HFEA Executive Licensing Panel Meeting

5 September 2014

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

Minutes – Item 3

Centre 0295 – (Bristol Centre for Reproductive Medicine) – Renewal Treatment & Storage Inspection Report

Members of the Panel:	**Committee Secretary:**
Juliet Tizzard – Director of Strategy & Corporate Affairs David Moysen – Head of IT Rachel Hopkins – Head of Human Resources	Dee Knoyle

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

The Panel 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 considered the papers, which included a completed application form, inspection report and licensing minutes for the past three years.

2. The Panel noted that this is a treatment and storage centre which provides a full range of licensed treatments. The Panel noted that in relation to activity levels this is a large centre.

3. The Panel noted that the centre has been licensed by the HFEA since 2007 and is on a four-year licence due to expire on 18 December 2014.

4. The Panel noted that in 2013, the centre reported 231 cycles of partner insemination with 37 pregnancies. This equates to a 16% clinical pregnancy rate which is consistent with the national average.

5. The Panel noted that for IVF and ICSI, HFEA-held register data for the period 1 March 2013 to 28 February 2014 show that the centre's success rates are in line with national averages.

6. Between 1 March 2013 and 28 February 2014, the centre's clinical multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 17%. This represented performance that was not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

7. The Panel noted that at the time of the inspection on 24 and 25 June 2014, the Inspectorate identified one critical, ten major and six other areas of non-compliance. The Panel noted the non-compliances and urged the centre to address all areas of concern.

8. The Panel noted that the Inspectorate will continue to monitor the centre's performance and that failure to implement the recommendations relating to these areas of non-compliance, within the prescribed timescales, may result in the submission of a further report to a licensing Committee, with the recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement Policy. The Panel noted that the Person Responsible (PR) was committed to fully implementing all of the recommendations.

Decision

9. 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.

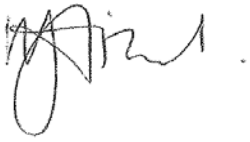
10. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licenced activities, and the PR has discharged their duty under section 17 of the HF&E Act 1990 (as amended).

11. The Panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

12. The Panel endorsed the Inspectorate's recommendation to continue to monitor the centre's performance and emphasised that failure to implement the recommendations relating to the various areas of non-compliance within the prescribed timescales may result in the submission of a further report to a licensing committee, with the recommendation that appropriate regulatory action should be taken in accordance with the Authority's Compliance and Enforcement Policy.

13. The Panel also agreed that given the volume and seriousness of the non-compliances a progress report should be submitted to the Executive Licensing Panel shortly after 25 September 2014.

14. The Panel endorsed the Inspectorate's recommendation to renew the centre's treatment and storage licence for a period of four years without additional conditions.



Signed: Date: 15 September 2014

Juliet Tizzard (Chair)

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 24 and 25 June 2014

Purpose of inspection: Renewal of a licence to carry out Treatment and Storage

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Inspectors: Karen Conyers (Lead), Douglas Gray, Susan Jolliffe, Chris Hall, Barbara Lewis

Date of Executive Licensing Panel: 5 September 2014

Centre name	Bristol Centre for Reproductive Medicine
Centre number	0295
Licence number	L/0295/2/c
Centre address	Department of Women Health, North Bristol NHS Trust, Southmead Hospital, Bristol, BS10 5NB, UK
Person Responsible	Dr Valentine Akande
Licence Holder	Mr Paul Wilson
Date licence issued	19 December 2010
Licence expiry date	18 December 2014
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Bristol Centre for Reproductive Medicine has held a Treatment and Storage licence with the HFEA since December 2007 and provides a full range of fertility services. The inspection team is satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

The centre provided 1,250 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 May 2014. In relation to activity levels this is a large centre.

Other licensed activities of the centre include storage of gametes and embryos.

The current licence was issued in December 2010 and was varied to reflect a change of Person Responsible (PR) in 2011.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 March 2013 to 28 February 2014 show the centre's success rates are in line with national averages.

In 2013, the centre reported 231 cycles of partner insemination with 37 pregnancies. This equates to a 16% clinical pregnancy rate which is consistent with the national average.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.

Between 1 March 2013 and 28 February 2014 the centre's clinical multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups is 17%: this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

[1]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. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the PR;
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under Section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by 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 ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement; one critical, ten major and six 'other' areas of non-compliance.

