Inspection Report

Date of Inspection: 16 and 17 April 2013
Purpose of inspection: Renewal of Treatment and Storage
Length of inspection: 16 hours over two days
Inspectors: Douglas Gray, Gill Walsh, David Gibbon, Chris Hall, Emer O'Toole

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 21 March 2012 and 21 June 2013.

Date of Executive Licensing Panel: 05 July 2013

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 (ELP) which makes the decision about the centre's licence renewal application.

Centre details

Centre name	**Bath Fertility Centre**
Centre number	**0139**
Licence number	**L/0139/12/c**
Centre address	**Royal United Hospital, Combe Park, Bath, BA1 3NG, UK[1]**
Person Responsible	**Mr Nicholas Sharp**
Licence Holder	**Mr David Walker**
Date licence issued	**01 September 2008**
Licence expiry date	**31 August 2013**
Additional conditions applied to this licence	**None**

[1]This inspection report presents findings from an inspection at the Centre's licenced premises at the Royal United Hospital. Since this inspection the Centre has moved to new licenced premises at Roman Way, Bath Business Park, Peasedown St John, Bath BA2 8SG; their licence has been varied to reflect this.

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

Bath Fertility Centre is a well established centre first licensed by the HFEA in 1994. The Centre was last inspected in March 2012 and this was an announced interim inspection.

At the time of the inspection, the Centre occupied premises in the grounds of the Royal United Hospital (RUH). The Centre has since this inspection relocated to new purpose built premises in Peasedown St John, approximately eight miles away. ELP are asked to note that this inspection report presents findings from the inspection held at the Centre's RUH premises, immediately prior to the Centre's relocation. It was not possible to conduct the renewal inspection at the new premises due to a delay in the final hand over of the new building.

Treatments are provided to both NHS and self funded patients. The Centre provided approximately 400 in vitro fertilisation (IVF) / intracytoplasmic sperm injection (ICSI) treatment cycles last year. In relation to activity levels, this is a small centre.

Variation to Licence

An application to vary the Centre's licence to reflect a change to premises was approved by ELP on 12 April 2013. Special directions for the storage of gametes and embryos were approved on 01 March 2013 to facilitate a controlled transfer of the storage dewers.

Activities of the Centre:

Type of treatment	Number of treatment cycles for 01 Mar 2012 - 28 Feb 2013
In Vitro Fertilisation (IVF)	111
ICSI	202
GIFT	0
FET	146
DI	23
Egg share provider (sharer)	3
Egg share recipient	3
Egg donation (non egg share)	8

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

Outcomes*

For IVF/ICSI, HFEA held register data for the period January to December 2012 show the Centre's success rates are in line with national averages.

For the year 2011 the centre reported 40 cycles of partner insemination with two pregnancies. The Centre's success rates in terms of clinical pregnancy rates are in line with national averages.

*The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems.

Summary for licensing decision

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

- The PR is suitable and that he 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.

ELP are asked to note that at the time of the inspection there were six areas of practice that required improvement, including one major area of non-compliance and five other areas of non-compliance.

Since the inspection visit the PR has provided evidence that the following recommendations have been fully implemented.

Major areas of non compliance:

- The PR should ensure egg donors who receive a benefit through their egg sharing programme, should be provided with that benefit in the course of the donation cycle unless there is a medical reason why not

'Other' areas of practice that require improvement:

- The PR should ensure that the identity of gametes or embryos are appropriately witnessed when being disposed of.
- The PR should ensure that all TPAs in operation are compliant with requirements in relation to quality and safety.
- The PR should risk assess whether not labelling all containers at egg collection could lead to misidentification.
- The PR should ensure that the Centre's strategy and protocols relating to multiple births are audited.

The executive will continue to work with the centre in relation to the following recommendation:

"Other"areas of practice that require improvement:

- The PR should ensure that relevant SOPs reflect consent to disclosure requirements relating to patients registered prior to 01 October 2009 returning to treatment and completing new consent forms; and donors and patients being treated with donor gametes registered after 01 August 2012. The inspector has requested that further information is provided from the PR in relation to this non-compliance.

Recommendation to ELP

The inspection team considers that, overall there is sufficient information available to recommend the renewal of this centre's treatment and storage licence for a period of four years without additional conditions. In making this recommendation it is noted that the PR has responded to all recommendations made in this inspection report and further evidence is required in only one area of practice.

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.

The centre uses a manual witnessing system to ensure the identification of gametes and embryos and the patient or donor to whom they relate at all critical points of the clinical and laboratory process, and to ensure that patients receive treatment using the correct gametes or embryos (standard licence condition (SLC) T71). All samples and the patients to whom they relate are identified and witnessed contemporaneously, with one exception (below).

There is a witnessing standard operating procedure (SOP) in place to direct witnessing practice (SLC T33(b)).

The following laboratory activities were observed in the course of the inspection: egg collection including the active identification of the patient, fertilisation checks and sperm preparation. All procedures observed were witnessed in accordance with HFEA guidance.

