Inspection Report

Date of Inspection: 16 December 2010
Purpose of inspection: Renewal of Treatment and Storage Licence
Length of inspection: 8hrs
Inspectors: Ellie Suthers, Sarah Parlett, Paula Nolan

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 21 October 2009 and 27 January 2011

Date of Licence Committee 27 January 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 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 Licence Committee which makes the decision about the centre's licence renewal application.

Centre details

Centre name	Reproductive Genetics Institute
Centre number	0206
Licence number	L0206/9/a
Centre address	32a Weymouth Street, London, W1G 7BX, UK
Person Responsible	Mr Mohamed Taranissi
Licence Holder	Mr Mohamed Taranissi
Date licence issued	04/03/2010
Licence expiry date	03/03/2011
Additional conditions applied to this licence	None

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Report to Licence Committee

Brief description of the centre and its licensing history:

The Reproductive Genetics Institute (RGI) is privately owned and was first licensed by the HFEA in 2003.

The centre provides facilities and services as part of the patient treatment pathway initiated at the Assisted Reproductive and Gynaecology Centre (ARGC, HFEA licensed centre 0157). Whilst a licence can only apply to one premises the inspectorate noted the arrangements for the integrated pathway of clinical care provided to patients at both centres.

No licensable treatments have been carried out at the RGI since March 2010. The Institute continues to provide long term storage for cryo preserved gametes and embryos.

It is noted that the Person Responsible (PR) has applied for 'procurement and processing' to be added to the RGI licence as part of the licence renewal process. If this is granted by the licence committee the PR and embryologist explained that all the systems and processes, as described in this report, currently used at ARGC will be used at RGI. The proposed patient pathway is described below.

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 RGI premises are located approximately 250 metres from the ARGC premises and consist of reception, waiting, administrative, laboratory and treatment room (for embryo transfer) facilities. The Institute will act as an "overspill" facility for ARGC to increase egg collection and laboratory capacity. All staff and processes are common to both units.

Licensing History

From 31 December 2005 to 04 March 2010 the centre was operating under special directions for the storage of gametes and embryos and the provision of some licensed treatments.

A one year treatment and storage licence was issued by the HFEA Licence Committee to commence on the 04 March 2010 following an inspection on the 20 and 21 October 2009. No treatment activity has been reported to the HFEA.

Variation to Licence

The current licence does not include the activities of "procurement and processing". The PR has applied for the licence to be varied to add these activities as part of this licence renewal process.

The PR has also requested the removal of the following from the licence:

- Sub zonal insemination (SUZI)
- Zona Drilling
- Gamete intra-fallopian transfer (GIFT)
- Zygote Intra-Fallopian Transfer (ZIFT)

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period March 2009 – October 2010
	No activity reported

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

Live and Multiple Birth Rates*
Not applicable to this centre, no licensed treatments have been undertaken.

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
- with the exception of a floor plan 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 Licence Committee is asked to note that at the time of the inspection several areas of practice required improvement, including five major areas of non-compliance and four other areas of non-compliance or areas of poor practice.

Since the inspection on 16 December 2010 the PR has provided verbal assurances to implement the following recommendations in areas that still require improvement:

- Embryos in storage beyond the consented statutory period;
- Audit of the procedures for the transportation of frozen gametes and embryos between the two centres;
- Informing the HFEA of the movement and gametes and embryos between the two centres;
- Completion of the validation of all equipment and processes;
- Submission of standard operating procedures to the inspection team

The inspection team recommends that the Licence Committee requires the Person Responsible to comply with these recommendations within the prescribed timeframes set out in this inspection report:

Recommendation to the Licence Committee

The inspection team considers that, overall there is sufficient information available to recommend

1. The renewal of the Reproductive Genetics Institute's licence for a period of four years;

2. That the licence is varied to include the activity of procurement and processing;

3. That the licence is varied to remove: sub zonal insemination (SUZI); Zona Drilling; Gamete intra-fallopian transfer (GIFT); Zygote Intra-Fallopian Transfer (ZIFT) from the list of licensed activities undertaken.

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 appropriately

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

What the centre does well.

Witnessing

The centre has witnessing protocols relevant to practices at ARGC and RGI in place to check the identification of samples at the patients to whom they relate at all critical points in the relevant process. Records are kept in each patient record. Staff at the centre carry out witnessing for the activities carried out on the premises as required by Standard Licence Condition T71.

No licensable activity other than storage of cryo preserved gametes and embryos has been carried out at the RGI since the last inspection. No gametes or embryos have been put into storage at RGI since the last inspection. Embryos have been taken out of storage and transferred in a dry shipper to ARGC for use in treatment. Witnessing of this process was seen to be compliant.

