Executive Licensing Panel Minutes

Centre 0167 (University College London Hospitals)

Renewal Inspection Report

Date:	7 September 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Richard Sydee (Chair) Dina Halai Helen Crutcher	Director of Finance and Resources Acting Head of Policy Risk and Business Planning Manager
Executive:	Bernice Ash	Secretary
Observers:	Catherine Burwood Annabel Salisbury	Licensing Manager Policy Officer - Induction

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:

- 9th 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 five years.

1.2. The panel noted that University College London Hospitals is part of the University College London Hospitals NHS Foundation Trust. The centre has held a licence with the HFEA since 1997 and provides intrauterine insemination (IUI) with partner and donor sperm. The centre also offers a sperm storage service for patients who are having treatment that may impair their fertility. Other licenced activity at the centre includes the storage of gametes.

1.3. The panel noted that the centre provides a satellite in vitro fertilisation (IVF) service to NHS patients with The Centre for Reproductive and Genetic Health (centre 0044) as the primary centre.

1.4. The panel noted that, in the 12 months to 30 November 2020, the centre provided 11 cycles of treatment (excluding partner intrauterine insemination treatments). In relation to activity levels this is a very small sized centre. The Covid-19 pandemic and suspension of fertility treatments, across the United Kingdom, will have impacted on treatment numbers during 2020.

1.5. The panel noted that, in 2020, the centre reported 75 cycles of partner insemination with 11 pregnancies. This is in line with the national average.

1.6. The panel noted that, in 2020, all the clinical pregnancies, following partner insemination, were singletons.

1.7. The panel noted that In March 2020, the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19). In response to UK measures to contain and mitigate the spread of the virus, new inspection methodologies were developed and implemented. These methods enable compliance to be reviewed through desk based assessment (DBA) and the use of virtual technology where available and appropriate. A risk based approach (RBA) can then be applied, balancing the risks of on-site inspection during the Covid-19 pandemic against those resulting from potential non-compliances, identified during DBA, if not adequately investigated.

1.8. The panel noted that HFEA licensed premises must be inspected on site every two years in accordance with Schedule 3B paragraph (4)(1) of the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended). Whilst the current restrictions of the pandemic do not prohibit on-site inspection, the risks of doing so must be balanced against the need for the Authority to fulfil its legal duties.

1.9. The panel noted that, for this centre, the DBA/RBA process identified some potential areas of concern which the assessors considered were associated with significant enough risk, to merit further review during an on-site inspection. Therefore, a shorter than normal on-site visit to the centre, with a smaller inspection team, was undertaken, thereby reducing the risks of travel and close contact during the pandemic. This on-site inspection allowed for the potential non-compliances to be appropriately reviewed.

1.10. The panel noted that an on-site renewal inspection was conducted on 25 May 2021.

1.11. The panel noted that, at time of the inspection, there was one major area of non-compliance concerning consent to storage. There were also two ‘other’ non-compliances regarding payment to donors and the Quality Management System (QMS). Since the inspection, the Person Responsible (PR) has provided evidence that actions have been taken to implement the

recommendation concerning the QMS and has committed, where required, to audit the effectiveness of those actions within the required timescales. The PR has given a commitment to fully implementing the recommendations surrounding payment to donors and consent to storage.

1.12. The panel noted that some improvement is required in order for the centre to demonstrate the suitability of their practices The centre has a QMS and the PR is encouraged to use it to best effect to monitor and improve the service provided to patients.

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

1.14. The panel noted that the inspection team recommends the renewal of the centre's treatment (insemination using partner/donor sperm) 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.

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 licensed activity.

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 her 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 (insemination using partner/donor sperm) 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. The panel agreed that if no representations or any other information is received within 28 days, the final renewal licence should be issued.

3. Chair's signature

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

Signature

Name

Richard Sydee

Date

13 September 2021

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 report provides information on the centre's application to renew its existing licence. Licensed centres usually receive a licence to operate for up to four years, although some centres have had their licence extended to five years due to the Covid-19 pandemic (five years being the maximum length of a treatment licence permitted by law).

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: 25 May 2021

Purpose of inspection: Renewal of a licence to carry out Treatment (Insemination using partner/donor sperm) and Storage.

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

In March 2020, the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19). In response to UK measures to contain and mitigate the spread of the virus, new inspection methodologies were developed and implemented.