Since the inspection visit the PR has given a commitment to fully implementing the following recommendations:

Critical area of non compliance:

1. **The PR should ensure that gametes and embryos are not kept in storage without effective consent to storage from the gamete providers.**

Major areas of non compliance:

2. The PR should ensure that blood samples are obtained within the timeframes specified by the Authority.
3. The PR should ensure that the laboratory which undertakes diagnostic semen analysis is accredited by Clinical Pathology Accreditation (CPA) (UK) Ltd. or equivalent, or provide evidence to support a status equivalent to accreditation.
4. The PR should ensure that evidence to demonstrate compliance with General Direction 0006 is obtained before gametes and/or embryos are imported or exported.
5. The PR should ensure that all critical equipment is validated.
6. The PR should ensure that all critical processes are validated.
7. The PR should ensure that egg donors, who receive a benefit through the centre's egg sharing programme, are provided with that benefit in the course of the donation cycle unless there is a medical reason why this cannot occur.
8. The PR should ensure that patient information satisfies all the regulatory requirements.
9. The PR should ensure that all clinical and laboratory test results are obtained prior to procurement or processing of gametes and /or embryos.
10. The PR should ensure the data submitted to the HFEA is accurate.
11. The PR should ensure all records can be readily retrieved and are fully traceable for such periods specified by the Authority.

‘Other’ areas that require improvement:

12. The PR should ensure the disposal of sperm is documented for traceability purposes.
13. The PR should ensure the development of documented standard operating procedures (SOPs) for the procedures identified in the body of this report.
14. The PR should review all agreements with satellite centres to ensure compliance with requirements.
15. The PR should audit the centre’s satellite units for their compliance with regulatory requirements, approved protocols and quality indicators.
16. The PR must ensure that assessments of competence are documented.
17. The PR should ensure that patient / partner consents to disclosure of information to researchers are reported accurately to the HFEA.

Recommendation to the Executive Licensing Panel

The centre has one critical, ten major and six ‘other’ areas of non-compliance.

The inspection team notes that the centre’s success rates are consistent with national averages and their multiple clinical pregnancy rates are likely to meet the target. The PR is encouraged to continue to use the quality management system (QMS) to best effect to monitor and continually improve their success rates and to improve the quality of the service offered to patients.

The inspector will continue to monitor the centre’s performance. Failure to implement the recommendations of this report within the prescribed timescales will result in the submission of a further report to the Licence Committee (LC)/ELP with the recommendation that regulatory action be taken in accordance with the Authority’s Compliance and Enforcement Policy.

The inspection team acknowledges the immediate actions taken by the PR in relation to addressing the critical area of non-compliance and the PR has confirmed that no samples remain in storage without effective consent, with the exception of two samples which have been subject to legal challenge.

The inspection team recommends the renewal of the centre’s Treatment and Storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)
The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better

Nothing identified at this inspection.

Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
The centre's procedures for screening donors are partially compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Payments for donors (Guidance note 13; General Direction 0001)
The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

Donor assisted conception (Guidance note 20)
A donor-conceived person is entitled to know details of their donor and any donor-

conceived genetic siblings they may have. Parents of a donor-conceived child are able to access information on their child's donor (and about any donor-conceived genetic siblings) from the HFEA or the clinic where they received treatment.

Therefore it is important that centres use donated gametes or embryos from identifiable donors. The centre's procedures are compliant with HFEA requirements to ensure the donor conceived will be able to receive this information.

What the centre could do better

Screening of donors (Guidance note 11)
Egg share donors were screened prior to treatment, but not at the time of donation as specified by the Authority (SLC T53b; see recommendation 2).

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transport and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account to ensure patients and staff are in safe surroundings that prevent harm.

The premises of the centre's satellite facilities and laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are broadly suitable.

The centre is compliant with HFEA requirements to processes gametes and/or embryos in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are partially compliant with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

Medicines management
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are compliant with guidance.

Pre-operative assessment and the surgical pathway
The centre has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

Multiple births (Guidance note 7; General Direction 0003)
The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy. The single biggest risk of fertility treatment is a multiple pregnancy.

Procurement of gametes and embryos (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to:

- document the justification for the use of the patient's gametes (or embryos created with their gametes) in treatment, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are broadly compliant with HFEA requirements. This is important to ensure that all gametes / embryos sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if the gametes and embryos are appropriately labelled and has enough information to permit the gametes and embryos be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; General Direction 0006)
The centre's procedures for import and export of gametes and embryos are partially compliant with HFEA requirements.