The PR provided an SOP (labsop45) used at ARGC 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. The embryologist explained that this SOP is followed by staff at RGI for the disposal from storage of gametes and embryos and would be used should further activity begin at RGI. (Standard Licence Condition T71).

The PR provided four sets of patient records from patients in treatment at the ARGC for review as an example of practice by ARGC staff. All witnessing records were seen to be correctly completed

What the centre could do better.

N/A

▶ Patient selection criteria and laboratory tests

What the centre does well.

Not applicable at RGI as patient selection and any diagnostic investigations are carried out at ARGC earlier in the patient pathway.

What the centre could do better.

N/A

Donor recruitment, assessment and screening (Guidance Note 11)
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.

Not applicable at RGI as the regulatory requirements for recruitment, assessment and screening of donors and donor assisted conception is carried out earlier in the patient and donor pathways at ARGC.

What the centre could do better.
N/A

Good clinical practice

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

What the centre does well.
The centre has suitable premises and equipment for the storage services provided and has a quality management system in place to continually improve the quality and effectiveness of the service it provides in accordance with good practice.

Quality Management System
A quality management system (QMS), including a quality manual and a signed quality policy has been developed and implemented which covers activity and practices for both ARGC and RGI. The same staff have implemented, manage and monitor the QMS for both centres. (Standard Licence Conditions T32 and T33).
The PR also provided a diagram of an organisational structure showing reporting responsibilities across both centres and a comprehensive list of all SOPs also used across both centres and explained that the RGI and ARGC use the same clinical governance practices, quality indicators and audit programme. The PR provided an SOP *monitoring quality – clinical governance* (mansop7) that describes the centre's policy and procedures for the monitoring of the quality of care provided. It describes the clinical audit process including the quarterly monthly meetings for all staff; for laboratory staff and nursing staff where audit outcomes are discussed. The SOP also describes the requirement and process for identifying and investigating adverse health events and near misses. The PR explained that these processes are used at both ARGC and where relevant at RGI.

Traceability
The PR provided a SOP (labsop56) used at both centres for the traceability of equipment, consumables and media used in the procurement, processing and storage of gametes and embryos. Records of equipment, batch numbers and date used are recorded in a traceability folder at ARGC. An audit of four patient records demonstrated the recording of traceability information.
The traceability system was considered suitable for the actual and the prospective activity at RGI. The long term storage of relevant data is done at ARGC. (Standard Licence Condition 101).

Validation of processes
The PR and embryologist explained that there is a single validation master plan for all equipment and processes for both centres.

The embryologist provided process validation records based on the Association of Clinical Embryologist (ACE) template/guidance explaining that the validation of critical procurement and processing procedures is ongoing and almost complete. The embryologist explained that KPIs are frequently monitored to ensure consistency of results. A sample of process validation records was reviewed including for IVF, ICSI and assessment of fertilisation. These processes are not carried out at RGI but were provided as examples of the process that would apply should activity commence. Although not used since the last inspection a copy of the Equipment Qualification Review Protocol (EQR) for the portable incubator used for transferring oocytes from ARGC to RGI was also provided as an example of equipment validation (Standard Licence Condition T72)

Equipment and materials
The laboratories at RGI contain incubators, flow hoods, a centrifuge a fridge and cryopreservation dewars. The centre is in the process of purchasing new equipment and transferring existing equipment between the two centres. The PR and embryologist explained that when further equipment is installed and prepared for use at RGI they will follow the processes for installation, validation, maintenance and monitoring used at ARGC. The only equipment in use and that requires constant monitoring at the time of inspection are the storage dewars and was found to be compliant with Standard Licence Condition T24.

The validation master plan, derived from the ACE template/guidance, details individual equipment but not its current location. If activity begins at RGI then an individualised validation master plan should be completed detailing the exact location of each piece of equipment.
The embryologist explained that staff follow the manufacturer's instructions for the operation of equipment and that all equipment at both locations is serviced either once or twice per year depending on the piece of equipment. It was observed that two incubators at RGI were serviced in February 2010 and that the low oxygen alarm had been serviced in January 2010 as recommended at the last inspection (Standard Licence Condition T23).

The embryologist provided documented evidence of the monitoring of critical equipment carried out at ARGC which will be used for the equipment at RGI if activity starts. Examples of the monitoring process include daily temperature and CO_2 checks of incubators and monthly temperature monitoring of heated stages. (Standard Licence Condition T24)

Premises
No patients have been treated in the centre since the last inspection but the premises were considered suitable for the provision of licensable activity and provide for the privacy, dignity and respect of prospective patients as well as providing a safe environment for staff. (Standard Licence Condition T17 and guidance 25.7).
The RGI premises are accessed via a secure/locked entrance from the main street. The ground floor consists of a lobby/entrance area with a waiting room for patients. The reception/administration office has a key pad lock and is inaccessible to unauthorised personnel. The lower floor consists of a changing room; dewar storage room; two laboratory areas; a treatment/operating room and toilet facilities. The dewar storage room and both laboratories are locked and inaccessible to unauthorised personnel (25.8).