These methods enable compliance to be reviewed through desk based assessment (DBA) and the use of virtual technology where available and appropriate. A risk based approach (RBA) can then be applied, balancing the risks of on-site inspection during the Covid-19 pandemic against those resulting from potential non-compliances, identified during DBA, if not adequately investigated.

For this centre, the DBA/RBA process identified some potential areas of concern which the assessors considered were associated with significant enough risk, to merit further review during an onsite inspection. Therefore, a shorter than normal on-site visit to the centre, with a smaller inspection team, was undertaken, thereby reducing the risks of travel and close contact during the pandemic. This on-site inspection allowed for the potential non-compliances to be appropriately reviewed.

Inspectors: Julie Katsaros (lead) and Andrew Leonard attended the onsite inspection. Nicola Lawrence undertook a DBA in relation to clinical activities but did not attend the onsite inspection.

Executive Licensing Panel: 7 September 2021

Centre name	University College London Hospitals
Centre number	0167
Licence number	L/0167/12/d
Centre address	Elizabeth Garrett Anderson Wing, University College London Hospitals 235, Euston Road, London, NW1 2BU, United Kingdom
Person Responsible	Dr Ephia Yasmin
Licence Holder	Dr Tim Hodgson
Date licence issued	1 November 2017
Licence expiry date	31 October 2021
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

University College London Hospitals is part of the University College London Hospitals NHS Foundation Trust. The centre has held a licence with the HFEA since 1997 and provides intrauterine insemination (IUI) with partner and donor sperm. The centre also offers a sperm storage service for patients who are having treatment that may impair their fertility.

The centre provides a satellite in vitro fertilisation (IVF) service to NHS patients with The Centre for Reproductive and Genetic Health (centre 0044) as the primary centre.

The centre provided 11 cycles of treatment (excluding partner IUI) in the 12 months to 30 November 2020. In relation to activity levels this is a very small centre.

The Covid-19 pandemic and suspension of fertility treatments across the United Kingdom will have had an impact on treatment numbers during 2020.

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

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

- March 2021 – All centres: Variation of licences without application (European Union (EU) Exit requirements).
- March 2020 – Change of Licence Holder
- January 2019 – Change of Person Responsible (PR).

Pregnancy outcomes

In 2020 the centre reported 75 cycles of partner IUI with 11 pregnancies, which is in line with the national average.

Multiple births[2]

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

In 2020, all the clinical pregnancies following partner insemination were singletons.

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) and standard licence conditions (SLCs), 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 her 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 the centre's licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note at the time of the inspection there were three areas of practice that required improvement, including one major and two 'other' areas of non-compliance.

Since the inspection visit, the PR has provided evidence that actions have been taken to implement the following recommendation and has committed, where required, to audit the effectiveness of those actions within the required timescales:

'Other' areas that require improvement:

- The PR should ensure that the centre's legal parenthood Standard Operating Procedure (SOP) is updated to reflect the inclusion of the marital / civil partnership status check and that relevant staff are well informed of this change to the centre's processes.

The PR has given a commitment to fully implementing the following recommendations:

Major area of non-compliance:

- The PR should ensure that valid consent to storage is documented for all stored sperm samples.

'Other' areas that require improvement:

- The PR should ensure that the donor compensation reports required by General Direction 0001 paragraph 13, are provided to the centre for all donors whose sperm has been imported since 1 January 2021, as well as for all future imports.

Recommendation to the Executive Licensing Panel

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

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 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 (Insemination using partner/donor sperm) 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.

At the time of the renewal inspection, centre 0167 had not been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. See section 'Imports and exports (Guidance note 16; General Direction 0006).

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) 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 sperm samples and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes.

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
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
The centre currently does not recruit donors. Donor sperm samples are sourced from sperm banks and were found to be compliant with HFEA screening requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes.

Payments for donors (Guidance note 13; General Direction 0001)
The centre currently does not recruit donors, however, the centre imports sperm from donor banks abroad, therefore this area of practice was reviewed at this inspection. The centre's procedures are broadly compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes. 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 from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes 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

Payments for donors (Guidance note 13; General Direction 0001)
Donor compensation reports in line with General Direction 0001, paragraph 13, have not been provided to the centre for some donors of imported sperm samples.

For such donors, evidence for compensation compliant with GD0001, paragraph 12, is based only on the relevant third party agreements and an assumption that the donor banks concerned have adhered to their terms. This is not robust or in line with the requirements of GD0001, paragraph 13.

See recommendation 2.

