commission and the Human Fertilisation and Embryology Authority. The quality manager explained that the centre does not receive many complaints but if they do they are logged and investigated and discussed at team meetings.

Three SOPs relating to complaints were provided *Information for patients about complaints mansop14a: Complaints process mansop14 and Workers concerns mansop14B*. No complaints from patients treated at the centre have been received by the HFEA.

Costed treatment plans:

Patients are provided with individual costed treatment plans following their first consultation. A comprehensive list of treatment, procedure and investigation costs is displayed on the centre's website. The list includes the costs for the centres more specialist services including immune blood screening, hormone profiling and embryo testing. 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). A patient information leaflet (*Fees and Payment INFO13)* provides information on what services are being provided, their cost and the payment methods.

Confidentiality and Privacy:
Staff at the centre ensure that information about people having treatment, donors and children born as a result of assisted conception is kept confidential and restricted to persons authorised by the PR. (SLC T43 and T45)

The centre has an SOP that describes the procedures to be followed to ensure the requirement that all information is kept confidential, secure at all times and that patient records are only accessible to authorised members of staff. (T33b and SLC T44)
Access to areas where confidential identifying information can be seen or obtained (records stores, laboratories, cryostores etc. is restricted to people authorised by the PR. Patient records are stored in rooms that are not accessible to patients and are locked in storage cupboards in locked offices when not in use. (SLC T44)

The quality manager explained that all members of staff receive training in maintaining confidentiality (SLC T15a) and are required to sign a confidentiality agreement with the centre. The centre has in place a process for considering and responding to applications for access to confidential records and correctly identifying applications. (SLC T44d)

What the centre could do better.

Nothing noted at this inspection

Information

- Information to be provided prior to consent (Guidance Note 4)
- Information about storage of embryos (including cooling off periods)
- Information about Intra cytoplasmic sperm injection (Guidance Note 21)
- Information about pre implantation genetic testing (Guidance Notes 9 & 10) – *only applicable to centres licensed to carry out pre implantation genetic diagnosis and screening*
- Information about legal parenthood (Guidance Note 6)

What the centre does well.

Patient information leaflets and centre specific consent forms given to patients prior to treatment provide information about the nature of the treatment, consequences and risks, analytical tests, confidentiality, consent, and the availability of counselling. (SLC T58)

Staff explained that information is provided and discussed during consultations and throughout the patient's treatment journey. The information provided to patients is recorded on a check list filed in the patient record and the treatment consent forms require the patient to acknowledge that they have been provided with sufficient information prior to treatment. An audit of ten patient records demonstrated that all checklists were completed and all consent forms signed appropriately. From the HFEA's patient questionnaire and the centres own survey patients appear to be satisfied with the information they are provided.

Patients are given a printed copy of the HFEA information leaflet on intra cytoplasmic sperm injection (ICSI) which includes information on the indications for using ICSI, the risk associated with the treatment. (Guidance 21.1 and 21.2)

Patients are provided with the HFEA consent to parenthood information and consent form guidance as part of their pre-treatment information pack. Staff demonstrated an understanding of the need for documented consent to legal parenthood and also described the procedure to follow if a patient or second parent chose to withdraw consent. Patients are informed of their right to withdraw consent in patient information leaflets.
All patient and where relevant their partners must see the centres counsellor where legal parenthood is discussed as part of the counselling consultation. (T60 and T61) A record of this conversation and the information provided was seen to be recorded in five patient records.

Patients being treated with pre-implantation genetic diagnosis techniques are provided with comprehensive information package that have previously submitted to the HFEA for inspection as part of a PGD application. The pack contains written information about: the unproven nature of the procedure and the risks associated with the procedure as required by SLC T89.

Website information: Chairs letter CH (11)02.
The centres website provides information and data on treatments offered and their cost, overall live birth success rates by maternal age range and treatment types. The centre's published success rates data make reference to the HFEA as the source of national information. The website includes like for like comparisons with London based clinics for patients treated in the same year and of the same maternal age etc. The displayed costs indicate a likely, overall cost for a typical cycle as well as individual items in tariffs.