Air quality
At the time of inspection the two laboratories are not being used for licensable activity but are cleaned weekly. Documented evidence showed that environment for both laboratories have an air quality of at least Grade C meeting the requirements of Standard Licence Condition T20.
The embryologist explained that if further licensable activity begins they will follow the standard operating procedure *monitoring of laboratory air quality* used at ARGC which documents the requirement for a background of grade D and grade C in the critical environment along with the use of six-monthly particle counts and settle plate testing.

Adverse incidents
The PR said that any incidents at the RGI would be reported and managed via the ARGC incident reporting procedure. A compliant SOP for the management and reporting of incidents was seen in the quality manual. No incidents from RGI have been reported to the HFEA since the last inspection (Standard Licence Condition T118).

Third party agreements
The RGI does not hold contracts with providers of goods and services. All services, equipment and consumables are purchased through ARGC and transferred to RGI for use. The PR said that all third party agreements are between the providers of goods and services and the ARGC.

What the centre could do better.
The embryologist explained that staff follow the manufacturer's instructions in the use of equipment but there is nothing documented to detail the local actions to be taken in the event of equipment malfunction or failure (Standard Licence Condition T27).

The centre does not have an SOP to describe the actions to take in response to alarms at RGI (Standard Licence Condition T33b).

The procedure for the transportation of frozen gametes and embryos from RGI to ARGC and the disposal of embryos has not been audited. (Standard Licence Condition T36)

The embryologist explained that the validation of equipment and processes is an ongoing process but not all equipment and processes have been validated. (Standard Licence Condition T24)

Multiple Births

Not applicable as no treatments have been carried out.

What the centre does well

N/A

What the centre could better

N/A

Staff engaged in licensed activity

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

What the centre does well.
The PR for RGI is also the PR for ARGC (the PR entry programme was successfully completed in 2007), is registered with the General Medical Council (GMC) and is the nominated medical practitioner for both centres (Standard Licence Conditions T8 and T16).

The PR explained that the staff employed at ARGC also, where relevant, work in their respective capacity at RGI. SOP's are in place for staff induction and training which apply to staff currently supporting licensed activity at RGI.

Three training files were reviewed at inspection (one nurse, one doctor and one 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 (Standard Licence Condition T15). Staff provided 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.

Prior to inspection the PR provided an organisational chart which clearly defines accountability and reporting relationships for staff practicing at ARGC and RGI (Standard Licence Condition T11).

The embryologist named as the laboratory manager on the centres organisational chart is HPC registered as are all bar two members of the laboratory team. One is in the process of registration and the other is planning to leave the centre's employ.

What the centre could do better.

The PR explained that competency assessments are carried out against key performance indicators for all staff but the outcomes are not documented. The process of training continued professional development and competency assessment is coordinated and monitored via ARGC with which all staff have their employment contract.

At the time of inspection at RGI staff could not provide documented evidence that their competency to carry out their designated tasks has been assessed (Standard Licence Condition T15 a).

Welfare of the Child (Guidance Note 8)

What the centre does well.
Not applicable at RGI as the regulatory requirements for welfare of the child assessments are carried out at ARGC earlier in the patient pathway.

What the centre could do better.

N/A

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.

No embryo testing or biopsies have been carried out at RGI since the last inspection. If embryo testing were to start at RGI the embryologist explained that they would follow the processes currently practiced at ARGC.

Embryo biopsy is currently undertaken at ARGC and the relevant practices and SOPs will be used at RGI if biopsy activity were to start. The embryologist said that ARGC has an SOP for the process to be followed when carrying out embryo biopsy and the process has been validated and this will be followed if embryo biopsy is carried out at RGI (Standard Licence Conditions T33b and T72). Biopsy procedures are audited against KPIs (including pregnancy rates post biopsy) annually. Biopsies for PGD and PGS are sent to the sister laboratory RGI in Chicago, USA. The trained embryo biopsy practitioner (assessed by the HFEA in 2005) demonstrated his understanding of the licensing procedure for existing and novel PGD conditions.

What the centre could do better.

N/A

2. Patient Experience

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

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

Treating patients fairly

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

What the centre does well.
No patients have received treatment or had cause to visit the RGI since the current licence was issued in Match 2010 although the premises appear to provide for the comfort, safety and dignity of patients and visitors. Patient feedback and complaints are facilitated through ARGC.

Complaints
The PR said that any complaints made about services at RGI would be managed via the Nurse Coordinator whose name, designation and contact details are provided in patient information. Three SOPs relating to complaints SOP's were provided *Information for patients about complaints mansop14a: Complaints process mansop14 and Workers concerns mansop14B*. No complaints have been received by the HFEA.