Traceability (Guidance note 19)
The centre's procedures are broadly compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability -

- to identify and locate gametes and embryos during any step from procurement to use for human application or disposal,
- to identify the donor and recipient of particular gametes or embryos,
- to identify any person who has carried out any activity in relation to particular gametes or embryos, and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS in place that is broadly compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's third party agreements are broadly compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has systems in place to manage satellite activities that are broadly compliant with HFEA requirements. This is important to ensure that activities performed by satellite clinics on behalf of the licensed centre are suitable and meet the HFEA requirements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

The centre is partially compliant with HFEA requirements to validate critical equipment.

The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's procedures are partially compliant with HFEA requirements to validate critical processes. Validations are required to ensure that the processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)

The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Safety and suitability of premises and facilities (Guidance note 25)
The centre has not audited the compliance of the satellite centres against regulatory requirements (SLC T112; see recommendation 15).

Laboratory accreditation (Guidance note 25)
The centre undertakes diagnostic semen analyses however the laboratory is not accredited by CPA or equivalent. Evidence to support a status equivalent to CPA accreditation was available apart from the process validation of diagnostic semen analysis (SLC T21; see recommendation 3).

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre does not have an SOP for the recall of gametes and embryos (CoP Interpretation of Mandatory Requirements 15C) and the SOP describing the procedures used in the transport of gametes and embryos did not include all requirements of SLC T107f, T108 and T122 (see recommendation 13).

Imports and exports (Guidance note 16; General Direction 0006)
The centre could not provide evidence that they had complied with the requirements of General Direction 0006 (Schedule 3, 1c: confirming that the supplying centre has a traceability system) for one of three gamete/embryo import cases reviewed (see recommendation 4).

Traceability (Guidance note 19)
Whilst it is acknowledged that staff witness the disposal of sperm, this process is not documented in the records thereby not ensuring that gametes are traceable from procurement to disposal (SLCs T71 and T99a; see recommendation 12).

Quality management system (QMS) (Guidance note 23)
The SOPs describing the following procedures did not adequately describe processes and procedures used in practice (screening timeframe requirements, consent, legal parenthood, transport distribution and recall of gametes and/or embryos) (SLCs T33b, T107f, T108, T122 and CoP Interpretation of Mandatory Requirements 15C; see recommendation 13).

Third party agreements (Guidance note 24)
Written agreements with satellite centres do not clearly define all responsibilities (SLC T116 and General Direction 0010; see recommendation 14).

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has not audited the compliance of the satellite centres against regulatory requirements, approved protocols and quality indicators (SLCs T36 and T112; see recommendation 15).

Equipment and materials (Guidance note 26)
The following critical equipment has not been validated: tube warmers, lasers, suction pump, fridges (SLC T24; see recommendation 5).

Process validation (Guidance note 15)
Documentation of process validations was not sufficiently detailed to provide assurance to the inspection team that all critical processes had been appropriately validated (SLC T72; see recommendation 6). Process validations for the proposed new activity of non-invasive assessment of embryos should also be completed prior to implementation.

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has broadly complied with HFEA requirements.

The PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (T/1131/7).

Staff (Guidance note 2)
The centre is broadly compliant with HFEA requirements. The centre has suitably qualified and competent staff, in sufficient number**,** to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

What the centre could do better

Staff (Guidance note 2)
Staff involved in donor recruitment, assessment and screening could not provide documented evidence of the assessment of their competence in this area of practice (SLC T15a; see recommendation 16).

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account the welfare of any child who may be born as a result of the licensed treatment, and of any other child who may be affected by that birth before treatment is provided are compliant with HFEA

requirements.

Safeguarding
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

What the centre could do better

Nothing identified at this inspection.

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

The centre does not carry out embryo testing.

What the centre could do better

Nothing identified at this inspection.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit the inspectors spoke to three couples who provided feedback on their experiences. A further 35 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was very positive and 25 of the individuals provided additional comments complimenting the care that they received. Feedback included statements such as “brilliant”, “fantastic”, friendly” and “supportive”.

Some patient complaints were fed back to the inspector and submitted directly to the HFEA regarding a private drug company used by the centre with issues such as late deliveries and incomplete orders. The PR and staff at the centre are aware of the problem and are in the process of taking action to resolve this issue.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)
The centre’s procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre’s procedures are compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)
The centre’s counselling procedures are compliant with HFEA requirements. This is

important to ensure that counselling support is offered to patients and donors providing relevant consent [and prior to consenting to legal parenthood].