What the centre could do better.

Nothing noted at this inspection.

Consent

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

What the centre does well.

Staff provided evidence to demonstrate that written consent is obtained from patients and where relevant their partners before any form of treatment is provided. (HFE Act 1990 (as amended), Schedule 3 2(2) and SLC T57).

The PR provided ten sets of patient records that contained all 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. The identity of the patient and partner providing consent is verified when they give it and copies of the patients and partners photographic identification are filed in their records. (Guidance 5.10) Staff explained that the identity to of the patient is crossed checked when procedures are carried out and at the beginning of the witnessing process. (Guidance 5.11)

The quality manager 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. The patient and/or partner would be sent a withdrawal of consent form which would be stored in the patient record. The PR demonstrated awareness of the permitted 12 month “cooling off period” and described the procedure for dealing with any disputes. The PR explained 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). Two standard operating procedures: *Consent to treatment (Mansop4)* and *Completion of consent forms (Nursop11)* are followed by staff at the centre. (SLC T33b)

Staff provided evidence to demonstrate that all consents are checked before treatment begins, prior to all treatment interventions e.g. egg collection, immunotherapy administration, embryo transfer and before laboratory procedures. The quality manager provided an audit of the presence and completeness of consent forms from a sample of patient records. No non-conformities had been identified or documented. (SLC T T36)

What the centre could do better.

Nothing noted at this inspection

3. Protection of gametes and embryos

Focus

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

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

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

What the centre does well.

From discussion, observation at the time of inspection and from documented evidence it appears that all staff at the centre has respect for the special status of the embryo when carrying out assisted conception treatment services.

What the centre could do better.

Nothing noted at this inspection

Storage of gametes and embryos

- Storage of gametes and embryos (Guidance Note 17) – *only applicable for centres licensed to store gametes and / or embryos*

What the centre does well.
Most of the gametes and embryos stored for patients registered at ARGC are stored at the centres "sister" centre Reproductive Genetics Institute. (RGI) This centre was inspected and issued with a four year licence in 2011 where no non-compliances were identified. The same staff, procedures and processes are followed at both centres.

Storage dewars at the ARGC site all have security padlocks in place, are linked to an automated dial out alarm and are stored in a locked room. Two embryologists check and document the nitrogen levels once a week and top up the dewars. The automated dial out alarm is tested weekly.

The embryologist provided SOPs for the cryo preservation of gametes and embryos. The PR explained that the centre has several quality indicators relevant to the efficacy of storage procedures including post thaw survival rates and pregnancy rates. The PR also explained that these are audited quarterly as part of the centres quality management system. (SLC T 33b, T35 and T36).

Prior to storage the patients and partners consents are checked by the embryologist. The *embryo freeze sheet* completed before freezing takes place includes a "check point" where consent forms are reviewed and checked for appropriateness and completeness and the length of storage consented to is recorded.

Prior to storage all providers of gametes are screened through a CPA accredited laboratory (the relevant laboratory was seen to be accredited on the CPA (UK) website) in line with regulatory requirements and the results checked and recorded on the *embryo freeze sheet*. An audit of five patient records at the time of inspection demonstrated that all patients had undergone the required screening prior to storage. (SLC T52)

The SOP for embryo and blastocyst freezing was seen to include the requirements for patient and partner screening. (SLC T21 and T50).

A SOP *storage tank audit and maintenance of database* described an annual storage audit. Minor administrative errors were seen to been corrected and documented. The centre has a "bring-forward system" to provide advance notice of the end of the statutory storage period for gametes or embryos in storage (guidance 17.18 and 17.19). An electronic database records when the gametes and embryos are frozen, when consent will expire and the name and contact details of the patients and the date they should be contacted. During inspection evidence was provided that staff review all consents to storage contacting patients via registered letter as required. A detailed process for contacting patients, extending storage, donating embryos to research and actions to be taken when embryos are to be discarded was seen described in SOP *Management of Cryopreserved Embryos and Gametes* (labsop43). The "bring forward" has been reviewed and updated since the last inspection.