Provision of a costed treatment plans
Not applicable at RGI as the regulatory requirements for costed treatment plans is discussed and agreed earlier in the patient pathway at ARGC.

Egg sharing arrangements
Egg sharing arrangements are not provided at either ARGC or RGI.

Surrogacy
Not applicable at RGI as the regulatory requirements for surrogacy are carried out earlier in the patient pathway at ARGC.

What the centre could do better.

N/A

Information

- Information to be provided prior to consent (Guidance Note 4)
- Information about storage of embryos (including cooling off periods)
- Information about Intra cytro plasmic 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.
Not applicable at RGI as the regulatory requirements for the provision of information prior to consent, is carried out earlier in the patient pathway at ARGC.

What the centre could do better.

N/A

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.
The PR indicated on the self assessment questionnaire that consent is occasionally taken on the day a procedure is carried out. The embryologist explained that in some cases at ARGC there may be an unexpected requirement for ICSI or sperm freezing for which consent is required. This is not relevant for this inspection as no licensable treatments have been carried out at RGI.

The taking and documenting of effective consent for treatment, storage, donation, training and disclosure of information is undertaken at ARGC earlier in the patient pathway and is not applicable at RGI.

What the centre could do better.

N/A

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 where 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.
Licensable activity (storage) conducted since the last inspection has been carried out on licensed premises. No patients have been treated or embryos created on the premises.

What the centre could do better.

N/A

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.
The embryologist explained that all samples in storage at RGI were cryo preserved at least three years ago. No gametes or embryos have been added to the dewars since the last inspection, only frozen material has been removed and either disposed of or transferred to the ARGC for treatment.

The RGI has 18 dewars containing stored gametes and embryos. The dewars all have security padlocks in place, are linked to an automated dial out alarm and are stored in a locked room in the basement of the RGI. 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 several relevant and compliant 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 quality management system at ARGC (Standard Licence Conditions T 33b, T35 and T36).

Prior to storage at both ARGC and RGI 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.

Screening for storage is not carried out at the RGI. Prior to storage all providers of gametes are screened at ARGC 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*. The SOP for blastocyst freezing was seen to include the requirements for screening. (Standard Licence Conditions T21 and T50).

The embryologist provided the last three random dewar audits performed in February, May and June 2010. A SOP *storage tank audit and maintenance of database* described an annual storage audit for both ARGC and RGI. 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 on a monthly cycle 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).

What the centre could do better.

Consent to storage

Several embryos are being stored without effective consent.

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 (HF&E Act 1990 (as amended), Schedule 3 8(2) and Standard Licence Condition T79).

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 "bring forward system" above. Most of the embryos in storage are from overseas patients and contacting them is proving difficult.

The embryologist explained that they had invoked the 12 month "cooling off period" in order to provide time to ensure that patients are provided with sufficient time to make their decision about extending storage or allow disposal.

The law allows consent to be varied or withdrawn at any point until the gametes and embryos are used in treatment. If one of the gamete providers withdraws consent to the continued storage of embryos intended for treatment, the law allows embryos to be stored for 12 months from the date the centre received written withdrawal of consent. This 12 month 'cooling off' period must not extend beyond the end of the statutory storage period. HFE Act 1990 (as amended) Schedule 3 Terms of Consent 4 (1).

The inspector explained to the embryologist and PR that consent has not been withdrawn for storage. The statutory consent period has expired so this aspect of the Act is not applicable.

The centre has embryos in storage beyond the consented statutory storage period (Act, Schedule 3 8(2) and Standard Licence Condition T79).

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.

No gametes and embryos are imported or exported to or from the RGI however, the staff at the centre receives frozen gametes and embryos from ARGC for storage.

What the centre could do better.

RGI has a documented SOP (labsop45) *protocol for packaging, release and acceptance of gametes and embryos from/to other centres* that is used for the transfer of frozen gametes from ARGC to RGI and vice versa. However this does not include all the requirements of Standard Licence Condition T109

▶ **Use of embryos for training staff** (Guidance Note 22) – *only applicable for centres which use embryo to train staff*
What the centre does well. At the time of inspection, embryologists do not use embryos for training purposes at the RGI. The PR explained that any training will be carried out in the laboratory at ARGC and when asked during inspection said he did not want training included on the RGI licence.
What the centre could do better. N/A

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. No licensable activity has been carried out at the RGI therefore no relevant patient records were available to inspect for accuracy.
What the centre could do better. N/A

Legal requirements [Human Fertilisation and Embryology Authority 1990 (as amended)] • Obligations and reporting requirements of centres (Guidance Note 32)
What the centre does well. All members of staff cooperated fully with the inspection team and information requested prior to and at the time of inspection was provided. The PR experienced difficulty in the electronic submission of completed documentation. The PR agreed to provide a paper version of the self assessment questionnaire, application form and supporting documentation sent to the HFEA via courier. Although this information was submitted outside the required timeframe this was outside the PR's control.
What the centre could do better. The PR has not informed the HFEA about when gametes or embryos have been transferred from RGI to ARGC. (Directions 0005 Collecting and recording information for the Human Fertilisation Embryology Authority)

Disclosure of information

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

What the centre does well.