Egg sharing arrangements (Guidance note 12; General Direction 0001)
The centre's procedures for egg sharing arrangements are partially compliant with HFEA requirements. This is important to ensure that:

- care is taken when selecting egg providers donating for benefits in kind
- egg providers are fully assessed and medically suitable, and
- the benefit offered is the most suitable for the egg provider and recipient(s) (where relevant).

Surrogacy (Guidance note 14)
The centre does not carry out any surrogacy treatments.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

What the centre could do better

Egg sharing arrangements (Guidance note 12; General Direction 0001)
Patient information states that potential donors of eggs through an egg sharing agreement can donate all eggs during their first cycle and receive their next cycle free of charge. General Direction 0001 requires that egg share 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 this cannot occur. The centre confirmed that their policy does not take into account any medical reasons that might prevent a donor from receiving the intended benefit during the course of their donation cycle (see recommendation 7).

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's procedures for providing information to patients and / or donors are partially compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better

Information (Guidance note 4; CH(11)02)
Information provided to patients regarding the following matters did not fully comply with

regulatory requirements; parenthood laws for patients using donated gametes (SLC T60), use of gametes/embryos in training (SLC T97c and d); and success rates quoted on the centre's website (which did not include live birth rates, Chair's Letter CH(11)02) (see recommendation 8).

Consent and Disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre's procedures for taking consent to disclosure to researchers are broadly compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases the patient identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

What the centre could do better

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
An audit of patient consent to disclosure decisions recorded in 27 patient notes against those submitted for inclusion on the HFEA register, showed that in seven instances discrepancies were found between the decisions recorded in patient files and those submitted for inclusion on the register (Chair's Letter CH (10)05, Guidance supplementary to Chair's Letter CH (10)05 and General Direction 0007) (see recommendation 17).

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities.

- 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 and
- embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

What the centre could do better

Nothing identified at this inspection.

Screening of patients
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)
The centre's procedures for screening patients are partially compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Storage of gametes and embryos (Guidance note 17)
The centre's procedures for storing gametes and embryos are partially compliant with HFEA requirements. This is important to ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre should only store gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

What the centre could do better

Screening of patients (Guidance note 17)
During review of patient files, in one case the screening test results for the male partner

were not in the records. It was noted that emails confirming negative screening test results were present but the laboratory test results were not (SLC T46g; see recommendation 9).

Storage of gametes and embryos (Guidance note 17)
On the day of the inspection the centre did not have effective consent for the storage of cryopreserved sperm for nine patients and embryos for two couples (HF&E Act 1990 (as amended), Schedule 3, 8(1); see recommendation 1). The storage of gametes and embryos without effective consent has been an ongoing issue and is discussed further in Section 3 'Monitoring of the centre's performance'.

Use of embryos for training staff (Guidance note 22)

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre's procedures for using embryos for training staff are partially compliant with HFEA requirements. The renewal application form records that the centre proposes use of embryos for training staff in embryo and blastocyst biopsy. These practices are expressly authorised by the Authority as those for which embryos may be used in training.

What the centre could do better

Use of embryos for training staff (Guidance note 22)
Information provided to patients regarding the use of gametes and embryos in training did not meet the requirements of SLC T97c and d (see recommendation 8).

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are partially compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32 ; General Direction 0005)
The centre's procedures for submitting information about licensed activities to the Authority are partially compliant with HFEA requirements. This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

What the centre could do better

Record keeping and document control (Guidance note 31)
The centre was unable to locate the record for a patient with stored embryos which was requested by the inspection team (SLC T47 & T48; see recommendation 11).

Obligations and reporting requirements (Guidance note 32 ; General Direction 0005)
The HFEA register audit team found some evidence of problems with the accuracy of the centre's submission of data to the Register (SLC T9e, and General Direction 0005) (see recommendation 10). Eight of 88 (9%) of the DI treatments reviewed at inspection had not been reported to the HFEA as required by General Direction 0005. This could impact upon the HFEA's ability to fulfil its statutory obligation to supply accurate information to a donor-conceived person. A small number of minor submission errors were also found at the time of inspection.

Section 3: Monitoring of the centre's performance

Following the last inspection of the centre in December 2012 (interim inspection), recommendations for improvement were made in relation to one area of critical non-compliance, two areas of major non-compliance and four 'other' areas of non-compliance.

