Executive Licensing Panel - minutes

Centre 0021 (Hull IVF Unit)

Renewal Inspection Report

Friday, 14 July 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard(Chair) Anjeli Kara Jessica Watkin	Director of Strategy & Corporate Affairs Regulatory Policy Manager Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers		

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:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

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

1.2. The panel noted that Hull IVF Unit holds a Treatment and Storage licence and provides a full range of fertility services.

1.3. The panel noted that the centre has been licensed by the HFEA since 1992.

1.4. The panel noted that, in the 12 months to 28 February 2017, the centre provided 512 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium sized centre.

1.5. The panel noted that HFEA held register data for the year ending 30 November 2016 show that the centre's IVF and ICSI success rates are in line with national averages.

1.6. The panel noted that the centre reported two cycles of partner insemination in 2016 with no pregnancies and this performance is in line with the national average.

1.7. The panel noted that for treatments performed in the year ending 30 November 2016, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 12%; this represents performance that is not likely to exceed the 10% live multiple birth rate target.

1.8. An inspection was carried out at the centre on 26 and 27 April 2017.

1.9. The panel noted that at the time of the inspection there were three major and three 'other' areas of practice which required improvement. The panel noted that the PR has provided evidence that actions had been taken to fully implement the major non-compliances recommendations concerning record keeping and medicines management alongside the 'other' areas of non-compliances regarding information provision, incident reporting and infection control. The PR has committed to audit effectiveness of the actions, within the required timescales, where required.

1.10. The panel noted the PR had taken actions to implement the 'other' non-compliance recommendation, regarding storage of sperm samples, and has committed to complete implementation within the required timescales, keeping the HFEA updated on progress.

1.11. The panel noted that some improvement is required for the centre to demonstrate the suitability of their practices and the PR has been encouraged to use their Quality Management System (QMS) to monitor and improve the success rates and the service provided to patients.

1.12. The panel noted that the inspectorate 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 the report being implemented within the prescribed timescales.

2. Decision

2.1. 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.

2.2. The panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

2.3. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR will discharge his duty under section 17 of the HFE Act 1990 (as amended).

2.4. 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 subject to the recommendations made in this report being implemented within the prescribed timescales.

3. Chair's signature

3.1. I confirm this is a true and accurate record of the meeting.

Signature

Name

Juliet Tizzard

Date

25 July 2017

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 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: 26/27 April 2017

Purpose of inspection: Renewal of a Treatment and Storage licence

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: Andrew Leonard, Janet Kirkland and Karen Conyers

Date of Executive Licensing Panel: 14 July 2017

Centre name	Hull IVF Unit
Centre number	0021
Licence number	L/0021/13/a
Centre address	Hull and East Yorkshire Women and Children's Hospital, Hull Royal Infirmary, Anlaby Road, Hull, HU3 2JZ, UK
Person Responsible	Mr Stephen Maguiness
Licence Holder	Dr John Robinson
Date licence issued	01/10/2013
Licence expiry date	30/09/2017
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Hull IVF Unit is located within the Hull and East Yorkshire Women and Children's Hospital. The centre has held a Treatment and Storage licence with the HFEA since 1992 and provides a full range of fertility services.

The centre provided 512 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28 February 2017. In relation to activity levels this is a medium-sized centre.

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

The current licence has not been varied since it was issued on 1 October 2013

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the year ending 30 November 2016 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

The centre reported two cycles of partner insemination in 2016 with no pregnancies, performance which is in line with the national average.

Multiple births[2]

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

For treatments performed in the year ending 30 November 2016, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 12%; this represents performance that is not likely to exceed the 10% live multiple 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 Person Responsible (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, comprising three major and three 'other' areas of non compliance.

The PR has provided evidence that actions have been taken to fully implement the following recommendations and, where required, has committed to audit the effectiveness of the actions within the required timescales:

Major areas of non compliance:

- The PR should ensure that patient records are kept which include all information required by licence conditions.
- The PR should ensure that the disposal of controlled drugs is recorded in the controlled drugs register and that any amendments to the register are made in accordance with professional best practice guidance.

'Other' areas that requires improvement:

- The PR should ensure the compliance of the information document provided to patients regarding the use of embryos in training and research.
- The PR should ensure that all adverse incidents and near misses are reported to the HFEA.
- The PR should ensure that the centre's facilities support effective infection control practices.