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes
Transport and distribution of gametes
Receipt of gametes
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 is compliant with HFEA requirements to process sperm 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 their gametes, are compliant with HFEA requirements to be accredited by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. This is important to assure the quality of the services provided.

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

Medicines management (Guidance Note 25)
The centre does not hold controlled drugs or provide medicines for self-administration directly to patients, therefore requirements related to medicines management were not relevant at this inspection.

Prescription of intralipid 'off label'
Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
The centre does not perform surgical procedures as part of its licensed activities therefore this area of practice is not applicable to this inspection.

Multiple births (Guidance note 7; General Direction 0003)
The centre is providing only insemination treatments, but such treatments still expose patients to the risks of multiple pregnancies and births if incorrectly applied. The single biggest risk of fertility treatment is a multiple pregnancy and birth. Thus it is important for centres providing insemination treatments to have a multiple births minimisation strategy. The centre's procedures are compliant with HFEA requirements to have a multiple births minimisation strategy and to conduct regular audits and evaluations of the progress and effectiveness of the strategy.

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

- document the justification for the use of sperm in the patient's 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 provider's records.

Transport and distribution of gametes (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of sperm samples are compliant with HFEA requirements. This is important to ensure that all sperm 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;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes (Guidance note 15)
The centre's procedures for the receipt of sperm samples are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes 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 sperm are compliant with HFEA requirements.

The Human Fertilisation and Embryology Act 1990 (as amended) was amended on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018, to incorporate procedures for assuring the quality and safety of gametes imported into licensed centres in the UK, i.e. 'importing tissue establishments' (ITEs), from tissue establishments in third countries, i.e. 'third country suppliers' (TCS). Before 30 June 2021, all countries outside of the European Economic Area (EEA) were third countries, whereas since 30 June 2021, all countries outside of the UK are third countries. UK clinics must apply to the HFEA for an ITE import certificate to allow imports from specified TCSs, a clinic's certificate being synchronised in lifespan with the treatment licence. This centre has not yet been allocated an ITE import certificate but imports of gametes from TCSs outside the EEA have not been made. The centre is therefore compliant with General Direction 0006. The centre is preparing an ITE import certificate application to allow it to undertake sperm imports in future.

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

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

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

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not have any transport or satellite centres, therefore this guidance note is not relevant.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements. All 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 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

Quality management system (QMS) (Guidance note 23)
Although the inspection team are assured that staff are undertaking checks of the marital / civil partnership status of patients, the centre's legal parenthood standard operating procedure (SOP) has not been updated to reflect the inclusion of this marital status check. During discussions with staff, it became apparent that not all staff are aware of the new process that has been recently implemented.

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See recommendation 3.

Staff engaged in licensed activity
Person Responsible (PR)
Leadership
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 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.

Leadership
The centre is compliant with HFEA guidance regarding effective leadership.

Good leadership improves patient care and is encouraged by the HFEA. A PR should have the necessary authority and autonomy to carry out the role. The PR should ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about patient care. The PR is legally accountable for the overall performance of the centre and should establish clear responsibilities, roles and systems of accountability to support good governance, including ensuring that appropriate action is taken following all forms of feedback from the HFEA or patients.

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
Nothing identified at this inspection.

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 create embryos or perform embryo testing and therefore this area of practice is not applicable to this inspection.
What the centre could do better Not applicable to this inspection.

2. The experience of patients

Patient feedback

What the centre does well

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Only three patients have provided feedback in the last 12 months, giving an average three-star rating to the clinic. The centre has a large number of patients with underlying medical conditions using their services, including those storing sperm prior to commencing cancer and other therapies which may affect their fertility. It is important that the feedback of this group of patients is also sought to ensure that there is consideration of their needs, as well as the needs of patients undergoing IUI treatments. For a system to work well, it's important that every patient knows about the rating system. The PR is asked to consider ways to promote the use of this facility. This issue will be followed up at the next inspection.

The centre's own most recent patient survey responses were also reviewed. Feedback was comparable to that provided to the HFEA.

Due to the ongoing covid-19 pandemic the inspection team did not approach any patients during the onsite inspection.

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

- treats patients with privacy and dignity;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- treats patients with empathy and understanding.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Patient support
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.

Patient support (Guidance note 3)
New HFEA guidance strengthens support provided by staff at all levels to patients, so as to improve their emotional experience of care. All clinics should have a policy outlining how appropriate psychosocial support from all staff is provided to patients, donors and their partners, before, during and after treatment. All staff should understand their responsibilities and be provided with appropriate training, information and functional aids to assist them. Patient feedback should be collected to enhance the patient support procedures.