A record of the manual witnessing checks is kept in the patient / donor's medical record, as confirmed by witnessing procedures observed and by an audit of 10 patient records seen on inspection.

The centre has established quality indicators (QIs) (SLC T35) relevant to witnessing and documented audits of witnessing procedures were seen on inspection (SLC T36). Staff competencies for witnessing are documented and were seen on inspection (SLC T15 (a)).

What the centre could do better.

When disposing of gametes or embryos, the centre does not cross-check information on

the storage container against information in the patient or donor records to confirm they are the correct gametes or embryos to dispose of (SLC T71). See recommendation 2.

Patient selection criteria and laboratory tests

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

What the centre does well.

Procuring, processing and transporting of gametes and embryos:
All critical procurement and processing procedures have been validated and documented in SOPs (SLC T72 and T33(b)). QIs relevant to procurement and processing procedures have been established. There are documented audits of witnessing procedures and when necessary, corrective actions and their implementation are documented (SLC T35 and T36). Documented evidence of the assessment of competence for relevant staff in procurement and processing procedures was seen on inspection (SLC T15(a)).

Prior to processing, the providers of gametes intended for use in treatment or storage are screened in accordance with SLC T50 by a laboratory accredited by Clinical Pathology Accreditation (UK) Ltd (CPA) (SLC T21 and T51).

Where a semen sample is produced at home, this is recorded in the gamete provider's medical record (SLC T68).
There are SOPs in place detailing the circumstances, responsibilities and procedures for the release of stored material before distribution and also a recall procedure for handling returned gametes and embryos (SLC T33(b)) and Code of Practice (CoP (15C).

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

Counselling:
Independent counselling is offered to all patients and their partners before they provide consent for treatment (SLC T60). Counselling services are provided by one counsellor who works at the centre on a part time basis and is due to retire shortly, a second counsellor is in training. Counselling is available throughout the treatment process and following its conclusion, if required. Counselling is also offered to those providing consent to donation, and legal parenthood where donor gametes are used. The senior counsellor was able to provide assurance of her competence to provide counselling to those consenting to treatment or donation. The counsellor in training is working towards accreditation by the British Infertility Counselling Association (BICA).

An SOP for counselling is in place (T33b). QIs have been established and are monitored to assess performance and user satisfaction with the counselling service (SLC T35). The counselling service was most recently audited in March 2013. The audit was seen to include analysis of a counselling specific user satisfaction survey and how far counselling procedures comply with the protocols, QIs and regulatory requirements (SLC T36).

The counsellors can, when required, refer patients for specialist counselling, for example counselling for oncology patients storing their gametes or embryos for the preservation of

their fertility.

What the centre could do better.

Nothing noted on 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.

Donor recruitment, assessment and screening:
The Centre provides treatment with donated gametes and embryos. An SOP was seen relating to the selection and recruitment of gamete and embryo donors (SLC T33b).
QIs have been established and audits are performed (SLC T35 and T36); the results of the most recent audit were seen on inspection.

The Centre imports donor sperm from outside the EEA in accordance with General Directions 0006, evidence of which was seen on inspection.

A review of six donor records confirmed that donors were selected on the basis of their age, health and medical history (SLC T52a). Other than egg sharers, the Centre has recruited only two egg donors. Both records were reviewed on inspection, both donors were seen to have been screened in accordance with SLC T52 using a laboratory with CPA accreditation (SLC T53).

Payment for donors:
The Centre ensures that payments to donors are restricted to the limits prescribed in Direction 0001. In the last year, payments have been made to a small number of egg donors. The records of payments made to these donors were reviewed on inspection and considered by the inspectors to be compliant with Direction 0001. A Third Party Agreement (TPA) is in place with the sperm bank from which sperm is imported that ensures compliance with Direction 0006, and the requirement within that compensation is made in accordance with Direction 0001.

Donor assisted conception:
Evidence was provided that those who are to receive treatment with donated gametes or embryos are provided with information on the importance of informing any resulting child at an early age of their donor origins and how best parents may do this (SLC T63a and b).

Confirmation was given that there are no gametes which were donated prior to April 2005 where the donor had not consented to being identifiable are stored or used (SLC T54).

What the centre could do better.

Nothing noted on 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)
- Intracytoplasmic sperm injection (ICSI) (Guidance Note 21)

What the centre does well.

The quality management system:
There is a comprehensive quality management system in place which includes a quality manual and training and reference materials (SLC T33).

From discussions with staff, observation and a review of documentation at inspection, the inspection team conclude that there are SOPs in place (SLC T33 (b)) to direct all activities to be provided in the course of providing treatment services and, where relevant, they specify any critical materials and reagents used in the procedure described (SLC T31). QIs have been established for the Centre's activities (SLC T35) and audits have been conducted within the last two years for the Centre's key activities. A sample of audits was reviewed in the course of the inspection (SLC T36). The inspection team considers that the scope and methodology for audit practised at the centre is well planned and comprehensive and demonstrates that audit is considered an important tool for continuous improvement by Centre staff.