The PR has taken actions to implement the following recommendation and has committed to complete implementation within the required timescale and to keep the HFEA updated regarding progress.

Major areas of non compliance:

- The PR should take appropriate actions to ensure all sperm samples are lawfully stored.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of concern but does have three major of areas of concern.

The inspection team notes that the success rates are consistent with the national average and the multiple clinical pregnancy/live birth rates meet the target.

Some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a quality management system (QMS) and the PR is encouraged to use it to best effect to monitor and improve the success rates and the service provided to patients.

The inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

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 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)
It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to

access non identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

The centre's procedures are compliant with HFEA requirements which ensure the donor-conceived and their parents will be able to receive all required donor-related 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 so that patients and staff are in safe surroundings that prevent harm.

The centre has no transport or satellite facilities but the premises of the centre's laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (and relevant third parties) are suitable.

The centre is compliant with HFEA requirements to process 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 compliant with HFEA requirements to be accredited by Clinical Pathology Accreditation (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided. The inspection team notes that the semen assessment service provided by the centre is certified to ISO standard 15189:2012.

Infection control (Guidance Note 25)
The centre has systems in place to manage and monitor the prevention and control of infection that are broadly compliant with guidance.

Medicines management (Guidance Note 25)
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are partially compliant with guidance.

Prescription of intralipid 'off label'
Intralipid is a sterile liquid soybean and egg yolk based fat emulsion which is licensed as an intravenous nutritional supplement for adults and children. Some healthcare professionals consider intralipid therapy may be beneficial to a particular subset of women having IVF. Intralipid is not however licensed for use in fertility treatment and if prescribed in this context, it represents 'off-label' use. Healthcare professionals' responsibilities when prescribing a medicine off-label may be greater than when prescribing a medicine for use within the terms of its licence.

In April 2015, the President of the Royal College of Obstetricians and Gynaecologists, published concerns regarding the evidence base for the use of intralipid in IVF treatment, in terms of its safety and efficacy. In July 2015, the HFEA published guidance to centres regarding the prescribing of intralipid (or other 'off label' therapies) to patients. This guidance required centres to take responsibility for prescribing the medicine and for overseeing the patient's care by:

- reviewing and recording the information provided to patients about intralipid therapy to ensure that the reasons for prescribing it 'off-label' are explained, including that there is currently little evidence to support its use in fertility treatment;
- recording the reasons for prescribing intralipid in the patient's records and;
- ensuring that patients who are prescribed intralipid are properly monitored and followed up.

The process for administering and monitoring patients during intralipid infusion was reviewed and considered to be suitable. Written information provided to patients offered intralipid therapy is also compliant with guidance. The inspection team notes that the centre provides intralipid therapy only to patients who have previously had the therapy and gone on to have a live birth, and who then ask for it in subsequent treatments.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
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 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 they are appropriately labelled and are accompanied by enough information to permit them to 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 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 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. The inspection team notes that the QMS at the centre is certified to ISO standard 9001:2008.

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

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre is not the primary centre to any satellite or transport centres therefore these regulatory requirements were not relevant at this inspection.

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 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 broadly compliant with HFEA requirements. The centre reports some 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

Infection control (Guidance Note 25)
The soap dispenser in the procedure room is not hands free and was considered a potential infection control risk (SLC T17; recommendation 6).

Medicines management (Guidance Note 25)
The disposal of part used ampoules of controlled drugs is witnessed but is not recorded in the controlled drugs register (Misuse of Drugs Regulations 2001, 27 3 and NICE Guideline 2016: Control drugs, safe use and management, 1.7.8; recommendation 3). In addition, one alteration in the controlled drugs register was not signed.

Adverse incidents (Guidance note 27)
The centre had not reported to the HFEA two adverse incidents, as defined in CoP Guidance 27.1, which impacted on embryo quality and safety (Interpretation of mandatory requirements 27A; SLC T118; recommendation 5). This was discussed with the PR and laboratory manager on inspection. It was clear that a thorough review and investigation of

the adverse incidents had been undertaken and consideration given to reporting them to the HFEA. Reports had not been submitted however because they considered the events did not meet the definition of adverse incident; the inspection team considered otherwise.

Staff engaged in licensed activity

Person Responsible (PR)

Staff

What the centre does well

Person Responsible (Guidance note 1)
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.

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have 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 before licensed treatment is provided, the welfare of any child who may be born as a result of that treatment and of any other child who may be affected by that birth, are compliant with HFEA requirements.

