HFEA Licence Committee Meeting

10 July 2014

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

Minutes – Item 6

Centre 0049 (Wales Fertility Institute – Cardiff) –Treatment and Storage Renewal Licence Inspection Report

Members of the Committee: Andy Greenfield (lay) (Chair) David Archard (lay) Debbie Barber (professional) Jane Dibblin (lay)	Legal Adviser: Tom Rider, Fieldfisher Committee Secretary: Lauren Crawford

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

The following papers were considered by the Committee:

- Licence renewal inspection report
- Licence renewal application form
- Previous Licence Committee minutes for the past three years:
    - 24 September 2013: Variation – removal of additional licence condition
    - 2 August 2013: Variation – change of centre name
    - 17 July 2013: Interim inspection report
    - 15 March 2103: Variation – change of Licence Holder
    - 16 November 2012: Variation – change of Person Responsible
    - 13 September 2012: Licence renewal report
    - 24 March 2012: Incident follow up- inspection report
    - 15 December 2011: Consideration of representations
    - 20 October 2011: Incident inspection report

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree); and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.

- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Background

1. The Wales Fertility Institute – Cardiff was formerly known as IVF Wales and is located on the University Hospital of Wales campus. The centre has held a treatment and storage licence with the HFEA since 1992 and provides a full range of fertility services. Other licensed activities of the centre include storage of gametes and embryos. The inspection team is satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

2. Management responsibility for the centre was transferred from Cardiff and Vale University (C & V) Health Board to Abertawe Bro Morgannwgg University Health Board (ABMU) in April 2013 as part of restructuring changes made by the Welsh Health Specialised Services Committee. The centre now works in tandem with its sister centre 0329 Wales Fertility Institute – Neath, a new centre which opened in summer 2013.

3. The centre provided 429 cycles of treatment (excluding partner intrauterine insemination) in the 12 months leading to March 2014. In relation to activity levels this would indicate that it is a small centre, however the centre has not worked to capacity since October 2011 when a condition was placed on the centre's licence whereby the centre was required to limit the number of IVF or ICSI cycles provided to an average of 24 cycles per calendar month in total, and frozen embryo transfers to an average of eight per calendar month in total. This condition was placed on the centre's licence by Licence Committee following a grade 'B' incident inspection, the report of which made recommendations for improvement relating to a number of critical and major non-compliances.

4. The condition capping activity was lifted by Licence Committee in September 2013. Going forward it is anticipated that activity levels will indicate that this is a medium sized centre. The Person Responsible (PR) has given assurance the increase in activity will be gradual and will be closely monitored to ensure activity levels are safe and commensurate with the resources available.

Discussion

5. The Committee noted that at the time of the inspection, the Inspectorate reported that there were a number of areas of practice that required improvement, including five 'major' areas of non-compliance or poor practice.

6. The Committee noted that since the inspection that four of those recommendations have been completed and that the PR has given a commitment to fully implement the following recommendation:

    - The PR should review the provision of serological pipettes to ensure that only CE marked products are used PR should ensure effective document control measures are in place and that only current versions of documents are in use.

7. The Committee noted that the centre has no critical areas of concern but had five major of areas of concern. Some improvement is required in order for the centre to demonstrate suitability of their practices. However the PR's proactive response to recommendations made is noted. The centre has a quality management system (QMS) in place and the PR is encouraged to use the QMS to best effect to monitor and improve the service provided.

8. The Committee noted the Inspectorate's recommendation to renewal of the centre's 'Treatment and Storage' licence for a period of four years without additional conditions subject to the recommendations made in the renewal inspection report being implemented within the prescribed timescales.

Discussion

9. The Committee referred to its decision tree. It was satisfied that the appropriate application and fee had been submitted, and noted that the executive had received the supporting information required by General Direction 0008.

10. The Committee noted that the PR holds academic qualifications in the field of medicine. The proposed PR also has more than two years' practical experience which is directly relevant to the activity to be authorised by the licence as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii). He has successfully completed the HFEA PR Entry Programme.

11. The Committee noted the PR is suitable and will discharge his duty under section 17 of the HF&E Act 1990 (as amended).