The recommendations relating to the two areas of major non-compliance and four 'other' areas of non-compliance were implemented, although it is noted in this report that the centre is again non-compliant in relation to the submission of data to the HFEA (previously recorded as an 'other' non-compliance).

The recommendation regarding the storage of gametes without effective consent was considered a critical non-compliance in December 2012, as it had continued from previous inspections. A large number of cryopreserved gametes had been transferred to the centre from two other centres during its formation in 2007/2008, including samples which were stored prior to 1991. Patient records and consent forms for many of these samples had been inadvertently destroyed by one of the previous centres and as a consequence the PR was not able to verify the consent status for those samples. This issue has been reported to the HFEA as an adverse incident. Following the renewal inspection in 2010, the Executive recommended that a complete physical audit of stored samples be performed. This audit and summary of proposed actions to manage samples identified as being stored without effective consent was reviewed during the inspection in 2012. The actions documented provided reassurance to the Executive that 36 samples identified (and eight for which a decision was still pending) were being actively managed. A further update provided in July 2013 indicated that five samples remained in storage without effective consent; four of the gamete providers were deceased and the centre did not have their original medical records. The PR had undertaken risk assessments of these samples and taken the decision to discard them after allowing a period of time for any potential partners to come forward.

During this inspection the PR advised the inspection team that his staff had identified a further nine sets of cryopreserved sperm and two sets of embryos in storage without effective consent. The PR was reminded that it is a criminal breach of the HF&E Act 1990 (as amended) to store such material without effective consent. The bring-forward system and management of cryopreserved material was discussed in detail with the PR and LH and they are investigating how and why the centre's systems had not alerted staff to these samples being in storage without effective consent and whether these samples should have been identified during previous audits. The PR and LH provided a commitment to review the continued storage of these samples immediately and to keep the Executive updated with their progress with these investigations.

On-going monitoring of centre success rates

At the time of the last inspection (December 2012) the centre's multiple pregnancy rate (MPR) was 26% and a recommendation was made to review practices in order that the HFEA's multiple birth target would not be exceeded. During 2013, the centre received five risk tool alerts relating to their MPR. No further alerts have been issued since December 2013 and the centre's MPR (1 March 2013 to 28 February 2014) for all IVF, ICSI and FET cycles was 17%. This rate represents performance not significantly different from that

needed to reach the current multiple birth target of 10%. During this inspection, the MPR was discussed in detail with the PR and LH, who provided evidence of ongoing audits, reviews and action plans to continue to monitor the rate. The centre's performance in this area will continue to be monitored by the inspector.

At the time of the last inspection (December 2012) the centre's clinical pregnancy rates for frozen embryo transfers (FETs) were lower than the national average and a recommendation was made to the PR to review practices. The PR responded to the request and provided the inspector with regular updates on their reviews and actions. The most recent data confirmed that the centre's FET success rates are now in line with the national averages.

Areas of practice requiring action

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, General 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, or a significant shortcoming from the statutory requirements. 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
1. On the day of the inspection the centre did not have effective consent for the storage of cryopreserved sperm for nine patients and embryos for two couples (Schedule 3, 8(1) HF&E Act 1990 (as amended)). This is in addition to samples identified from previous inspections. **This was identified as a non-compliance at the last inspection.**	The inspector advised the PR both during the inspection and immediately thereafter that he should take immediate actions to resolve this non-compliance. The PR should provide the HFEA with an update on how many gametes and embryos remain in store without effective consent by the time this report is considered by a Licensing Committee. Also by the time this report is considered by a Licensing Committee, where gametes or	Please see the PR comment section for further information. Noted & agreed Noted & agreed.	The lead inspector acknowledges the PR's immediate responses and actions taken to resolve this non-compliance. The PR has confirmed that no samples remain in storage without effective consent, with the exception of two which have been subject to legal challenge by the gamete providers. The PR has also provided a review of the centre's

	embryos remain in store without effective consent, a plan should be submitted to the centre's inspector documenting the PR's intended actions and the anticipated timescale for their implementation.		bring forward system and has confirmed that corrective actions which were identified have already been implemented. Further action is required in relation to the completion of the audit
	The PR should provide monthly updates to the centre's inspector on progress in implementing the proposed actions.	Noted & agreed.	
	The PR should review the bring-forward systems and procedures for auditing storage of cryopreserved material. Summary reports of the findings of both reviews including corrective actions and the timescale for their implementation should be submitted to the centre's inspector by 25 September 2014.	Noted & agreed.	
	Within three months of the implementation of corrective actions, the centre should conduct an audit of consent to storage and a summary report of the findings of the audit should be provided to the centre's inspector by 25 December 2014.	Noted & agreed.	
	The PR is reminded of guidance	Noted & agreed.	

	issued by the HFEA in CH(03)03 (http://www.hfea.gov.uk/2687.html) in relation to the timely disposal of cryopreserved material where there is consent to do so and actions should there be a possibility of legal challenge to the disposal of cryopreserved material.		