All records are currently stored at ARGC. Patient records are not stored at the RGI.

The PR said that if licensable treatments were to start at the RGI then all the relevant standard operating procedures relating to confidentiality and privacy from ARGC will be followed.

Disclosure of information
Not applicable at RGI as the regulatory requirements relating to the taking and recording of consent to the disclosure of information held by the HFEA to researchers is carried out at ARGC earlier in the patient pathway.

What the centre could do better.

N/A

5. Changes / improvements since the previous inspection on 20/21 October 2010

Area for improvement	Action required	Action taken as evidenced during this inspection
Evidence of the servicing of the low oxygen sensor and monitoring equipment currently in use at RGI. SLC T24 and T26	To provide evidence of the servicing of the low oxygen sensor and monitoring equipment currently in use at RGI	The low oxygen sensor and monitoring equipment was serviced on the 26/01/10 No further action required
The PR should ensure that requests for information and/or documents from the Authority should be responded to promptly HFE Act 17(1)e and SLC T9f and T4	The PR must respond promptly to requests for information and/or documents from the Authority	With the exception of a floor plan of the RGI and a staff list the PR provided the relevant information prior to inspection. No further action required
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 HFE Act 17(1)e and SLC T9e	The PR must 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 has not informed the HFEA about transfer of gametes and embryos from RGI to ARGC. (Directions 0005 Collecting and recording information for the Human Fertilisation Embryology Authority) Further action required
There is no centre-specific QMS in place at RGI SLC T32	The PR must establish a centre-specific QMS at RGI	The PR and staff provided evidence that the QMS and relevant documentation from ARGC also includes the activity carried out by staff at RGI. During inspection the embryologist described how processes and procedures are (or would be) carried out at RGI in line with the QMS at ARGC. No further action required

Area for improvement	Action required	Action taken as evidenced during this inspection
There is no centre-specific quality manual in place at RGI SLC T33a	The centre must establish a centre-specific quality manual at RGI	The PR and staff provided evidence that the quality manual held at ARGC also includes the activities at RGI. No further action required
The centre has not validated all of its critical care equipment and processes. SLC T24	All critical care equipment and processes at RGI must be validated	The PR provided evidence of a validation programme for both equipment and processes for ARGC and RGI See page 8 of this report for further details of action required.
There are no centre-specific SOP's, which cover all aspects of the licensed activities undertaken at the centre in place at RGI SLC T33b	The centre must establish a centre-specific standard operating procedures (SOP's), which cover all aspects of the licensed activities undertaken at RGI	The PR provided activity specific SOP's that cover most aspects of licensed activity for ARGC and RGI. Further action required
There are no centre-specific key performance indicators established for the centres activities in place at RGI SLC T35	The centre must establish a centre-specific key performance indicators for activities undertaken at RGI	The PR explained that there are activity related key performance indicators against which performance is audited. These were not provided at the time of inspection. Further action required
Review/amendment of current third party agreements established at ARGC which make reference to services undertaken at RGI SLC T111b	Establishment of centre-specific third party agreements for all third-party services undertaken at RGI	Third party agreements are managed and monitored via ARGC. No further action required

Area for improvement	Action required	Action taken as evidenced during this inspection
Review/amendment of the SOP for the induction of new staff to incorporate staff evidence logs of induction activities having been performed and signed off by a supervisor SLC T33b	Review/amendment of the SOP for the induction of new staff to incorporate staff evidence logs of induction activities having been performed and signed off by a supervisor	All new members of staff have the same induction training. Evidence of completion of induction was seen in training logs. No further action required
Formulation of a SOP for the transport of embryos between RGI to ARGC and vice versa SLC T33b	Formulation of a SOP for the transport of embryos between RGI to ARGC and vice versa	The PR provided an SOP for the transport of cryo preserved gametes and embryos from ARGC and RGI. No further action required An SOP (lapsop65) for the transfer of fresh gametes from ARGC to RGI has been provided. No further action required
RGI needs to develop a centre-specific incident log and adverse incident/event reporting structure. HFE Act 1990 S17 (1g) SLC T118; 119	Development of a centre-specific incident log and adverse incident/event reporting structure for RGI	The PR provided evidence that any incidents that may occur at RGI are managed via an incident management SOP (compliant with requirements) at ARGC. No further action required
Formulation of a SOP for the transfer of patients notes between RGI to ARGC and vice versa SLC T33b	Formulation of a SOP for the transfer of patients notes between RGI to ARGC and vice versa	An SOP was not provided at the time of inspection. Further action required
Formulation of a SOP for responding to cryo-alarms at RGI SLC T33b	Formulation of a SOP for responding to cryo-alarms at RGI	The centre does not have an SOP to describe the actions to take in response to alarms at RGI. Further action required