What the centre could do better.

The centre does not have written effective consent for all cryopreserved gametes and embryos currently in storage. (HFE Act 1990 (as amended), Schedule 3 8(2) and Standard Licence Condition T79).

The PR acknowledged this in response to the self-assessment question prior to this and the last inspection visit. Since the last inspection staff have audited the consent status of all gametes and embryos in storage and have implemented an action plan for addressing the issue of expired consent.
Since the last inspection the PR and embryologist provided documented evidence to demonstrate that they have:

- developed and implemented an *Action plan for audit of cryopreserved gametes/embryos with expired storage consent*. The plan 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. This was a recommendation made following the last inspection;
- contacted seventy five per cent of the patients who have gametes or embryos stored beyond the storage period;
- convened a case conference process to discuss cases where patients can't be contacted and decide on any actions to be taken;
- reviewed and amended their "bring forward" system to allow more time to contact patients and/or GP's where necessary before the expiry of the consented storage period; (This was a recommendation made at the last inspection)
- provided two reports of progress against the action plan. April 2011 and February 2012

It is acknowledged that the centre is making steady progress in resolving the issue of storage without consent; however, the centre has embryos in storage beyond the consented storage period. (HFE Act 1990 (as amended), Schedule 3 8(2) and Standard Licence Condition T79)

This is a repeat non-compliance from the last inspection.

Distribution and / or receipt of gametes and embryos

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

What the centre does well.

The centre has procedures in place that protect the safety and quality of gametes and embryos when imported, exported or distributed.

Between February and December 2011 the centre exported sperm samples for two patients and embryos for two patients under general directions. During the same time period they imported sperm samples for 18 patients under general directions.
Staff provided documented evidence to demonstrate compliance with Directions 0006.

An audit of two imports and one export of gametes and embryos to centres within the EEA and from outside the EEA demonstrated compliance with requirements of Directions 0006. All samples had been received and distributed complete with all relevant required information, documentation, consent forms, receipt of delivery, screening reports etc.

An audit of five patient records demonstrated that all patients who had exported or distributed their gametes or embryos to other centres had completed and signed appropriate consent to transport forms. (*CON515(4))*

Staff provided documented evidence to demonstrate that when gametes have been donated overseas they check that the donor has not received more than the prescribed amount of compensation for loss of earnings or compensation. Each donor bank has provided a signed letter to confirm that the organisation has not paid more than the amount prescribed by the HFEA to donors. (Directions 0001)

An SOP for the import and export of gametes and embryos is available to staff and part of the quality management system. (SLC T33) The import/export coordinator provided evidence of regular audit of procedures, completeness of documentation, relevant consents forms screening requirements. (SLC T36) No non-conformities have been identified.

What the centre could do better.

Nothing noted at this inspection

4. Good governance and record keeping

Focus

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

- maintains accurate records and information about all licensed activities
- conducts all licensed activities with regard for the regulatory framework governing treatment involving gametes and embryos within the UK, including
    - maintaining up-to-date awareness and understanding of legal obligations
    - responding promptly to requests for information and documents from the HFEA
    - co-operates fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare

Record keeping

- Record keeping and document control (Guidance Note 31)

What the centre does well.

All ten patient/partner and five donor records seen at the time of inspection, were seen to be clear, legible and well organised. Each record reviewed was seen to include: patient/donor first name, surname, date of birth, age and sex. Details of how the patient/donor had been identified (passport/driving licence): the treatment provided; a medical history; welfare of the child assessment; relevant documented consents and clinical and laboratory data and the results of tests carried out.

All records and documented requested on the day of inspection were promptly provided, readily retrievable, in good condition and where relevant document controlled. (SLCs T38, T39, T46, T47)

What the centre could do better.

Nothing noted at this inspection

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

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

What the centre does well.

The PR and staff at the centre cooperated fully with the inspection team and, on the day of inspection, provided all requested information.

At the time of inspection the PR and staff provided evidence to demonstrate that they have responded to some of the recommendations from the previous inspection; however, there are four issues that remain outstanding as described in this report.