Safeguarding (Guidance Note 25)
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

Welfare of the child (Guidance note 8)
It was clear from the records that a thorough welfare of the child assessment is performed in all cases but, in some patient records reviewed, it was not clear which member of staff had performed the review. This matter is included in the 'Record Keeping' section below.

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
The centre does not undertake embryo testing therefore these requirements were not considered at this inspection.

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, no patients were available to speak to the inspectors. Six patients have provided feedback directly to the HFEA in the time since the last inspection. Feedback was generally positive, with two of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

An analysis of the centre's most recent patient survey responses was also reviewed, which detailed that 39% of patients (171/442) returned survey forms, of which 95%, expressed satisfaction with the service.

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;
- has committed, capable and supportive staff.

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 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'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. The inspection team notes that information governance processes at the centre are certified to ISO standard 27001:2013.

What the centre could do better
Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients and/or donors are broadly 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
The information document provided to patients regarding the use of embryos in training and research does not include the requirements of SLC T97 b,c,d. The document also describes the option to agree, using the HFEA consent forms, to the use of embryos in research. The current HFEA consent forms do not however include this consenting option. This suggests the document has not been recently reviewed (SLC T97 and CoP Guidance 31.6; recommendation 4).

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.

Legal parenthood (Guidance note 6)
Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about its effectiveness and, in some cases, it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required timeframe. The audit showed that no couples were affected by legal parenthood consent anomalies. The audit was reviewed and was found to have been performed according to the method specified by the HFEA.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR responded to this communication and provided the required reassurances to the satisfaction of the Executive.

To provide further assurance of the effectiveness of the centre's procedures, the inspection team reviewed five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required. Effective consent to legal parenthood with a prior offer of counselling was seen to be in place before treatment in all cases. The inspection team also reviewed a recent audit of legal parenthood consent by the centre, which provided further evidence of the compliance of the centre's procedures in this area.

In summary, the inspection team considers the processes used to collect legal parenthood consent at this centre to be compliant with HFEA requirements.

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 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 Nothing identified at this inspection.

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) and ensure that the special status of the embryo is respected when licensed activities are conducted at the centre because:

- 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 ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. 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

Storage of gametes and embryos (Guidance note 17)

Consent to initial storage had been documented by the providers of five sperm samples reviewed on inspection (stored 2001 - 2004), however for three of the samples consent to extended storage beyond 10 years had not been clearly documented. Thus it was not clear to the inspection team that storage beyond 10 years can be lawfully provided (The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009; recommendation 1).

These samples were all provided by patients who were storing because of impending medical treatment likely to impact on their fertility. Centre staff noted that the storage consent form used (HFEA form (00)6) records a consent to the maximum storage period of 10 years (tick box), with a footnote that 'centres are allowed to store sperm for longer periods for limited uses only'. Centre staff are confident and assured that information provided to these patients before they signed HFEA form (00)6, advised them that storage up to the age of 55 years was allowed in their specific circumstances. Centre staff therefore consider it reasonable to interpret that the storage consents are for a period until the providers are 55 years of age, rather than just for the 10 year statutory storage period. Medical practitioner statements regarding actual or likely premature infertility were documented in the records, albeit not using the appropriate HFEA forms.

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, notwithstanding the non compliance in the information provided to patients discussed in the 'Information' section. 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 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 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.

What the centre could do better

Record keeping and document control (Guidance note 31)
A review of patient records showed that the patient records do not always document:

- Which staff member reviewed the photo identification documents provided by a patient, to confirm the patient's identity in preparation for treatment;
- Conversations with patients returning to the centre regarding the on-going validity of the consent forms they signed at the time of previous treatment cycles;
- Which staff member performed the welfare of the child assessment;
- Marital or civil partnership status.

(SLC T46; CoP Guidance 6.7; recommendation 2)

It was also noted that an audit of patient records against the requirements of SLC T46 has not been recently performed (SLC T36; recommendation 2).

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2015, no recommendations for improvement were necessary.

On-going monitoring of centre success rates

In January 2017, the centre was asked to review procedures for the provision of ICSI treatment. The PR responded appropriately to the request and provided details to the centre's inspector of a thorough review and consideration of practice in this area. During discussions at the time of the inspection, the PR and laboratory manager provided a commitment to keep success rates in this group of patients under review.