Area for improvement	Action required	Action taken as evidenced during this inspection
Formulation of a SOP for the recording of currently performed competency assessments at RGI SLC T33b	Formulation of a SOP for the recording of currently performed competency assessments at RGI	The PR explained competency assessments are carried out for all staff but the outcomes are not documented. Further action required
Review/amendment of current SOP for cryo-audit, to ensure that the present tank inventory is reconciled against the laboratory record of frozen patient embryos, and which identifies any errors revealed via the audit and any subsequent corrective actions taken by the centre in order to prevent such errors occurring again. SLC T33b	Review/amendment of current SOP for cryo-audit, to ensure that the present tank inventory is reconciled against the laboratory record of frozen patient embryos, and which identifies any errors revealed via the audit and any subsequent corrective actions taken by the centre in order to prevent such errors occurring again	The SOP for the cryo-audit was found to be compliant and appropriate for use at both ARGC and RGI. No further action required.
Updated patient information relevant to the proposed licensed activities to be performed at RGI HFE Act (1990) S13 (6); SLC T58	The centre to provide updated patient information which includes reference to licensed activities to be undertaken at RGI	Patients are provided with information earlier in the patient journey at ARGC. This will form part of the inspection for ARGC.

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.			

Major area of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
The centre has embryos in storage beyond the consented statutory storage period HFE Act, Schedule 3 8(2) and SLC T79.	The PR should ensure that embryos do not remain in storage beyond the statutory 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 should be submitted to the HFEA by 1 March 2011	*Verbal response via telephone:* The PR provided verbal assurance that an action plan and update would be provided.	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
The procedures for the transportation of frozen gametes and embryos from RGI to ARGC and the disposal of embryos have not been audited. SLC T36	The procedures for the transportation of cryopreserved gametes and embryos from RGI to ARGC should be audited and any corrective actions documented. By 1 May 2011	No response	Further action required. This will be monitored via the compliance cycle.
The PR has not informed the HFEA about when gametes or embryos have been transferred from RGI to ARGC. Directions 0005 Collecting and recording information for the Human Fertilisation Embryology Authority	Using the Authorities EDI forms the PR should inform the HFEA about the transfer of gametes and embryos from RGI to ARGC. By 1 May 2011	*Verbal response via telephone* The PR explained that the RGI does not have an EDI access and therefore cannot submit gamete movement forms in this way. The PR has requested that EDI access is re established in order that he can submit the relevant information.	When the EDI connection is re established between RGI and HFEA the PR should inform the HFEA about the transfer of gametes and embryos from RGI to ARGC. 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
Staff cannot provide documented evidence that their competency to carry out their designated tasks has been assessed. SLC T15a	The PR should ensure that there is documented evidence that each individual has demonstrated competence in the performance of their designated tasks The PR should provide the inspector with an action plan documenting a list of staff requiring documented competency assessments and the anticipated timeline for completion. The action plan should be submitted to the HFEA by1 February 2011 By 1 August 2011	*Verbal response via telephone:* The process of training continued professional development and competency assessment is coordinated and monitored via ARGC with which all staff have their employment contract. No competency assessments have been carried out at RGI since the last inspection.	It is acknowledged that assessment of competency is coordinated and monitored via ARGC. All practices relevant to Licence Condition T15a will be inspected at the next inspection at ARGC in March 2011 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
The validation of equipment and processes is an ongoing process but not all equipment and processes have been validated SLC T24	The PR should ensure that all equipment and processes are validated before beginning related licensable activity at RGI 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 February 2011.	*Verbal response via telephone:* Most of the equipment and processes have been validated.	The PR should provide the inspector with an action plan listing the critical equipment and processes 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 February 2011 Further action required. This will be monitored via the compliance cycle.