Traceability:
Centre staff were able to demonstrate that gametes and embryos and materials coming into contact with gametes or embryos used in treatment which may affect their quality and safety are traceable throughout from procurement to treatment and that there is are SOPs to direct this process (SLC T22, T33 (b) and T99).

With the exception of tubes and dished used to transfer follicular fluid at egg collection, all tubes and dishes are labelled with patient / donor name and a unique identifier. This was confirmed during the inspection by the observation of procedures in the laboratory which demonstrated the identification and labelling of dishes containing patient / donor gametes (SLC T101).

QIs relevant to traceability have been established and procedures audited. Audits were seen by the inspection team and included findings, corrective actions and record of their implementation. Staff competence to perform traceability procedures has been documented (SLC T35, T36, T15(a)).

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

Process validation:
Critical procurement and processing procedures have been validated. Documentary evidence of this was seen on inspection (SLC T24 and T72).

Equipment and materials:
Documented evidence was available to see on inspection which demonstrated all critical equipment used in patient treatment or the storage of gametes and embryos has been validated and will not render the gametes or embryos clinically ineffective or harmful to the recipient (SLC T24 and T25).

Manuals and documented procedures (SOPs) for the operation of all critical equipment are readily available to staff in the work areas which included the actions to be taken in the event of equipment malfunction or failure (SLC T27). Key equipment or materials that affect the critical processing or storage parameters where observed to be calibrated to traceable standards and subject to appropriate monitoring and alarms (SLC T24). Documented evidence of regular cleaning, decontamination and preventative maintenance and servicing was also seen (SLC T26 and 28). Sterile instruments are used for the procurement of gametes and embryos. CE marked instruments/materials are used where possible (SLC T30).

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

Adverse incidents:
There is an SOP in place to direct the reporting of adverse incidents or near miss events to HFEA. Staff were able to describe the process to be followed for reporting and the investigation of an incident or untoward event and demonstrated a good understanding of the nature of events or incidents that should be reported to HFEA (SLC T118).

Third Party Agreements:
The Centre has established written agreements with all third parties who provide goods or services that influence the quality and safety of gametes (SLC T111). Evidence was seen that confirmed that the Centre has evaluated the ability of third parties to meet the required standards (SLC T112) and that the content of most agreements is compliant with SLC T113 and T114. A list of all third party agreements (TPAs) is maintained by the centre (T103). The inspection team audited five of the Centre's TPAs and considered them to be compliant with the relevant standard licence conditions with one exception detailed below.

ICSI:
There is an SOP in place to direct ICSI practice (SLC T33(b)) which has been validated based on historical data (SLC T72). Staff conducting ICSI procedures were able to provided documented evidence of the assessment of their competence in this procedure (SLC T15(a)). QIs for performance have been established and are monitored (SLC T35). The results of the most recent audit of ICSI practice were seen on inspection (SLC T36).

What the centre could do better.

An audit of five TPAs identified one TPA in which the third party was not compliant with SLC T112 & T114e; the third party provider could not provide reassurance of their ability to meet requirements of SLCs and the CoP, or their ability to meet specific requirements in relation to quality and safety. See recommendation 3.

Tubes used to collect follicular fluid which are transferred to the laboratory, and dishes into which the fluid is poured for egg collection were not labelled with the patient's/donor's full name and a further identifier or a uniquely identifying donor code. See recommendation 4.

Multiple Births (Guidance Note 7)

For the period April 2010 to April 2011 the Centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 20 %: this represented performance that was not likely to be statistically different from the no greater than 20 % multiple live birth rate target for that time period.

For the time period April 2011 to September 2012 the Centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 17 %: this also represents performance that is not likely to be statistically different from the no greater than 15 % multiple live birth rate target for that time period.

The progress in reducing the clinical multiple pregnancy rates from 2010/11 to 2011/12 suggests that the centre is being proactive and effective in adapting their strategy to meet the HFEA's multiple birth rate target.

What the centre does well

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

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

What the centre could better

No documented evidence could be provided that staff at the Centre have audited their multiple birth minimisation strategy and protocols as part of the quality management audit programme. See recommendation 5.

Staff engaged in licensed activity

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

What the centre does well.

Person Responsible:
The PR has academic qualifications in the field of medicine and has more than two years of practical experience that is directly relevant to the activity to be authorised by the

licence (HF&E Act 1990, as amended, section 16(2)(c)(i) and (ii)). The PR has successfully completed the Person Responsible Entry Programme (PREP) certificate number: T/1068/7).

Staff:
The Centre has suitably qualified staff to carry out all of the licensed activities and associated services provided. All staff that require registration with professional and/or statutory bodies are appropriately registered (SLC T14).

The Centre has a stable workforce with a low turnover of staff. The PR confirmed they have an adequate number of staff to assure patient safety and quality of care (SLC T12), and to accommodate the move to the new premises. One of the most recently appointed members of the embryology team was interviewed on inspection and described a comprehensive induction programme (SLC T15).