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
2. Blood samples from egg share donors are not obtained within a timeframe specified by the Authority, i.e. at the time of donation. SLC T53b	The PR should review the centre's practices to ensure that blood samples are obtained in the timeframes specified by the Authority (see Clinic Focus March 2013). A summary of the findings and proposed corrective actions should be submitted to the centre's inspector in responding to this report. Updates in training on screening timescales should be provided to relevant staff and confirmation of this submitted to the centre's inspector by 25 September 2014. The PR should ensure that the revised screening processes are audited 3 months after implementation and a summary	Noted & agreed. Noted & agreed. Noted & agreed.	The PR confirmed that the review of the centre's practices has been completed. The PR also confirmed that corrective actions and staff training have already been implemented. Further action is required in relation to the completion of the audit.

	of the findings should be submitted to the centre's inspector by 25 December 2014.		
3. The centre undertakes diagnostic semen analyses however the laboratory is not accredited by CPA or equivalent. SLC T21	The PR should ensure that the laboratory which undertakes diagnostic semen analysis is accredited by CPA or equivalent, or provide evidence to support a status equivalent to accreditation. Evidence of CPA accreditation, or equivalent should be forwarded to the centre's inspector by 25 September 2014.	Noted & agreed. Noted & agreed	The lead inspector acknowledges the PR's response. Further action is required in relation to the submission of the requested evidence of CPA accreditation or equivalence.
4. The centre could not provide evidence that they had complied with all the requirements of General Direction 0006 (Schedule 3, 1c) for one of three gamete/embryo import cases reviewed.	The PR should review the centre's procedures for import and export of gametes and/or embryos to ensure that evidence required demonstrating compliance with General Direction 0006 is obtained before gametes and/or embryos are imported or exported. A summary of the review and any changes implemented as a result should be provided to the centre's inspector by 25 September 2014. The PR should audit the records relating to imports and exports of	Noted & agreed. Noted & agreed. Noted & agreed.	The lead inspector acknowledges the PR's response. Further action is required in relation to the completion of the review and the subsequent audit.

	gametes or embryos six months after the implementation of corrective actions against compliance with General Direction 0006 and forward a summary of the audit to the centre's inspector by 25 December 2014.		
5. The following critical equipment has not been validated: tube warmers, lasers, suction pump, fridges. SLC T24	The PR should ensure that all critical equipment is validated and submit an action plan listing all critical equipment, the date of validation and /or the expected date by which validation will be achieved, to the centre's inspector when responding to this report. The PR should ensure all critical equipment is validated and that all validations are completed by 25 December 2014. On completion of the validations the centre's inspector will ask for a sample of validation documents to be submitted for review.	Noted & agreed. Action plan submitted with response. Noted & agreed Noted & agreed	The lead inspector acknowledges receipt of the action plan for validation of equipment and will request a sample of the validation documents for review in due course. Further action is required.
6. Documentation of process validations was not sufficiently detailed to provide assurance to the	The PR should ensure that all critical processes and any proposed new activities are adequately validated and an	Noted & agreed. Action plan submitted with response.	The lead inspector acknowledges receipt of the action plan for process validations and will request a

inspection team that all critical processes had been appropriately validated. SLC T72	action plan listing all critical processes, the date of validation and /or the expected date by which validation can be achieved should be submitted to the centre's inspector in responding to this report. It is expected that validation will be prioritised on the basis of risk associated with the procedure and that validation will be complete by 25 December 2014. On completion of the validations the centre's inspector will ask for a sample of validation documents to be submitted for review.	 Noted & agreed. Noted & agreed	sample of the validation documents for review in due course. Further action is required.
7. Patient information states that potential donors of eggs through an egg sharing agreement could donate all eggs during their first cycle, and receive their next cycle free of charge. The centre confirmed that their policy does not take account of what medical reasons might prevent a donor from receiving the intended benefit during the course of their donation cycle.	The PR should ensure egg donors who receive a benefit through their egg sharing programme, are provided with that benefit during the course of the donation cycle unless there is a medical reason why this cannot be. The PR should consider reviewing the centre's SOPs and patient information to ensure they accurately reflect the requirements of General Direction	Noted & agreed. The Centre would like to make the Authority aware that no patients have received benefit in kind in a subsequent cycle while being an egg share donor. Noted & agreed.	The lead inspector acknowledges the PR's response. Further action is required in relation to completion of the review and updates to staff.