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
No issues identified			

Major area of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Storage For three sperm samples (stored 2001 - 2004) consent for initial storage was present but consent to an extended storage period beyond 10 years had not been clearly documented. Thus it was questionable whether the extended storage period can be provided (The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009).	The PR should seek legal advice on the legality of sperm storage in this situation and should take appropriate actions to ensure all sperm samples are lawfully stored. The PR should provide an update on the number of patients with sperm in storage affected by this potential non compliance when responding to this report. The PR should provide the HFEA with a summary of the legal advice obtained as well as with an update including the centre's intended actions and the anticipated timescale for their implementation, by 26	We have reviewed all notes of patients who had stored sperm prior to 2009. All patients had complete HFEA consent forms, consenting for storage for the maximum storage period; notes included a referral letter from the relevant medical specialist, confirming the patient's condition, treatment and prognosis. It is conceded that there is a lack of clarity about the consent to extend storage beyond 10 years. This was because all patients had signed an in-house consent form for long term storage (i.e. beyond 10 years). The default position was to offer storage up until the age of 55 years, the	The inspection team notes the PR's responses and details of actions taken, which confirm that the recommendation is being effectively implemented and should be completed within the required timeframes. The centre's inspector will continue to liaise with the centre and will regularly review progress through the on-going monitoring system. **Further actions are required**

	July 2017, with a goal to resolve this situation by 26 October 2017.	evidence for this being the inclusion of a copy of HFEA Statutory Instrument 1991 No. 1540 in each patient set of notes- used to calculate permitted duration of storage. It is agreed that as HFEA Consent Form (00) 9 was not used, the exact period of storage may not have been sufficently explicit. This issue relates to 77 patients (17 of these are now deceased) and the time period ranges from 1991 to 2006. All 60 patients have been written to at their current addresses and we are awaiting responses. Legal advice has been sought and the summary will be fowarded to the HFEA.	
2. Record Keeping Centre staff do not always document in the patient records: • Which staff member reviewed the photo identification documents provided by a patient, to confirm the patient's identity in preparation for treatment;	The PR should review current record keeping practices and relevant SOPs and take appropriate corrective actions, to ensure that patient records are kept which include all required information. A copy of the review report should be provided to the	The Unit believed that it was acting in compliance with the HFEA Act (specifically T46), as SOPs and records provide evidence of patient ID checks at the point of procurement and details of who had performed / witnessed this check. The Unit acknowledges that at the point of registration/	The inspection team note the PR's responses and further information provided. The team confirms that one aspect of this non compliance relates to the name of the staff member who reviews photo identification documents not being recorded, and not to any failings in ID checks at

• Conversations with patients returning to the centre regarding the on-going validity of the consent forms they signed at the time of previous treatment cycles; • Which staff member performed the welfare of the child assessment and considered the couple suitable for licensed treatment; • Conversations with patients regarding any risks associated with treatment; • Marital or civil partnership status. (SLC T46) It was also noted that an audit of patient records against the requirements of SLC T46 has not been recently performed (SLC T36).	centre's inspector by 26 July 2017. An audit of patient records should subsequently be performed to confirm the corrective actions have been effective. A report of the audit should be provided to the centre's inspector by 26 October 2017. Thereafter patient records should be audited against the requirements of SLC T46 as part of the centre's normal audit schedule.	assessment, although the patient ID is verified (evidenced by GP referral letter and copy of passport/ driving licence- as required by 18.18 of the Act), a record of which member of staff has copied/ reviewed this document is not clear in the notes. SOPs have been amended to ensure compliance with all points listed in T46- specifically T46b. Record forms have been amended to include this signed ID check and check of evidence of marital status - these amended record forms were made available to inspectors during the inspection - after the Unit had been alerted to this issue and an audit report will be provided. The current practice at the clinic is that the Unit requires the patient to return a form from the GP asking them if they are aware of any WOC concerns, this is in addition to the HFEA self assessment form and staff are then	procurement. These are performed in a compliant manner. The inspection team confirms that a revised record sheet was produced during the inspection which allows the capture of the name of the staff member who reviews photo identification documents and also the marital status of the couple being treated. The inspection team notes the reassurances provided by the PR that the staff member completing the welfare of the child assessment will in future be recorded and that conversations with patients, including those regarding any additional risks and the on-going validity of consent forms, will be documented in the records. The inspection team looks forward to receiving a report of the audit of record keeping by 26 October 2017, to assess whether all the actions taken have been effective.