Evidence was provided that staff are competent in their designated tasks. Samples of staff competence assessments were reviewed and considered comprehensive, including for example donor recruitment and assessment, provision of information and obtaining consent (SLCT15(a)). The PR informed the inspection team that opportunities for professional development are well supported.

What the centre could do better.

Nothing noted on this inspection.

Welfare of the Child (WcC) (Guidance Note 8)

What the centre does well.

Patients are not provided with treatment until account has been taken of the welfare of any child who may be born as a result and of any other child who may be affected by the birth (SLC T56). There is an SOP to guide the assessment process (SLC T33(b)). The Centre has audited their welfare of the child (WoC) procedures (SLC T36) and a copy of a recent audit was seen on inspection.

An audit of five patient records showed that both patient and partner had completed WoC assessment questionnaires and that the forms had been reviewed by a member of the nursing team prior to treatment. A ‘matched’ file for both a surrogate and the commissioning couple were also noted to have appropriate WoC assessments documented.

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

What the centre could do better.

Nothing noted on this inspection.

Embryo Testing – ***only applicable to centres licensed to carry out***

preimplantation genetic diagnosis and screening) · Preimplantation genetic screening (Guidance Note 9) · Embryo testing and sex selection (Guidance Note 10)
This section is not applicable as the centre does not carry out embryo testing.

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)
- Complaints (Guidance Note 28)
- Provision of costed treatment plans (Guidance Note 4)
- Egg sharing arrangements (Guidance Note 12) – *if applicable*
- Surrogacy (Guidance Note 14) – *if applicable*

What the centre does well.

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

Complaints:
There is an SOP for managing complaints (SLC T33(b)) and information on how to make a complaint is available to patients. A log of all complaints received is maintained and was reviewed on inspection. All complaints appear to have been appropriately managed.

Costed treatment plans:
Before treatment and/or storage are offered, a personalised costed treatment plan is provided to the patient and her partner (when applicable) and the proposed plan is discussed prior to treatment commencing. A copy of a costed treatment plan provided was reviewed during the inspection (CoP 4.3).

Egg sharing arrangements:
The Centre recruits egg donors through egg sharing arrangements and patient information is available. Patients choosing to egg share are screened in accordance with SLC T52 using a laboratory with CPA accreditation (SLC T53).

Surrogacy:
The Centre has a surrogacy programme and the patient records of a commissioning couple and host were reviewed on inspection. All parties were seen to have been offered counselling and all necessary consents were in place. The commissioning couple had been appropriately screened and registered as donors (SLC T52 and 53).

What the centre could do better.

Egg sharing arrangements:
Direction 0001 sets out arrangements by which gamete donors may receive licensed services, such as treatment, in return for supplying gametes for donation. Egg donors who receive a benefit should be provided with that benefit in the course of the donation cycle unless there is a medical reason why they cannot be. The Centre's patient information provides the option for patients that do not have sufficient eggs available to share during that cycle, to donate all eggs retrieved and return to receive a separate cycle of free treatment. This is not compliant with Direction 0001 because the benefit (treatment) is not provided in the course of the donation cycle. See recommendation 1.

Information

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

What the centre does well.

The inspection team concluded that detailed information about the nature of the treatment, consequences and risks, tests, confidentiality, consent, and the availability of counselling is given to patients consenting to treatment or to donation or to donation to research. Those giving consent are given adequate opportunity to discuss the implications of their consent before treatment or donation commences. A suite of patient information that had changed since the time of last inspection was audited by the inspection team and was considered to meet the recommendations of the CoP. The Centre's website was broadly compliant with the HFEA Chairs letter Ch(11)02.

SOPs incorporating the provision of information were seen to be in place in addition to QIs and audits (SLC T33(b), T35 and T36). The Centre audit regularly against provision of information requirements, and the results of a recent audit was seen.

What the centre could do better.

Nothing noted on 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.

Consent to treatment, storage, donation, training and disclosure of information:
Centre staff provided evidence that written consent is obtained from patients / donors prior

to treatment and the centre has a documented SOP for obtaining consent (SLC T33 (b)).

QIs have been established and audits performed (SLC T35 andT36). An audit seen by the inspection team documented that no non conformities were observed.

Centre staff explained that photographic evidence is used to verify patient/partner identity in addition to a check of a signature against the original in the patients file. Evidence of this was seen in the files reviewed on inspection (CoP 5.10).

A review of the centre's records of consent to storage of sperm showed that all sperm currently in store was being stored in accordance with the consent of the sperm providers and was within the consented storage period. A review of the centre's records of consent to storage of embryos showed that all embryos currently in store were being stored in accordance with the consent of the gamete providers and were within the consented storage period. For one set of embryos in store, a notification of withdrawal of consent had been recently received and centre provided evidence to satisfy the inspection team that continued storage was in accordance with the HF&E Act 1990, as amended, Schedule 3 4A(4) (the 'statutory cooling off' period).