HFEA Register Audit:
On the day of inspection an audit of laboratory records of 127 cycles of treatment carried out between 01/12/2010 to 30/11/2011 demonstrated that all cycles had been reported to the HFEA register. (SLC T9e)

What the centre could do better.

At the time of inspection seven recommendations from the previous inspection were found, to have been fully implemented; however, completion was not reported to the inspector within the requisite timeframe. (SLCs T4 and T9e)

HFEA register submissions:
The PR does not ensure that data provided to the Authority about activities and data, which the Authority is required to hold on its Register of Information, is accurate and provided by dates specified in Directions or in writing. This includes not verifying the centres data prior to publication on the HFEA website. (SLCT9e)

In the few months before the inspection there was an increase in outstanding register submissions and the PR explained that the centre has experienced staffing issues relating to the submission of data which have now been resolved.

However, the PR has not submitted all the required register information in the required timeframe and some submissions remain outstanding. This is a recurrent issue and has been cited as a non-compliance in previous inspection reports. (SLC T9e)

At the time of inspection there are:

- July 1 2010 to June 30 2011:
  92 early outcome forms[3] (required for each clinical pregnancy) and 381 outcome forms[4] (required for each live birth) that have not been submitted.
- July 1 2009 to June 30 2010
  2 early outcome forms (required for each clinical pregnancy) and 100 outcome forms (required for each live birth) have not been submitted.

[3] Early pregnancy outcome: To inform the HFEA of the early outcome of a treatment (clinical pregnancy)

[4] Pregnancy outcome: to inform the HFEA of the outcome of any early outcome (live birth)

The centre has carried out 481 treatments between July 2009 and June 30 2011 where the HFEA has not been informed of the outcome. This represents 27% of unreported outcomes. This may have an impact on the centres published success rates.

An audit of records of patients treated between 01/12/2010 to 30/11/2011 demonstrated that:

- information on three out of five donor insemination cycles had not been submitted to the HFEA, nor had the patient been registered with the HFEA.
- 77% of the treatment cycles in the audit period were not submitted within the 5 working day time period given in Directions 0005.

Details of the patient/donor and the missing data submission have been provided to the PR for resolution.

Disclosure of information

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

What the centre does well.

Staff at the centre ensure that information about people having treatment, donors and children born as a result of assisted conception is kept confidential and restricted to persons authorised by the PR. (SLC T43 and T45)

Staff at the centre have an SOP that describes the procedures to be followed to ensure the requirement that all information is kept confidential, secure at all times and that patient records are only accessible to authorised members of staff. (SLC T33b and T44)
Access to areas where confidential identifying information can be seen or obtained (records stores, laboratories, cryostore etc. is restricted to people authorised by the PR. Patient records are stored in rooms that are not accessible to patients and are locked in storage cupboards in locked offices when not in use. (SLC T44)

The quality manager explained that all members of staff receive training in maintaining confidentiality (SLC T15a) and are required to sign a confidentiality agreement with the centre. The centre has in place a process for considering and responding to applications for access to confidential records and correctly identifying applications. (SLC T44d)

As part of the consenting process staff at the centre seek consent to the disclosure of information held on the HFEA register to medical or other researchers. (Guidance 30)

What the centre could do better.

Consent to the disclosure of information held on the HFEA register to researchers: An audit of 13 sets of patient records at the time of inspection demonstrated that eight patients had provided consent to the disclosure of their information held on the HFEA register to researchers, however, the centre had reported to the HFEA that the patient had not provided consent.

The PR has not accurately submitted register information regarding patients consent to the disclosure of information held on the HFEA register to researchers. (SLCT9e) This failure would mean that patient's wishes (as expressed through their consent) would not be complied with in relation to the sharing of their information with researchers.

This is a recurrent issue and has been cited as a non-compliance in previous inspection report.