		required to act on any comments. To comply with the HFEA recommendations in this report, this form and the HFEA patient self-assessment form will now be signed by the member of staff reviewing this information. SOPs have been amended accordingly and an audit of compliance will be provided. Whilst standard risks associated with treatment are discussed and recorded on the appropriate Unit record form, aberrant non-treatment related infections had not always been recorded in the notes to evidence that these discussions had been held. Action will be taken to ensure that all conversations are recorded in the notes, including the duly mentioned discussions about on-going validity of consents. Evidence that the Unit staff are aware of these required improvements and how they are to be implemented has been provided to the inspector	**Further action is required**

		already and audits of compliance will be provided by the appropriate dates.	
3. Medicines Management The disposal of part-used ampoules of controlled drugs is witnessed but is not recorded in the controlled drugs register (Misuse of Drugs Regulations 2001, 27 3 and NICE Guideline 2016: Control drugs, safe use and management, 1.7.8). One alteration in the controlled drugs register was not signed.	The PR should ensure that the disposal of controlled drugs is recorded in the controlled drugs register and that any amendments to the register are made in accordance with the centre's procedures and professional best practice guidance. The PR should inform the centre's inspector of the actions taken to implement this recommendation by 26 July 2017. An audit of the controlled drug register should subsequently be performed to confirm the corrective actions have been effective. A report of the audit should be provided to the centre's inspector by 26 October 2017.	With regard to the disposal of drugs, the Unit was asked to check for compliance with local Hospital Trust policy - with which it is compliant. However, the Unit will adopt the reccommendations in this report to record the amount of drug disposed and in addition an absorbent silicon pad for waste is now provided in all sharps bins. An audit of compliance will be provided as requested.	The inspection team notes the PR's response and engagement in implementing the recommendation. The inspection team looks forward to receiving the audit of the controlled drugs register by 26 October 2017, to assess whether the actions taken have been effective. **Further action is required**

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
4. Information provision The information document provided to patients regarding the use of embryos in training and research does not include the requirements of SLC T97 b,c,d (SLC T97). The document also describes the option to agree, using the HFEA consent forms, to the use of embryos in research. The current HFEA consent forms do not however include this consenting option. This suggests the document has not been recently reviewed (CoP Guidance 31.6).	The PR should review and revise the information document provided to patients regarding training and research to ensure its compliance. The document once revised, should be provided to the centre's inspector by 26 July 2017.	Documentation has been revised accordingly.	The inspection team notes the PR's response and the information provided to them. No further action is required
5. Incident reporting The centre has not reported to the HFEA two adverse incidents, as defined in CoP Guidance 27.1, which impacted on embryo quality and safety (Interpretation of	The PR should ensure that all adverse incidents, including serious adverse events and reactions, as well as near misses, are reported to the HFEA in line with SLC T118 and the centre's incident	As stated in the report, the guidence had been mis-interpretated and the reccomendations have been implemented.	The inspection team notes the PR's response and further evidence provided, which indicates that the centre's incident log has been reviewed and incidents which fulfil the criteria as reportable, have

mandatory requirements 27A; SLC T118). This non compliance has been downgraded to 'other' because the inspection team accepts that incident reporting and investigation at the centre is thorough and generally compliant. In both cases, which involve the same issue, the PR and laboratory manager simply mis-interpreted guidance.	reporting SOP. The PR should review all adverse incidents in the centre's incident register in the last year and should report retrospectively to the HFEA any which fulfil the criteria of adverse incidents or near misses, as defined in CoP Guidance 27.1. This recommendation should be implemented by 26 July 2017 and the centre's inspector advised of the actions taken.		been reported to the HFEA. The recommendation has been fully implemented. No further action is required.
6. Infection control The soap dispenser in the procedure room is not hands free and was considered a potential infection control risk (SLC T17).	The PR should arrange for the soap dispenser to be replaced with one which allows hands free operation by 26 July 2017. The PR should advise the centre's inspector when this recommendation has been implemented.	The reccomendation has been implemented.	The inspection team notes the PR has already replaced the soap dispenser with a 'hands free' version. No further actions are required.

Reponses from the Person Responsible to this inspection report
The Unit felt that the inspection was a positive experience and was pleased to receive affirmative endorsement of the good practice in place and positive patient feedback. We hope that the rapid actions undertaken as requested are acceptable and serve to reassure the HFEA about our continuing desire to be a compliant Unit.