The storage periods for three sets of embryos and three sets of sperm samples as recorded on the centre's database were cross checked against the consent given by the gamete providers on HFEA consent forms. The storage period had been accurately recorded in the centres database in all but one case in which the date recorded on the system would have led to consent being reviewed at an earlier date than necessary. As the Centre regularly review their storage consent records, the inspection team consider this to be a minor error that does not warrant a recommendation.

The centre operates a 'bring forward' system to ensure gamete providers have sufficient notice of the end of their consented storage period, the SOP for which was seen on inspection.

To determine whether the register properly reflects the consent given by patients and their partners for the use of register information for research purposes, a sample of 14 completed patient and partner disclosure consents were reviewed against disclosure consent data supplied by the centre for inclusion on the HFEA register.

11 of 14 patient / partner consent to disclosure to researcher decisions recorded in the patient's primary medical record were seen to correspond with the consent to disclosure decision submitted to the HFEA register.

Consent to legal parenthood:
The Centre provides treatment with donor gametes to women and couples who may or may not be married or in a civil partnership. SOPs were seen to be in place to guide the process for obtaining the relevant written records of consent to parenthood (SLC T33(b)). Those affected by legal parenthood legislation are informed of how the nomination of a second legal parent affects them and of the consent process prior to treatment being offered (SLC T60), and this process was described by staff interviewed on inspection. Staff demonstrated an understanding of the process for seeking consent and the need to ensure that should a nominated second parent withdraw their consent the woman would not be treated until she had been informed (SLC T64(b)).

What the centre could do better.

In two instances a patient and partner registered prior to 01 October 2009 returned for treatment and subsequently completed new disclosure consent forms but the register has not been updated to reflect the consent given. In one instance a patient undergoing donor insemination completed only Part 1 of a Consent to Disclosure form (CD) (i.e. without the relevant consent questions). The CD form had been completed after 01 August 2012 when consent became relevant to such patients. See recommendation 6.

3. Protection of gametes and embryos

Focus

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

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

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

What the centre does well.

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

The inspection team considered that staff at the Centre have respect for the special status of the embryo when carrying out assisted conception treatment services and that only permitted embryos are used in the provision of treatment.

Assurance was provided that no money or benefit is given or received in respect of the supply of gametes or embryos unless authorised by the Authority

What the centre could do better.

Nothing noted on 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.

An SOP is in place for the storage of gametes and embryos (SLCT33(b)). Storage procedures have been validated and QIs established (SLC T72, T75 and T35). Audits have been performed and the results of a recent audit were available on inspection (SLC T36). Staff competence is assessed and practice audited against the centre's SOP (SLC T15(a) and T36).

The laboratory manager confirmed that prior to storing their gametes and embryos patients are screened in accordance with SLC T50 and T51. This was confirmed in SOPs, checklists and in patient records seen on inspection.

What the centre could do better.

Nothing noted on this inspection.

Distribution and / or receipt of gametes and embryos

- Distribution of gametes and embryos (Guidance Note 15)
- Export of gametes and embryos (Guidance Note 16) Receipt of gametes and embryos (Guidance Note 15) Import of gametes and embryos (Guidance Note 16)

What the centre does well.

The centre has processes and procedures in place to ensure gametes and embryos are only sent to other licensed centres in conditions that protect the safety and quality of the gametes and embryos.

There are documented procedures that detail the circumstances, responsibilities and procedures for the release of stored material before distribution (SLC T33b). SOPs include transport conditions (temperature and time limits for example) (SLC T107), a recall procedure and procedures for the handling of returned gametes and embryos. The Centre's dry shipper has been validated as fit for its purpose (SLC T108). The SOP describes procedures to ensure gametes and embryos are packaged for transport in a manner that minimises the risk of contamination and preservers their required characteristics and biological function (T105).

The Centre was able to provide evidence that they had complied with all the requirements of Directions 0006 when importing or exporting gametes or embryos. The inspection team reviewed the details of three imports received by the Centre and confirmed that in these instances the requirements of Directions 0006 had been met.

What the centre could do better.

Nothing noted on this inspection.

Use of embryos for training staff (Guidance Note 22)

What the centre does well.

Embryos are only used for training activities authorised by the Authority (SLC T93).This was evidenced on inspection by reviewing the training log. Evidence was shown to the inspection team that embryos are only used in training when both gamete providers have consented for such use.

Patients' consent to use of their embryos in training is documented and checked at the time of embryo culture. The Centre uses only embryos not suitable for treatment for training purposes; this ensures that there is no actual or perceived conflict of interest between the use of embryos in training and the use of embryos in the provision of treatment (SLC T95). Embryos are only use for training purposes expressly authorised by the Authority (SLC T93). Patients are provided with information on the nature of training for which their embryos will be used (SLC T97).
What the centre could do better. Nothing noted on 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.

Patient records reviewed during the inspection were seen to be clear and legible and satisfied all of the requirements of SLC T46. Each record reviewed included: 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, WoC assessment, relevant documented consents and clinical and laboratory data and the results of tests carried out.