5. Changes / improvements since the previous inspection on 31/03/2011

Area for improvement	Action required	Action taken as evidenced during this inspection
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 HFE Act, Schedule 3 8(2) and SLC T79		The PR submitted a documented process to be followed by staff to resolve this non-compliance. (19/04/2011) The PR was reminded about the requirement for an action plan and regular updates, however, the action plan and update on progress were not submitted to the inspector by 1 October 2011. At the time of inspection the PR provided a documented update on the progress made and a detailed description of the procedure being followed to resolve this issue. Further action required. See page 26 and 27 of this report for further detail.
	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.	The PR did not submit a root cause analysis (or similar type of investigation) of the centres “bring forward” procedures in order to demonstrate that they are sufficiently robust to ensure that embryos do not remain in storage beyond the consented storage period by 1 October 2011. At the time of inspection staff demonstrated that they have reviewed the “bring forward” system and have implemented changes and improvements to ensure that

		it is sufficiently robust to ensure that embryos do not remain in storage beyond their consented storage period.
The embryologist provided documented evidence to show that the validation of all critical equipment and processes is on-going, however this is not complete. SLC 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.	The PR did not 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 by 1 October 2011 At the time of this inspection evidence was provided to demonstrate that all equipment and processes have been validated. No further action required.
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. SLC T36 Directions 0003 3b	The PR should audit and review the efficacy of their multiple birth minimisation strategy in reducing the number of multiple pregnancies and ensuring 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.	The PR did not provide the inspector with an audit and review of their multiple birth minimisation strategy by 1 October 2011. Further action required See page 13 of this report for further information.

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. SLC 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	At the time of inspection staff provided evidence to demonstrate that 12 embryo biopsies have been carried out during 2011 for the purpose of PGD and PGS. An embryologist peer audit has been carried out and documented. No further action required.
The PR does not submit data and information to the HFEA Registry forms are being submitted to the HFEA outside the timescales laid out in Directions 0005 Collecting and recording information for the HFEA. SLC 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.	Staff at the centre have submitted a substantial amount of data over two months prior to the inspection, however, at the time of inspection there are still outstanding submissions. Further action required. See page 27 of this report for further detail. The PR has not submitted an annual return to the Authority of IUI treatments for the calendar year 2011/2012. The PR has not submitted an annual return for IUI treatments or confirmed a null return for 2010/2011 by the verification period of 1 October 2011. Further action required.

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. SLC 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 on the HFEA register to researchers to the HFEA are corrected. To be completed by 1 October 2011.	The PR did not provide evidence to demonstrate that this issue has been addressed or resolved. See page 29 of this report for further information. Further action required.
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.	The PR did not submit a copy of the summary log by 1 October 2011 At the time of inspection staff provided evidence of an electronic embryo transfer log recording all embryo transfers, outcomes and reason for the number of embryos transferred. No further action required.
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. SLC T33b	The PR should review the SOP *Witnessing Protocols for Laboratory Procedure (labsop35)* and ensure that it reflects actual practice. To be completed by 1 October 2011.	The PR did not submit evidence to show that the SOP had been updated by 1 October 2011 At the time of inspection staff provided evidence to demonstrate that they have reviewed and amended the witnessing SOP which now reflects actual practice. No further action required.

The PR and embryologist described training, supervision and continued professional development for members of staff, however, competency assessments are not documented for all staff SLC T15a	The PR should ensure that all members of staff have documented competency assessments. By the time of the next inspection.	The PR provided evidence of competency assessments at the time of this inspection. No further action required.
A third party agreement between the centre and embryo testing laboratory was not available at the time of inspection. SLC 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.	The PR did not provide a copy of the third party agreement by 1 October 2011 At the time of inspection staff provided a copy of this third party agreement. No further action required**.**