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
The embryologist explained that staff follow the manufacturer's instructions in the use of equipment but there is nothing documented to detail the local actions to be taken in the event of equipment malfunction or failure. SLC T27	The PR should have a documented SOP that describes the local actions to be taken in the event of equipment malfunction. By 1 May 2011	*Verbal response via telephone* An SOP is in place at ARGC that is relevant for RGI	The PR should provide this SOP to the inspector by the 1st of May 2011 Further action required. This will be monitored via the compliance cycle.
The centre does not have an SOP to describe the actions to take in response to alarms at RGI. SLC T33b	The centre should have a documented SOP that describes the actions to take in response to alarms. By 1 May 2011	*Verbal response via telephone* An SOP is in place at ARGC that is relevant for RGI	The PR should provide this SOP to the inspector by the 1st of May 2011 Further action required. This will be monitored via the compliance cycle.
Formulation of a SOP for the transfer of patients notes between RGI to ARGC and vice versa. SLC T33b	The PR should have a documented SOP that describes the requirements for confidentiality and security of patient records during transfer between RGI and ARGC and vice versa. By 1 May 2011	No response	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
RGI has a documented SOP entitled *protocol for packaging, release and acceptance of gametes and embryos from/to other centres* that is used for the transfer of frozen gametes from ARGC to RGI and vice versa. However this does not included all the requirements of Standard Licence Condition T109. SLC T109	The PR should review the SOP *protocol for packaging, release and acceptance of gametes and embryos from/to other centres* used for transporting frozen gametes and embryos between the two centres and ensure it contains all the requirements of SLC T109 By May 1 2011	*Verbal response via telephone* This will be reviewed	This will be monitored via the compliance cycle.

Additional information from the Person Responsible

The PR telephoned on Thursday 13 January 2011 and provided verbal comments on the report.

HFEA Licence Committee Meeting

27 January 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 1

Centre 0206 (Reproductive Genetics Institute) – Renewal Inspection

Members of the Committee: Sally Cheshire (lay) – Chair Mair Crouch (lay) Jane Dibblin (lay) Rebekah Dundas (lay) Sue Price (professional) David Archard (lay) (did not participate) Debbie Barber (professional) (did not participate)	Committee Secretary: Terence Dourado Legal Adviser: Rosalind Bedward

Declarations of Interest

Legal advice was sought on the legal position regarding bias and declarations of interest. The Legal Adviser advised as follows:

- Members should always ensure they approached all matters impartially and with an open mind. Any member who felt unable to adopt such an approach should declare the relevant interest and take no further part in the discussion of the matter in question;

- The test for bias (and therefore the existence of a disqualifying interest). was whether the fair minded and reasonable observer, knowing all the facts and circumstances, would consider there to be a real possibility of bias. Case law had established that previous involvement with a matter in the ordinary course of events, such as sitting on a previous Licence Committee that had considered an application by a Centre, was not of itself sufficient to constitute bias. Some further level of involvement would be required.

Having considered this advice, David Archer and Debbie Barber both declared interests in the item and left the meeting. The Committee agreed that Sally Cheshire would stand as Chair of the Committee for the remainder of the meeting in accordance with 1.7 of the Protocol for the Conduct of Meetings of Licence Committee/Research Licence Committee.

The following papers were considered by the Committee:

- Signed application form
- Renewal inspection report with PR telephone verbal response
- Licence Committee minutes relevant to special directions and licensing of the RGI
    - 29th September 2009: in relation to the special directions in force in respect of RGI
    - 5th January 2010: Application for treatment and storage licence
    - 4th March 2010: Considerations of the special directions currently in force.
- Hard copy of submitted information provided as a bound document at the time of the Licence Committee

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 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); and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Background

1. The Committee was in receipt of a renewal application for Centre 0206 (Research Genetics Institute). The Centre was first licensed by the HFEA in 2003; from December 2005 to March 2010 it operated under special directions for the storage of gametes and embryos and the provision of some licensed treatments; and, in early 2010, the licence committee granted the Centre a one year treatment and storage licence commencing on 4th March 2010.

2. The Committee noted that the Centre provides facilities and services as part of a patient treatment pathway initiated at Centre 0157 (The Assisted

Reproductive Gynaecology Centre). Although the Committee was mindful of the integrated pathway arrangements between Centres 0206 and 0157, it confirmed that each Centre required a separate treatment and storage licence, and that the application for Centre 0206 would be considered on its own merits.

General Comments

3. The Committee was concerned that the renewal application for Centre 0206 potentially gave rise to some confusion because it did not always appear to distinguish between Centre 0206 and 0157. For example, under the activity levels heading, the figures provided for the maximum number of treatments the unit can accommodate for IUI/DI, IVF/ICSI/FET and PGD/PGS appeared to reflect an accumulated total for both Centres. The Committee agreed that although this did not materially affect its decision making, it confirmed that Centre 0157 should be acknowledged as an autonomous licensed centre.

Consideration of Application

4. The Committee had regard to its Decision Tree. The Committee was satisfied that the renewal application was submitted in the form required, and contained the supporting information required by General Direction 0008. It was satisfied that the appropriate fee had been paid.