Procedures are in place to ensure records are protected from unauthorised amendment, are retained and can be retrieved throughout the designated retention period (SLC T47). Documents submitted to the HFEA as part of the renewal application and viewed on inspection were seen to be controlled, recording the history of document reviews and systems are in place to ensure that only the current version is in use and accessible to staff (SLC T34).

What the centre could do better.

Nothing noted on 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.

A data submission SOP has been developed and was reviewed by the inspection team (SLC T33b). Relevant QIs have been developed and are used to monitor the effectiveness of data submission processes on an on-going basis (SLC T35). Regular periodic audit of register submissions is undertaken and appropriate corrective action is taken to address issues identified (SLC T36).

To determine whether all licenced treatment activity is reported to HFEA within required timescales, a sample of treatments undertaken over a 12 month period recorded within the

centres laboratory records was compared to data submitted by the centre for inclusion on the HFEA register. All 24 donor insemination treatments and 123 IVF treatments within the audit sample had been reported to HFEA as required by Direction 0005.

To confirm that data submitted by the centre for inclusion on the statutory register accurately reflects that found in source records on-site a sample of 56 assorted form type data submissions were reviewed against source documentation held on patient and donor files. No critical errors or omissions were found in the data (i.e. errors or that would prevent the authority fulfilling its statutory obligations). Additionally no systematic error was identified within the sample.

What the centre could do better.

Nothing noted on this inspection.

Disclosure of information

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

What the centre does well.

Confidentiality and privacy: (Guidance Note 30)
This inspection report presents findings from the Centre's premises at RUH; the Centre has since moved to new premises.

With one exception, a tour of the RUH premises confirmed that access to all confidential information is restricted to authorised personnel and that patient records are stored securely (SLC T43). Access to the premises is not restricted although key pad locks provide restriction to sensitive areas (laboratories, cryostore).

SOPs are in place to ensure that all information is kept confidential and only disclosed in circumstances permitted by law (T33 (b)). Evidence of training in confidentiality for the administration team was seen on inspection.

What the centre could do better.

Access was not controlled to the Centre's 'red box' in which records were stored for patients awaiting scans; this represents a risk that confidential information could be disclosed under circumstances not permitted by law (SLC T43). It is however noted that since the time of this inspection, the Centre has relocated to new purpose built premises with access control, and staff have verbally committed to implementing systems to ensure confidential information is protected. Therefore, no recommendation will be made and this issue will be reassessed in the new premises at the next inspection.

5. Changes / improvements since the previous inspection on 21 March 2012.

Area for improvement	Action required	Action taken as evidenced during this inspection
Consent to disclosure to researchers In one of the 18 registration forms reviewed on inspection, a discrepancy was noted where a patient had consented for research, but this consent decision was incorrectly entered on the HFEA register. This discrepancy was corrected at the time of inspection. In two of the 18 registration forms audited, a discrepancy was again noted where a patient had consented for research, but this consent decision was not correctly recorded on the HFEA register. However, evidence was provided on inspection that the information submitted to the HFEA via the centre's database was consistent with that consented by the patient. This discrepancy is being further investigated by the Executive. General Direction 0005.	The PR should conduct an audit of a representative number of consent to disclosure forms (completed since October 2009) in the patient records against the consent decisions that have been submitted to the HFEA. The findings of the audit and any relevant corrective actions should be documented and a copy provided to the Executive by 21 June 2012. If the audit findings indicate a systemic problem, a full audit of all consent to disclosure forms completed since October 2009 may be required. The PR should ensure that in future, all data submitted regarding consent to disclosure of identifying information from the HFEA register is entered accurately and is supported by the patient record. Further action may be required of the PR, depending on the outcome of the investigation into the two other discrepancies noted on inspection.	The inspection team have no continuing concerns following an audit by the Centre. No further action is required.
Sperm storage At the time of inspection the sperm samples of one patient were in storage without valid consent. HF&E Act 1990 (as amended) Schedule 3,	At the end of the inspection, the laboratory manager confirmed that the samples had been thawed and allowed to perish. Post inspection, the laboratory manager provided details of a comprehensive	No further action was required.

Paragraph 8 (1).	notification system that has been implemented to remind centre staff when consent to storage for sperm samples is about to expire, to ensure that samples destined to be allowed to perish do not remain in storage past the consented period. A system is already in place for embryos in storage. No further action is required.	
Process validation The validation of the process for assisted hatching has not been performed. SLC T72.	Post inspection, the laboratory manager submitted evidence demonstrating that this process has now been validated. No further action is required.	No further action was required.
Completion of consent forms In one set of notes, the patient's details on page one of the consent to disclosure consent form had not been documented. The nurse manager took corrective action at the time of inspection by completing the required information. General Direction 0007.	The PR should ensure that systems are in place to confirm that consent forms are completed appropriately prior to treatment. The nurse manager explained on inspection that the centre uses checklists to ensure that consent is in place prior to treatment and that staff would be reminded to review the content of the consent forms for completeness prior to completing the checklist.	The inspection team have no continuing concerns following an audit of consent forms.
Witnessing In three sets of patient notes audited on inspection, the record of the practitioner performing one of the required witnessing steps was absent. In two of these cases, the final 'witnessing check' box had been checked. SLC T71. This was an issue at the last inspection.	The PR is reminded that all witness checks must be recorded at the time of the procedure. The laboratory manager has submitted the report of a witnessing audit carried out post inspection, detailing the findings and corrective action to take. A re-audit is planned for three months time. The Executive is satisfied with this response and recommends that accurate	An audit of five sets of patient notes showed that witnessing checks had been appropriately recorded (see Section 1 of this report). The inspection team were able to view the centres most recent audit of witnessing that was completed within an appropriate time scale. No further action is required