Areas of practice that require the attention of the Person Responsible

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

Critical area of non-compliance

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None 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 and reference	Action required and timescale for action	PR Response	Executive Review
1) Consent to storage The PR has developed and implemented an action plan for addressing the issue of expired consent and is making steady progress in resolving the issue; however, the centre has embryos in storage beyond the consented storage period. HFE Act 1990 (as amended), Schedule 3 8(2) and SLC T79. **This is a repeat non-compliance from the last inspection.**	The PR should continue to carry out their established action plan and "bring forward" system in order to ensure that all embryos and gametes are stored within the consented storage period. The PR should provide update information to the inspector on the first Monday of each month until the action plan is complete. The PR should ensure that the action plan is complete by the 1 September 2012.	The PR gave a verbal response on 12 April 2012 stating that the centre are working towards achieving full consent and that they had resolved about 70% of the embryos that were being stored without consent. He reiterated his comments from the inspection that he did not want to dispose of any embryos without contacting all the patients and that these women had worked so hard to create embryos he did not think that they should be disposed of unless the woman could be contacted. He said that they would continue to contact patients.	The Executive acknowledge that the centre is working to resolve this issue. The inspector looks forward to receiving updates on the first Monday of each month.

2) Multiple Births The centre has not reduced the incidence of multiple pregnancies and has not met the Authority's multiple birth rate target for 2009-10 and 2010-11. From the incomplete data submitted by the centre for 2011-12, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups is likely to be between a range of 18% to 31%. The centre did not provide an audit or review of its multiple births' minimisation strategy in November 2011, as required. Prompt action by the centre is now necessary to demonstrate to the Authority that a substantial reduction in the centre's multiple birth rates is achieved in accordance with Directions.	The PR provided evidence to demonstrate that the centre audits all embryo transfer and clinical outcomes as part of their quarterly audit programme, however, this has not resulted in a reduction in multiple pregnancies or multiple births. The PR should submit the centre's multiple birth minimisation strategy and practice to external peer review. A report of the completed external peer review and a plan documenting the actions to be implemented to reduce the multiple clinical pregnancy rate to a level likely to meet the current multiple live birth rate target should be submitted to the inspector by 1 August 2012. The HFEA would not seek to advise the PR on the individual (s) carrying out the review; this is at the discretion of the PR.	The PR gave a verbal response on 12 April 2012 reiterating his point that he treats each patient individually and that he is not concerned over the centre's multiple birth rate.	The Executive is aware that the PR is formally challenging this Licence Condition. The PR has been reminded that he should obtain a peer review of his multiple births policy. This peer review and a plan to reduce the multiple clinical pregnancy rate to a level likely to meet the current multiple live birth rate target should be submitted to the inspector by 1 August 2012.

Directions 0003 **This is a repeat non-compliance from the last inspection.**			
3) Submission of data and information to the HFEA The PR has not ensured that data provided to the Authority about activities, which the Authority is required to hold on its Register of Information, is accurate and provided by dates specified in Directions or in writing. 27% of all outcome forms have not been submitted to the HFEA Register. The PR has not verified the centres data prior to publication on the HFEA website SLC T9e **This is a repeat non-compliance from previous inspections.**	The PR should ensure that data provided to the Authority about activities and data, which the Authority is required to hold on its Register of Information, is accurate and provided by dates specified in Directions or in writing. The PR should ensure that all missing outcome information is submitted to the HFEA register by 1 September 2012. The PR should ensure that all information is provided to the inspector within the recommended timeframe. The PR should acknowledge and verify the centres data in order to ensure that all data from the centres is accurately	The PR gave a verbal response on 12 April 2012 stating that he saw no reason why information had to be submitted by a certain date or time as the HFEA does not use the information and that he submits the information for the CaFC on time.	27% of outcomes were missing at the time of inspection and the PR did not verify data to be published on the 'Choose a Fertility Clinic' (CaFC) website by 1 May 2012 as requested by the inspectorate. The required information is used to monitor success and multiple birth rates. Failure to provide the information undermines the effectiveness of tools the Authority has designed to help it improve quality and safety. The data published via the 'Choose a Fertility Clinic' website is also an important source of information for patients. The reason why the information requested must be submitted to