General Direction 0001	0001. A summary of that review and any consequent changes should be provided to the centre's inspector by 25 September 2014. The PR should ensure that any changes made are communicated to staff effectively and inform the centre's inspector when this is done by 25 September 2014.	 Noted & agreed. Noted & agreed.	
8. Information provided to patients regarding the following matters did not fully comply with regulatory requirements: parenthood laws for patients using donated gametes, (SLC T60), use of gametes/ embryos in training (SLC T97c and d) and success rates on the centre's website (Chairs Letter CH(11)02). This puts the centre at risk of failing to provide proper information to patients/donors giving consent, as required by the HF&E Act 1990 (as	The PR should ensure that patient information fully incorporates the regulatory requirements and provide the centre's inspector with a summary report of the changes and copies of the updated patient information by 25 September 2014.	Noted & agreed	The lead inspector acknowledges the PR's response. Further action is required in relation to the summary report and providing copies of updated information to the lead inspector.

amended), Schedule 3 (1) (b).			
9. In one of the patient files reviewed, the screening test laboratory results for the male partner were not present. It was noted that emails confirming the screening test result status were present but the laboratory test results were not. SLC T46g	The PR should review the centre's practices to ensure that all clinical and laboratory test results are obtained prior to procurement or processing of gametes and /or embryos. A summary of the findings and proposed corrective actions should be submitted to the centre's inspector by 25 September 2014. The PR should ensure that the revised screening processes are audited 3 months after implementation of any changes and a summary of the findings should be submitted to the centre's inspector by 25 December 2014.	Noted & agreed. This Centre would like to inform the Inpectors that this finding does not reflect accepted practice within the centre. Noted & agreed	The lead inspector acknowledges the PR's response. Further action is required in relation to the completion of the review and the subsequent audit.
10. The HFEA register audit team found some evidence of problems with the accuracy of the centre's submission of data to the Register. A small number of minor submission errors were also	The PR should ensure that the treatments identified as outstanding at the time of inspection are reported to the Authority immediately. The systems and processes used for licensed treatment data submission should be reviewed to	These treatment cycles have now been reported to the Authority. Noted & agreed.	The lead inspector acknowledges the PR's response confirming that the outstanding treatments have been reported to the HFEA and the review of processes has been undertaken. Further action is required in

found at the time of inspection. SLCs T9e and T41, General Direction 0005	enable the reasons for non-reporting to be identified and addressed. The PR should inform the centre's inspector of the findings and corrective actions by 25 July 2014. The PR should conduct an audit six months after implementing any changes to confirm that any changes made to systems and processes are having the desired effect. A summary report of the findings of the audit should be provided to the centre's inspector by 25 January 2015.	Noted & agreed	relation to the completion of the audit.
11. The staff at the centre were unable to locate the records for a patient with stored embryos during the inspection. SLCs T47 and T48	The PR should review the centre's SOP for retention of records and ensure staff are aware of the requirements for record keeping. A summary of the findings and any corrective actions should be submitted to the centre's inspector by 25 September 2014. The PR should conduct an audit six months after implementing any changes to confirm that any changes made to systems and processes are having the desired effect. A summary report of the	Noted & agreed. Noted & agreed.	The PR has kept the lead inspector updated on the centre's extensive efforts to locate this record and has confirmed that the embryos are stored with effective consent. This is being actively followed up by the centre's senior management. The lead inspector will liaise with the PR on the outcome of this issue. Further action is required in

	findings of the audit should be provided to the centre's inspector by 25 December 2015.		relation to the completion of the review and the subsequent audit.