5. The Committee noted that the application was made by the current designated Person Responsible (PR). It was satisfied that the PR will discharge his duties under section 17 of the Act because he has the relevant academic qualifications; at least two years practical experience which is directly relevant to the licensed activity to be carried out; and he has satisfactorily completed the PR entry programme (7th Code of Practice edition).

6. Based upon the evidence provided within the inspection report the Committee was satisfied that the premises to be licensed are suitable for the conduct of licensed activities there.

7. The Committee was satisfied that the licence application concerned treatment and storage relating to gametes and embryos intended for human application. Furthermore, it was satisfied that the application did not involve the use of embryos for training purposes or the testing of embryos.

8. The Committee noted that the inspection team had identified five major areas of non-compliance and four other areas of non-compliance which required improvement. It noted that the PR, in providing his response to the draft inspection report, had given verbal assurances that the Centre would correct its major areas of non-compliance, namely:

- That embryos do not remain in storage beyond the consented statutory period;
- That the audit of the procedures for the transportation of frozen gametes and embryos between the two centres is implemented;
- That the HFEA is appropriately informed about the movement of gametes and embryos between the two centres;
- That the validation of all equipment and processes is completed;
- That standard operating procedures (SOPs) are submitted to the HFEA inspection team.

9. The Committee noted that under General Direction 0005 the HFEA must be notified of the movement of gametes and embryos between Centres 0206 and 0157 via Electronic Data Interchange (EDI) and that EDI access must be established in order to do this. The Committee agreed that this access should be established as soon as practicable.

10. The Committee noted that while much of the required documentation (such as SOPs and third party agreements) may already be in place at Centre 0157, it was nonetheless highly important, for practical and compliance reasons, that any documents that originated at Centre 0157 but were in use at or relevant to Centre 0206, were also available at Centre 0206's premises to enable access by its staff and its patients.

11. The Committee noted that some SOPs specific to Centre 0206 were now in place.

12. The Committee agreed that the PR must comply with the recommendations set out in the inspection report within the prescribed timeframes. However, it wished to amend the suggested timeframes for two particular areas:

    - The Centre should have a documented SOP that describes the actions to take in response to alarms and that SOP shall be provided to the inspector by 1st March 2011;
    - The Centre should have a documented SOP that describes the local actions to be taken in the event of equipment malfunction and that SOP shall be provided to the inspector by 1st March 2011.

    The timescales for complying with these recommendations had been brought forward due to the importance of efficient responses to alarms and equipment malfunction for the safety of gametes and embryos in storage at the Centre in the interest of the patients.

13. The Committee noted the section of the inspection report which stated that no centre-specific key performance indicators (KPIs) had been established for the activities in place at Centre 0157. It also noted that, subsequently, the PR had clarified that the Centre does have activity related KPIs against which the Centre's performance is audited.

- The Committee requested that the KPIs, which had not been provided at the time of inspection, are submitted to the Executive by 31st May 2011.

14. The Committee suggested that any concerns that the recommendations have not been complied with in the prescribed timeframes be referred to the Committee should the Executive consider it appropriate to do so.

Decision

15. The Committee had regard to the 'Guidance on Periods for which New or Renewed licences should be Granted.' The Committee took into account evidence of the matters set out in paragraph 4.3 and noted paragraph 4.4 of the guidance which states that '[the Licence Committee] will normally grant a renewal licence for treatment/storage/non medical fertility services licence for a period of up to four years where the evidence before it reveals no concerns in the matters specified in paragraph 4.3 above.

16. The Committee after much deliberation agreed that it would be appropriate to renew the Centre's licence for a period of four years. The Committee was keen to ensure that all recommendations contained within the inspection report, as amended and added to by the Committee, were complied with, and that appropriate steps were in place to ensure that SOP's and procedures applicable to both Centres were implemented and available at Centre 0206. The Legal Adviser accordingly advised Committee that such requirements should be imposed as conditions on the licence, as opposed to remaining as recommendations. The licence was therefore renewed for a period of four years with the following two conditions:

    - That the Centre complies with the matters and recommendations detailed in paragraphs 8-12 (above) within the prescribed timeframes;
    - That, where SOPs and other operational procedures that relate to Centre 0157 include or apply to activities carried out at Centre 0206, those SOPs and procedures shall be implemented at Centre 0206 and copies of those SOPs and procedures shall be available at Centre 0206 for inspection at all times.

17. The Committee recommended that the Centre's licence should be varied to include the following activity, as permitted under the Act:

    - Procurement and processing

18. Furthermore, the Committee recommended that the Centre's licence should be varied to remove the following activities from its list of licensed activities:

    - Sub zonal insemination (SUZI);
    - Zona drilling;

- Gamete intra-fallopian transfer (GIFT);
- Zygote Intra-Fallopian Transfer (ZIFT).

Signed: S Cheshire Date: 14/2/11

Sally Cheshire (Chair)