The centre's documented QI monitoring SOP states that the frequency for auditing of the witnessing QI is quarterly, however the last audit was performed in February 2011. SLC T35.	completion of witnessing records continues to be frequently monitored as part of the centre's audit programme. The PR should ensure that there is consistency between the documented frequency for auditing of the centre's witnessing QI and the actual frequency of audit. The PR should submit: • The report of the witnessing audit due to be carried out in three months time. And • The QI monitoring SOP, if revisions to the auditing frequency are required.	
Hepatitis B screening One set of patient notes reviewed, where the patient had recently had treatment, had not been screened for anti-HBc. SLC T50.	The PR should ensure that, prospectively, all patients are screened for anti-HBc. The PR should inform the Executive of the actions to be taken to ensure that this is performed.	The inspection team were able to review patient notes confirming that patients/donors had been appropriately screened. No further action is required
Submission of data Submission of outcome forms for treatments that involved donor gametes, where the donors are not registered with the HFEA. It is likely that the donors are registered with the HFEA, but that discrepancies with the donor code naming convention caused the errors. Post inspection, the HFEA registry team has confirmed that all but one of the recent	The PR should review the centre's processes to ensure that donors are registered correctly with the HFEA. The PR should ensure that where errors in the data submitted to the HFEA are identified, these are cleared within two calendar months. Immediately.	Following an audit on inspection, the inspection team had no continuing concerns relating to submission of data. No further action is required

errors has been resolved and that the centre is actively working to resolve the historic errors. General Direction 0005.		
Staff complement The laboratory manager stated that the laboratory team was not at full staff complement. As such, the laboratory manager explained that she does not currently have sufficient time to carry out the quality management role. SLC T12 and CoP Guidance 23.3 (d).	The PR should regularly review staff resource levels to ensure that there is sufficient time available for the laboratory manager to allocate to the quality management role. Particular consideration should be given to the significant increase in quality management activities that will be required with respect to the planned new premises.	The laboratory manager reported on inspection that sufficient time was now allocated to complete the quality management role. The inspection team had no continuing concerns relating to staffing or the quality management system. No further action is required

Areas of practice that require the attention of the Person Responsible

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

Critical area of non compliance

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None noted on 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. The centre’s patient	The PR should ensure egg	Patient information has been	The inspector has reviewed

information provides the option for patients that do not have sufficient eggs available to share during that cycle, to donate all eggs retrieved and return to receive a separate cycle of free treatment. This is not compliant with Direction 0001 because the benefit (treatment) is not provided in the course of the donation cycle.	donors who receive a benefit through their egg sharing programme, should be provided with that benefit in the course of the donation cycle unless there is a medical reason why not. The centre's SOP and patient information should be amended in accordance with Direction 0001. A copy of any amended documents should be forwarded to the Centre's inspector. If necessary, the PR should ensure that relevant staff receive training in the amended policy and confirmation of training provided to the centre's inspector. To be completed by 17 July 2013.	amended and is now fully compliant with directions. A copy has been provided to our inspector.	the amended patient information and is satisfied that no further action is required.

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
2. When disposing of gametes or embryos, the centre does not cross-check information on the storage container against information in the patient or donor records to confirm they are the correct gametes or embryos to be disposed of. SLC T71	The PR should ensure that the identity of gametes or embryos is appropriately witnessed when being disposed of. Relevant SOPs and/or associated documentation should be amended to reflect any changes and a copy provided to the centre's inspector. Staff should receive training in the implemented procedure and confirmation of the receipt of training should be provided to the centre's inspector. By 17 July 2013.	All containers of gametes/embryos are witnessed whenever movement takes place, including at the time of disposal. Labelled containers are checked against patient records. We have recently installed and are currently in the process of validating an electronic witnessing system which will automatically record the identity of all dishes and tubes containing gametes/embryos at the time of movement. We will send a copy of the "Witness" SOP to our inspector once validation is complete.	Following telephone discussions with Centre staff and the PR's response, the inspector is satisfied that no additional action is requested beyond the centre's on-going efforts to validate their electronic witnessing system. The inspection team will reassess compliance with SLC T71 upon receipt of the revised witnessing SOP.
3. An audit of five TPAs identified one TPA in which the third party was not compliant; the third party provider could not provide reassurance of their ability to meet requirements of	The PR should ensure that all TPAs in operation are compliant with requirements in relation to quality and safety. Appropriate action should be taken when the PR has	This third party has now provided reassurance of their ability to comply with quality and safety requirements. A copy of the TPA has been provided to our inspector.	The inspector has reviewed the TPA provided and is satisfied that no further action is required.