12. The Committee was satisfied that the licence application concerns treatment, storage or non-medical fertility services which relate to gametes or embryos intended for human application.

13. The Committee was satisfied that premises to be licensed are suitable for the conduct of licensed activities based on evidence provided within the report except within regard to the recommendations outstanding which relate to the premises.

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

Decision

15. The Committee agreed to renew the centre’s treatment and storage licence for a period of four years without any additional conditions.

16. The Committee urged the centre to complete the outstanding recommendation within the prescribed timescales.

Signed: Date: 23/07/2014

Andy Greenfield (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 (rather than unannounced) 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 Licence Committee (LC) 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: 29 and 30 April 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: Gill Walsh (lead), Vicki Lamb, Helen Kendrew, Cathy Hodgson and Kayleigh Adams

Date of Licence Committee: 10 July 2014

Centre name	Wales Fertility Institute - Cardiff
Centre number	0049
Licence number	L/0049/15/e
Centre address	University Hospital of Wales, Heath Park, Cardiff, CF14 4XW, UK
Person Responsible	Dr Paul Knaggs
Licence Holder	Mr Pushpinder Mangat
Date licence issued	1 October 2012
Licence expiry date	30 September 2014
Additional conditions applied to this licence	None – additional licence condition removed 24 September 2013

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
The Wales Fertility Institute – Cardiff was formerly known as IVF Wales and is located on the University Hospital of Wales campus. The centre has held a treatment and storage licence with the HFEA since 1992 and provides a full range of fertility services. Other licensed activities of the centre include storage of gametes and embryos. The inspection team is satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

Management responsibility for the centre was transferred from Cardiff and Vale University (C & V) Health Board to Abertawe Bro Morgannwgg University Health Board (ABMU) in April 2013 as part of restructuring changes made by the Welsh Health Specialised Services Committee. The centre now works in tandem with its sister centre 0329 Wales Fertility Institute – Neath, a new centre which opened in summer 2013.

The centre provided 429 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 March 2014. In relation to activity levels this would indicate that it is a small centre, however the centre has not worked to capacity since October 2011 when a condition was placed on the centre's licence whereby the centre was required to limit the number of IVF or ICSI cycles provided to an average of 24 cycles per calendar month in total, and frozen embryo transfers to an average of eight per calendar month in total. This condition was placed on the centre's licence by Licence Committee following a grade 'B' incident inspection, the report of which made recommendations for improvement relating to a number of critical and major non-compliances.

The condition capping activity was lifted by Licence Committee in September 2013. Going forward it is anticipated that activity levels will indicate that this is a medium sized centre. The Person Responsible (PR) has given assurance the increase in activity will be gradual and will be closely monitored to ensure activity levels are safe and commensurate with the resources available.

The centre was issued with a two year licence by Licence Committee in 2012. No application to remove the additional licence condition was made by the centre at that time.

The centre was last inspected for an announced interim inspection in April 2013. The report of this inspection was also considered by Licence Committee. The Committee noted that the number of licenced treatments undertaken at the centre to 10 April 2013 was compliant with the additional licence condition imposed in 2011 and also the significant progress made by the centre since the last report. During this time the centre had undergone considerable change, including the PR, the Licence Holder (LH) and governing Hospital Board. The Committee directed that the centre's renewal inspection report should also be considered by a Licence Committee.

No application was made by the centre at this point to vary the centre's licence to remove the additional condition. An application to remove this condition was made subsequently and was agreed by Licence Committee in September 2013.

This current licence has been varied to reflect the following changes:

September 2013 – removal of licence condition capping activity as described above
August 2013 – change of centre name
March 2013 – change of Licence Holder
November 2012 – change of Person Responsible

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 February 2013 to 31 January 2014 show the centre's success rates are in line with national averages.

In 2013, the centre reported eight cycles of partner insemination with one pregnancy. This clinical pregnancy rate is consistent with the national average.

Multiple births[2]

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

Between 1 February 2013 and 31 January 2014 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups is 14%: this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target for this period.

[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 fulfilled 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 Licence Committee is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including five major areas of non-compliance.