The centre's patient support procedures are compliant with HFEA guidance.

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.

Sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre does not undertake egg and sperm sharing arrangements and therefore this area of practice is not applicable to this inspection.

Surrogacy (Guidance note 14)
The centre does not provide surrogacy treatments and therefore this area of practice is not applicable to this inspection.

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)
The centre's procedures for providing information to patients 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.

Legal parenthood (Guidance note 6)
Where a couple to be treated with donated gametes 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 the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

The centre commenced treating patients with donor sperm at the beginning of 2018 and was therefore not in operation in February 2014 when the HFEA asked all centres to audit their practices in this area.

To provide assurance of the compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements with the exceptions noted in the 'QMS' section of this report.

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 does not create or store embryos therefore this area of practice is not applicable to this inspection.

What the centre could do better
Not applicable to this inspection.

Screening of patients and Storage of gametes

What the centre does well

Screening of patients (Guidance note 15)
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.

Storage of gametes (Guidance note 17)
The centre's procedures for storing gametes are partially compliant with HFEA requirements. These measures ensure that the gametes are stored appropriately to maintain their quality and safety and in accordance with the consent of the gamete providers. The storage of gametes 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.

What the centre could do better

Storage of gametes (Guidance note 17)
The inspection team evaluated the centre's processes for storing gametes and these were compliant with HFEA requirements with the following exception; sperm from one patient was in storage beyond the expiry date of the consent to store.

The PR had already advised the HFEA of this case but it was discussed in detail with the PR on inspection. The PR explained that the sample in storage was that of a deceased man who had consented to posthumous use of his sperm. Due to various factors, the patient's widow was not ready or able to proceed with treatment before the expiry date of the storage consent. The sperm provider had consented to store his sperm for a period which expired after his death but the storage consent cannot now be extended without the sperm provider's consent. The patient's widow has stated to the PR that she will take legal action to ensure the sperm samples remain in storage until they can be used in her treatment.

The case is under constant review and the PR feels that it presents a particularly difficult situation. Staff are reluctant to discard the sperm until it is clear whether or not a legal challenge will ensue. The sperm remains in storage without effective consent whilst a

resolution is sought.

The inspection team note the steps that the PR has taken in trying to resolve this issue.

The HFEA's assessment framework recommends classification of storage without consent as a critical non-compliance but in consideration that the sperm of only one patient is being stored without consent and that there are specific issues that have made the centre reluctant to dispose of the sperm, the inspection team considers it proportionate to classify this non-compliance as major.

Schedule 3, 8(1) HF&E Act 1990, as amended.

See recommendation 1.

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre does not use embryos for training staff therefore this area of practice is not applicable to this inspection.

What the centre could do better
Not applicable to this inspection.

4. Information management

Record keeping and 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; 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.

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

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2019, recommendations for improvement were made in relation to one area of critical non-compliance, one area of major non-compliance and two 'other' areas of non-compliance.

The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales.

On-going monitoring of centre success rates

The centre has not received any risk tool alerts relating to success rates in the last two years.

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 areas 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.

A critical area of non-compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
None			

Major areas 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.

A major area of non-compliance is identified in the report by a statement that an area of practice is partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
1. Consent to storage Sperm from one patient is held in storage beyond the expiry date of the consent to store. (See the body of this report for further details) Schedule 3, 8(1) HF&E Act 1990, as amended.	The PR should ensure that valid consent to storage is documented for all stored sperm samples. The centre should continue to engage with the patient's widow and the HFEA regarding this matter and ensure that there is ongoing communication. The PR is reminded of HFEA guidance in relation to the timely disposal of cryopreserved material if there is the potential for legal challenge (see Chair's letter	The centre made contact with the patient's widow (ME) on 26.05.2020 informing her that her partner's consent expires in January 2021 and made her fully aware of regulations.ME understood that she had to use the sperm if that was her intention before the expiration of consent. As there was no response, the centre made phone calls to ME. On 31/12.2021, contact was made. ME very concerned and explains that the pandemic	The inspection team note the PR's response and commitment to implementing this recommendation. The PR should ensure that any legal advisors are fully conversant with the requirements of the HF&E Act 1990. The PR should continue to engage with the partner's widow and provide an update to the centre's inspector by 25 November 2021 and upon receipt of the update the centre's inspector will advise