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
12. Whilst it is acknowledged that staff witness the disposal of sperm, this process is not documented in the records. SLCs T71 and T99a	The PR should review current practice to ensure the disposal of sperm is documented for traceability purposes and advise the centre's inspector of the implementation of the changes by 25 September 2014. The PR should conduct an audit six months after the implementation of any changes to practice and processes and forward a summary of the audit to the centre's inspector by 25 December 2014.	Noted & agreed. Noted & agreed	The lead inspector acknowledges the PR's response. Further action is required in relation to the completion of the review and the subsequent audit.
13. The SOPs describing the following procedures did not adequately describe the processes and procedures used in practice (screening timeframe requirements, consent, legal parenthood, transport, distribution and recall of gametes and/or embryos).	The PR should ensure the development of documented SOPs for these procedures. Copies of the SOPs should be provided to the centre's inspector by 25 September 2014.	Noted & agreed	The lead inspector acknowledges the PR's response and awaits copies of the updated SOPs by 25 September 2014 Further action is required.

SLCs T33b, T107f, T108, CoP 15C and T122.			
14. Written agreements with satellite centres do not clearly define all responsibilities. SLC T116 and General Direction 0010	The PR should review all agreements with satellite centres to ensure compliance with requirements. A summary report of the findings of the review should be provided to the centre's inspector by 25 September 2014. The report should also document any corrective actions required to ensure compliance and the anticipated timescales for the implementation of the corrective actions.	Noted & agreed.	The lead inspector acknowledges the PR's response. Further action is required in relation to the completion of the review.
15. The centre has not audited the compliance of the satellite centres against regulatory requirements and their own approved protocols and quality indicators. SLCs T36 and T112	The PR should audit the centre's satellite units' compliance with regulatory requirements and approved protocols and quality indicators. A copy of the audit including any corrective actions and timescales for implementation should be provided to the centre's inspector by 25 September 2014.	Noted & agreed.	The lead inspector acknowledges the PR's response. Further action is required in relation to the completion of the audit.
16. Staff involved in donor recruitment, assessment and screening could not provide documented evidence of	The PR must ensure that assessments of competence are documented and evidence of the relevant assessment of	Noted & agreed.	The lead inspector acknowledges the PR's response.

assessment of their competence in this area of practice. SLC T15a	competence should be forwarded to the centre's inspector by 25 September 2014.		Further action is required.
17. An audit of patient consent to disclosure decisions recorded in 27 patient notes against those submitted for inclusion on the HFEA register showed that in seven instances discrepancies were found between patient disclosure consent decisions recorded in patient files and the related consent data submitted for inclusion on the register. Chair's Letter CH (10)05 Guidance supplementary to Chair's Letter CH (10)05 and General Direction 0007	The PR should ensure that patient / partner consents to disclosure of information to researchers are reported accurately to the HFEA. The PR should correct the submissions that have been identified as being incorrect and review systems and processes to ensure that going forward, the patient and partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on completed disclosure consent forms by 25 September 2014. A summary of that review and any consequent changes should be provided to the centre's inspector by 25 September 2014. Six months after implementing any changes to this process the PR should audit the submission of consent to disclosure data to confirm that any changes made	Noted & agreed. Incorrect submissions have now been corrected. Noted & agreed.	The lead inspector acknowledges the PR's response confirming that the incorrect submissions have been corrected. Further action is required in relation to the completion of the review and the subsequent audit.

	to systems and processes are having the desired effect. A summary of this audit should be provided to the centre's inspector by 25 June 2015.		

Reponses from the Person Responsible to this inspection report

As confirmed to the Inspection team during the recent inspection, the centre immediately instigated contact procedures, where they were not already ongoing, for the patients/partners where samples were in storage without effective consent and had contacted 9 of the 11 patients within 24hours to inform them of their options. Contact was made with the two remaining patients/partners shortly thereafter.

The Centre can confirm to the authority that all samples identified during the inspection will be held with effective consent or will have been discarded at patient request/in line with regulatory requirements by 15th August 2014. Furthermore, the Centre has already forwarded a summary of findings and corrective actions to prevent future recurrence to its Inspector. Implementation of corrective actions has already commenced.

The Centre would also like to inform the Authority that it recently sought and received legal advice relating to two pre chemotherapy sperm storage patients where consent has expired but the patients have indicated that they wish to explore legal avenues in in order to ensure the samples remain in storage. The PR has therefore concluded, in line with HFEA guidance in this area and legal advice received that the continued storage of the samples for these two men is both reasonable and prudent until the situation is clarified/a Court Order is obtained and the Centre will forward further information relating to these cases seperately to the Authority.

The Centre can also confirm that all other stored samples are held with effective consent.