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

Major areas of non-compliance:

- The PR should review the process for documenting the positive identification of the woman to be treated, and the sperm to be used in treatment to ensure that witnessing is correctly documented.
- The PR should ensure a suitable third party agreement is established with the blood testing laboratory.
- The PR should ensure gametes and embryos are stored within the consented storage period. The PR should provide the HFEA with an update on the number of patients for whom gametes or embryos remain in store without effective consent and a plan to manage this be submitted to the HFEA documenting the centre's intended actions and the anticipated timescale for their implementation.
- The PR should correct the consent to disclosure 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;

and that the following recommendation is being implemented:

- The PR should review the provision of serological pipettes to ensure that only CE marked products are used.

Recommendation to the Licence Committee

The inspection team notes that the centre's success rates are consistent with the national average and their multiple clinical pregnancy rates meet the target.

The centre has no critical areas of concern but had five major of areas of concern. Some improvement is required in order for the centre to demonstrate suitability of their practices. However the PR's proactive response to recommendations made is noted. The centre has a quality management system (QMS) in place and the PR is encouraged to use the QMS to best effect to monitor and improve the service provided.

The inspection team recommends the renewal of the centre's treatment with storage licence for a period of four years without additional conditions, subject to the remaining 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 partially compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better
An audit of witnessing records showed that in one patient record where a woman was inseminated with sperm prepared in the laboratory, the active identification of the patient and checking of patient documentation including the sperm provider to be used was not documented. See recommendation 1.

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 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; Directions 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. However the centre is not currently recruiting donors and where known egg donors are used, no payment is made.

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

Nothing identified at this inspection.

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
Transports 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 laboratories conducting tests that impact on the quality and safety of gametes and embryos (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to process gametes and embryos in an environment of appropriate air quality

Laboratory accreditation(Guidance note 25)
The centre's laboratories and 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 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; Directions 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;
- if 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; Directions 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are 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; Directions 0006)
The centre's procedures for import and export of gametes and embryos are compliant with HFEA requirements.

Traceability (Guidance note 19)
The centre's procedures are 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 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 partially compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; Directions 0010)
The centre has not transport or satellite IVF arrangements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are partially 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 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 compliant with HFEA requirements to validate critical processes. This ensures that these 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
The centre does not have a third party agreement with the University Hospital Laboratory which conducts blood testing for the centre. See recommendation 2.

Serological pipettes currently in use are not CE marked. See recommendation 3.

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

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

The PR has academic qualifications in the field of biological sciences 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 (PREP number T/1225/8).

Staff (Guidance note 2)
The centre is 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

Nothing identified at this inspection.

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 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
This centre does not conduct embryo testing.

What the centre could do better

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit the inspectors spoke to three patients who provided feedback on their experiences. A further 40 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with 24 of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

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 [and sperm] 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 (or sperm) sharing arrangements (Guidance note 12; Directions 0001)
The centre does not facilitate egg or sperm sharing.

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

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

Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's procedures for providing information to patients and donors are 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

Nothing identified at this inspection.

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 (Directions 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 patients 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 (Directions 0005)
An audit of patient consent to disclosure decisions recorded in the patient notes and that submitted for inclusion on the HFEA register showed that in five instances discrepancies were found between patient/partner disclosure consents decisions recorded in patient files and the related consent data submitted for inclusion on the register. These discrepancies were not considered by the register team to pose a risk of inadvertent disclosure of information by the HFEA but does not accurately represent the consent giver's wishes. See recommendation 5.

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 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. These measures are important to ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores 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

At the time of inspection it was noted that one set of embryos and three sperm samples were being stored outside of the period consented to by the gamete providers. The centre

is awaiting a response from the gametes providers regarding consent to continued storage. The inspection team does however consider the centre's bring forward system to be robust. See recommendation 4.

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 compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

What the centre could do better

Nothing identified at this inspection.

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 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; Directions 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are 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.

The HFEA register audit team found no evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register other than that for consent to disclosure.

What the centre could do better

Nothing identified at this inspection.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2013, recommendations for improvement were made in relation to two major areas of non-compliance and seven 'other' areas of non-compliance.

The PR provided information and evidence that the recommendations were fully implemented within the agree timescales.