SLCs and the Code of Practice, or their ability to meet specific requirements in relation to quality and safety. SLC T112 & T114e	identified that a third party provider is unable to meet the requirements of T112 to ensure that the provider is able to, or when the PR deems necessary, to find an alternative provider. A summary of action taken should be provided to the centre's inspector. By 17 July 2013.		
4. Not all dishes and tubes used egg collection were labelled with the patient's/donor's full name and a further identifier or a uniquely identifying donor code (including labelling in the form of electronic tags). SLC T101	The PR should risk assess whether not labelling all containers at egg collection could lead to misidentification and take corrective action where appropriate. The risk assessment and details of any action taken should be provided to the centre's inspector by 17 July 2013.	We are confident that our processes are robust. Checks are carried out and signed for by two embryologists prior to commencement of egg collection. A copy of the risk assessment has been provided to our inspector.	The inspector has reviewed the centre's risk assessment and is satisfied that no further action is required.
5. No documented evidence could be provided that staff at the centre has audited their multiple births strategy and protocols as part of the quality management audit programme.	The PR should ensure that the Centre's strategy and protocols relating to multiple births are audited, and the documented evidence of this is provided to the Centre's inspector by 17 July 2013.	The BFC multiple births strategy had in fact been audited and discussed at our Quality Management review meeting in October 2012. A copy of the minutes has been provided to our inspector.	A copy of the audit has been received by the inspector. No further action required.

Direction 0003			
6. In two instances a patient and partner registered prior to 01 October 2009 returned for treatment and subsequently completed new disclosure consent forms but the HFEA register has not been updated to reflect the consent given. In one instance a patient undergoing DI treatment completed a CD for Part 1 only (i.e. without the relevant consent questions). The CD form had been completed after 01 August 2012 when consent became relevant to such patients. Guidance Note 5 – Consent to treatment, storage, donation and disclosure of information Chair's Letter CH(10)05 Guidance supplementary to Chair's Letter CH(10)05 and Direction 0007	The PR should ensure that relevant SOPs reflect consent to disclosure requirements relating to patients registered prior to 01 October 2009 returning to treatment and completing new consent forms; and donors and patients being treated with donor gametes registered after 01 August 2012. Any amended documents should be forwarded to the Centre's inspector. The PR should ensure that staff receive training if necessary, and a summary of training provided should be forwarded to the Centre's inspector. By 17 July 2013.	A check list is completed at the beginning of each treatment cycle. Nursing staff use this to ensure the correct consent forms are completed and the HFEA register information is completed. Patient registration forms are checked against CD forms at the time of ITT form submission. The importance of this has been discussed by the nurses at their departmental meeting.	The inspector acknowledges that steps are taken to ensure completed consent forms are in place and that appropriate staff training has been given. The PR is requested to provide further assurance that the steps in place would ensure that all required sections of the appropriate consent forms have been completed, and in circumstances that new consent is taken that the register is updated as necessary.

Additional information from the Person Responsible

HFEA Executive Licensing Panel Meeting

5 July 2013

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

Minutes – Item 1

Centre 0139 – (Bath Fertility Centre) – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard – Head of Policy and Communications (Chair) Hannah Darby – Senior Policy Manager David Moysen – Head of IT	Rebecca Loveys

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 small centre which has held a treatment and storage licence with the HFEA since 1994.

2. The Panel noted that the centre is currently on a five year licence which expires on 31 August 2013.

3. The Panel noted that, in the 12 months to December 2012, the centre's success rates for IVF/ICSI were in line with the national averages.

4. The Panel noted that, for the time period April 2011 to September 2012, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 17%, and that this represents performance that is not likely to be statistically different from the 15% multiple live birth rate target for that time period.

5. The Panel noted that, at the time of the inspection, the centre occupied premises in the grounds of the Royal United Hospital (RUH). Since this inspection, the centre has relocated to new purpose-built premises in Peasedown St John, approximately eight miles away. This inspection report thus presents findings from the inspection held at the centre's RUH premises, immediately prior to the centre's relocation, and it was not possible to conduct the renewal inspection at the new premises due to a delay in the final hand over of the new building.

6. The Panel noted that, at the time of inspection, the Inspectorate identified one major and five other areas of non-compliance.

7. The Panel noted that, since the time of inspection, the Person Responsible (PR) has resolved all but one of these non-compliances (one other area of non-compliance).

Decision

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

9. The Panel noted that the Inspectorate was satisfied with the centre's new premises and deemed them to be suitable for the conduct of licensed activities.

10. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of the licensed activities.

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

12. The Panel commended the centre for reducing its multiple clinical pregnancy rate.

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

Signed: [signature] Date: 17 July 2013

Juliet Tizzard (Chair)