	CH(03)03).	and her health did not enable her to have treatment in 2020 and was very distressed about impending expiry of consent. Advised ME of the need for a court order to keep in storage. Offered counselling and support. Also offered option of moving samples abroad. HFEA informed of issue and M E's wishes Centre contacted again on 06.01.2021 seeking an update of court order or intended action. ME explained she was having fertility assessments and still looking to speak to a solicitor. M E contacted again on 09.01.2021 for update. She is having assessments at another clinic who is also checking ability to treat post consent expiry with clinic inspector. ME emailed clinic on 01.03.2021 with ews that her clinic unable to treat due to consent expiry and that she	the PR of any further actions that may be required to be undertaken. Further action required.

		will pursue legal action. We emphasised that we are in breach of regulation and we need to hear from her solicitor soon. Offered continued psychological support which ME is taking up. Followed up again on 24. 05. 2021 as not heard from patient or solicitor. Case discussed with inspectors on the day of inspection. Calls and emails not responded promptly but patient responded on 16.06.2021. ME reported being unwell. She had been in touch with a solicitor but could not afford fees so got in touch with another solicitor. ME iinformed the centre that she is writing to the HFEA directly so she can take the response to her solicitor. Contacted ME again on 22.07.2021 as a month has elapsed with no update. Centre offering continued	

		support and counselling. Centre has engaged the trust lawyers for advice as it feels that ME has been given enough time. The centre has received information that the HFEA has not received any communicaton from ME.	

Other areas of practice that require improvement

'Other' areas of practice that require improvement are any areas of practice which cannot be classified as either a critical or major area of non-compliance, but which indicate a departure from statutory requirements or good practice.

An 'other' area of non-compliance is identified in the report by a statement that an area of practice is 'broadly' compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
2. Payments to donors Donor compensation reports in line with General Direction 0001, paragraph 13, have not been provided to the centre for some imported donors. General Direction 0001, paragraphs 12 and 13.	The PR should ensure that the donor compensation reports required by General Direction 0001 paragraph 13, are provided to the centre for all donors whose sperm have been imported since 1 January 2021, as well as for all future imports. The PR should audit the compensation provided to all donors whose gametes have been imported since 1 January 2020 and should report to the HFEA where it does not comply with the requirements of General Direction 0001, paragraph 12. This recommendation should be implemented and the HFEA informed of the actions taken	The centre contacted ESB seeking information about compensation and remuneration of donors. The centre has received information about expenses paid per sample which is 35 euros per sample and does not breach maximum limit. The centre has asked for more information about any additional compensation of loss of earning. The full audit will be supplied by 25 August 2021	The inspection team note the PR's response and commitment to implementing this recommendation. Further action required.

	by 25 August 2021.		
3. Quality management system (QMS) Although the inspection team are assured that staff are undertaking checks of the marital / civil partnership status of patients, the centre's legal parenthood standard operating procedure (SOP) has not been updated to reflect the inclusion of the marital / civil partnership status check. During discussions with staff, it became apparent that not all staff are aware of the new process that has been recently implemented. SLC T32.	The PR should ensure that the centre's legal parenthood SOP is updated to reflect the inclusion of the marital status / civil partnership check and that relevant staff are well informed of this change to the centre's processes. The PR should provide confirmation to the centre's inspector that the SOP has been updated to reflect the changes and the changes have been discussed with the relevant staff, when responding to this report.	The SOP for legal parenthood has been updated to include o information about marital status before any treatment. The SOP also guides obtaining the relevant consents based on status. The advise provided on day of inspection was shared at the team MDT and also individually to all team members involved in DI services. It was also highlighted at MDT that is is the responsibility of all team members to read the clinic focus and the minutes of every MDT so that team members absent on the day of MDT and dissemination of information are still up to date with changes or updates.	The PR has provided suitable information to indicate that appropriate actions have been taken in relation to these issues. No further action required.

Reponses from the Person Responsible to this inspection report
I have read the inspection report and I am in agreement with the contents. I thank the inspectors for their constructive advice for improvememt. I am also very grateful for the engagement on the part of the HFEA in supporting the centre through the challenging issue of a bereaved partner seeking to have treatment with partner sperm after expiration of consent. We are making every effort to offer support to the distressed partner, recognising that sadly the posthumous nature of the use does not allow the beveaved partner to make use of the CVS regulations which other patients and couples benefitted from. After allowing what we consider to be reasonable time (keeping the pandemic in mind), we have instructed the trust lawyers to advice.