The following recommendations have now been implemented but were not completed within the required timescales:

On-going monitoring of centre success rates

The centre has not received any HFEA Risk Based Assessment Tool (RBAT) alerts relating to their success rates.

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, 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
None			

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. An audit of witnessing	The PR should review the process	PR has reviewed the	The Executive acknowledges

records showed that in one patient record seen where a woman was inseminated with sperm prepared in the laboratory, the active identification of patient, checking of patient documentation including sperm provider to be used was not documented. SLC T71	for documenting the positive identification of the woman to be treated and the sperm to be used in treatment to ensure that witnessing is correctly documented. The PR should provide a summary of actions taken following this review to the centre's inspector by 30 July 2014. Three months after the implementation of any changes, the PR should audit a sample of witnessing records to determine the efficacy of the change in practice. A summary of this audit is to be provided to the centre's inspector by 30 October 2014.	witnessing protocol and relevant paperwork. These were found to be satisfactory. The findings seem to be a simple case of ommission and as such all members of the nursing team have been reminded that all witnessing steps must be signed for. An snapshot audit of previous treatments undertaken was performed. As requested further audits will be performed and submitted in line with the required dates.	the PR's actions in response to this recommendation and awaits the centre's own audit in due course.
2. The centre does not have a third party agreement with the University Hospital Laboratory which conducts blood testing for the centre. SLC T111 and T114	The PR should ensure a suitable third party agreement is established with the blood testing laboratory by 30 July 2014.		Since the inspection the PR has provided evidence that this is now in place. No further action is required.
3. Serological pipettes currently in use at the centre are not CE marked. SLC T30	The PR should review the provision of serological pipettes to ensure that only CE marked products are used, and provide the centre's inspector with a time		Since the time of the inspection the PR has provided evidence that the manufacturer for CE marked pipettes is currently unable to

	line for the introduction of the alternative CE marked product by 30 July 2014.		provide a supply of this product due to increased demand. The PR has given assurance that, once available, the product with be used in place of the pipettes currently in use and will keep the centre's inspector informed regarding this. The Executive acknowledges the PR's actions in regard to this recommendation.
4. At the time of inspection it was noted that one set of embryos and three sperm samples were being stored outside of the period consented to by the gamete providers. SLC T57	The PR should provide the HFEA with an update on the number of patients for whom gametes or embryos remain in store without effective consent when responding this report. Also, in response to this report, where gametes or embryos remain in store without effective consent, a plan should be submitted to the HFEA documenting the centre's intended actions and the anticipated timescale for their implementation. The PR is reminded of guidance issued by the HFEA in CH(03)03 (http://www.hfea.gov.uk/2687.html) in relation to the timely disposal of		Since the inspection the PR has provided confirmation that the sperm samples have now been allowed to perish and that consent to continued storage has now been provided by the gamete providers for the embryos in question. No further action is required.

	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.		
5. An audit of patient consent to disclosure decisions recorded in the patient notes and that submitted for inclusion on the HFEA register showed that in five instances discrepancies were found between patient/partner disclosure consent decisions recorded in patient files and the related consent data submitted for inclusion on the register. Guidance supplementary to Chair's Letter CH(10)05 and Direction 0007 This is a recurrence of a non-compliance noted at the last inspection and therefore has been escalated to 'major'.	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 30 July 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 to systems and processes are having the desired effect. A summary of this audit should be provided to the centre's inspector by 30 January 2015. *(NB. The Centre's designated HFEA Form Returnee has been provided with the relevant patient*	As a result of the register team data report an investigation showed that patients were completing and 'old' style HFEA paper registration form which was then transcribed to EDI. However, discrepancies between this and the CD forms caused the mismatches found by the HFEA. The PR has implemented a new registration form which does not contain data covered in the CD form. All raised incorrect submissions have been corrected and EDI submissions made. Patients have been sent a new form for completion in relation to blank submissions.	The Executive acknowledges the PRs actions in response to this recommendation and awaits the findings of the centre's own audit in the new year.

	and partner numbers so that the form data can be reviewed and corrected).	The requested audit will be completed and forwarded by 30/1/2015.	

Other areas of practice that requires improvement

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

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

Reponses from the Person Responsible to this inspection report