	published on the HFEA website by 1 May 2012		the Authority by certain dates are set out within SLC 9(e). In addition, CaFC publication requires a co-ordinated verification sign-off process. In the event that the PR fails to verify the next set of CaFC data (October 2012) the Executive will ask the ELP to consider whether the centre's data should continue to be published on the CaFC web page..
4) Consent to the disclosure of information on the HFEA register to researchers. In eight out of thirteen cases the consent to disclosure to researchers in the patient records did not match the information held by HFEA. Directions 0005 (8) and (9) and T9 (e)). This non-compliance has been moved from "other" in the last inspection report to a "major" non-compliance in this report	The PR should audit all patient consent records against the consent decisions which have been submitted to the HFEA via EDI and all discrepancies corrected. This audit is required to encompass all patients for whom consent to disclosure has been taken by staff at the centre and submitted over the EDI system. The Executive recognises that this audit will be time consuming and recommends	The PR did not wish to comment on this during the conversation on 12 April 2012.	The inspector will await submission of the audit report by 5 October 2012.

as it is a repeat non-compliance from the last inspection.	completion by 30 September 2012. The audit report should be submitted to the Executive by 5 October 2012 or when complete if earlier. The PR should ensure that in future, all data submitted through the EDI system regarding consent to disclosure of identifying information from the HFEA register is accurately entered.		
Seven recommendations from the previous inspection were found, at the time of inspection, to have been completed; however, completion was not reported to the inspector within the requisite timeframe. SLC T4 and T9e	The PR should provide information to the inspector within the recommended timeframe.	No comment was received from the PR.	

Other areas of practice that requires improvement

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

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

Additional information from the Person Responsible
The PR responded to the inspection report verbally on 12 April 2012. He did not wish to respond in writing.

HFEA Executive Licence Panel Meeting

18 May 2012

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

Minutes – Item 2

Centre 0157 – (Assisted Reproduction and Gynaecology Centre) – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Mark Bennett, Director of Finance & Facilities (Chair) Danielle Hamm, Senior Policy Manager Rachel Hopkins, Head of Human Resources	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 that has held an HFEA licence since 1995. The Panel noted that the current licence is for three years with no additional conditions and is due to expire on 30 June 2012.

2. The Panel noted that this centre has a separately licensed "sister" centre (Reproductive Genetics Institute RGI) located approximately 250 metres from the Assisted Reproduction and Gynaecology (ARGC) premises. All staff, policies, documented procedures and quality management are common to both centres.

3. The Panel noted that, depending on the types of treatment, patients and their partners may receive treatment and/or care at both sites.

4. The Panel noted that the Person Responsible (PR) is in the process of challenging the application of Licence Condition T123 (The centre must not exceed the maximum multiple birth rate specified by Directions) on the centre's licence[1]. The representations are to be heard by a Licence Committee in due course. The Panel also noted the report's review of performance against the Authority's annual multiple birth rate targets. This was stated as either not having met, or unlikely to meet, the targets.

5. The Panel considered the paper tabled from the Inspector regarding the application and the type of licence to be renewed. The Panel agreed to accept the paper as it clarified the licence position and the application.

6. The Panel noted that the centre's current licence is for treatment and storage, including embryo testing as a licensed activity. The Panel also noted that, since October 2011, such licences are no longer issued in this form. The Panel therefore had to consider this application to be for atreatment (including embryo testing) and storage licence.

7. The Panel noted from the information that has been submitted by the centre, and which is held on the HFEA register for December 2010 to November 2011 for IVF and ICSI treatment, that the centre's success rates are in line with national averages with the following exceptions: IVF with fresh embryos age range 16-37; ICSI with fresh embryos age ranges 16-37 and 38-65. These categories have success rates above the national average at a statistically significant level.

8. However, it was also noted that the PR has not submitted 27% of required outcome information to the HFEA and, as a result, the analysis of success rates is not complete and may not be accurate.

[1] As issued during the HFEA re-licensing project in October 2011

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

10. The Panel noted that the Inspectorate identified four major areas of current non-compliance. The Panel also noted the progress made on seven non-compliances identified at the previous inspection. However, much of the information on progress on these seven was only obtained at the recent inspection. The Panel was disappointed that reports on progress were not submitted to the original deadlines set out in the earlier inspection report.

11. The Panel was concerned that there were four incomplete actions from the previous inspection report; all of which directly contributed to the major non-compliances reported at this inspection.

12. The Panel noted that, since the inspection, the PR has made progress with and given a commitment to fully implement the following recommendation:

    - The PR should continue to carry out the established action plan and "bring forward" system in order to ensure that all embryos and gametes are stored within the consented storage period; continue to provide update information to the Inspector and complete the action plan by 1 September 2012.

13. The Panel noted the actions recommended for the three major areas of non-compliance that remain outstanding:

    - The PR should submit the centre's multiple birth minimisation strategy and practice to external peer review and provide a report and any action plan to the Inspector by 1 August 2012.

    - The PR should ensure that data provided to the Authority about activities and data, which the Authority is required to hold on its Register of Information, is accurate and provided by dates specified in Directions or in writing. The PR should ensure that all missing outcome information is submitted to the HFEA Register by 1 September 2012.

    - The PR should audit all patient consent records against the consent decisions which have been submitted to the HFEA via EDI and have all discrepancies corrected by 1 September 2012. The PR should provide a report to the Inspector by 5 October 2012.

14. The Panel noted the Inspectorate's recommendation for the renewal of the centre's licence for a period of four years without additional conditions.

Decision

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

16. The Panel agreed that the type of licence applicable to the range of activities performed and inspected at this centre is treatment (including embryo testing) and storage. The Panel was satisfied from the application, the inspection report and the tabled paper that the PR intended to renew the licence to include all currently licensed activities.

17. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of the licensed activities. The Panel was also satisfied that the PR will discharge the duties under section 17 of the Act, provided the actions set out are taken on the three remaining outstanding areas of major non-compliance.

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

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

20. The Panel noted that the application does not involve the use of embryos for training purposes.

21. The Panel noted that the application does involve the testing of embryos and that the inspection reported no non-compliances or need for improvement in this area.

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

23. The Panel considered the matters in paragraph 4.3 and agreed the clinic is reported to adhere, generally, to several of them, to perform well in others and to have no critical non-compliances. The Panel then considered whether the four reported major non-compliances caused it concerns in the matters in paragraph 4.3.

24. The Panel noted one major non-compliance partly related to the Authority's Multiple Birth's Minimisation Policy and targets. The Panel considered that any arising concerns were reported as being dealt with by other licensing action. The remainder of this non-compliance was covered to the satisfaction of the Panel by the recommendation to

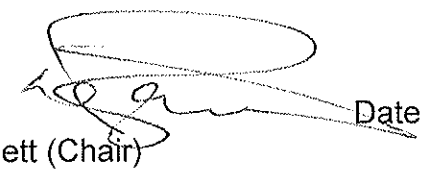
submit the centre's multiple birth minimisation strategy and practice to external peer review.

25. The Panel considered the three other major non-compliances, which did not directly affect current patient treatments and were capable of being readily fixed as set out in the report, but was concerned at the absence of a reported commitment by the PR to action two of them, as well as the external peer review described above. However, on balance, the Panel considered its concerns were mitigated by the Inspectorate's recommendations and the proposals made to follow-up and ensure timely completion. There were no other areas for improvement outside of the four areas of non-compliance reported. The Panel therefore agreed with the Inspectorate's recommendation for the duration of the licence.

26. The Panel agreed, after consideration of the evidence before it, to renew the centre's licence for a period of four years with no additional conditions. As noted earlier, the licence would be of the type, applicable since October 2011, of treatment (including embryo testing) and storage.

27. The Panel endorsed the Inspectorate's recommendations in the report and urged the PR to implement the actions on the four major areas of non-compliance within the timescales stated in the report. The Panel agreed to the Inspectorate revisiting in six months, from the date of this Panel meeting, if key evidence of progress is not submitted.

28. The Panel agreed that if progress is not made available to the Inspectorate in relation to any of the recommendations then the Inspectorate should consider further regulatory action, including that set out in the report.

Signed:  Date: 1 June 2012

Mark Bennett (Chair)