Executive Licensing Panel Minutes

Centre 0149 (Royal Derby Hospital)

Renewal Inspection Report

Date:	24 August 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Clare Ettinghausen (Chair) Joanne Anton Kathleen Sarsfield-Watson	Director of Strategy and Corporate Affairs Head of Policy (Job-share) Communications Manager
Executive:	Bernice Ash	Secretary
Observers:	Catherine Burwood	Licensing Manager

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 six years.

1.2. The panel noted that Royal Derby Hospital is located in Derby and has held a licence with the HFEA since 1995. The centre provides intra uterine insemination using partner/donor sperm treatments. Other licensed activities at the centre include the storage of gametes. The centre also provides a satellite service for CARE Nottingham, centre 0101.

1.3. The panel noted that, in the 12 months to 31 March 2021, the centre did not provide any cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels, this is a very small sized centre.

1.4. The panel noted that the Covid-19 pandemic and suspension of fertility treatments across the United Kingdom will have had an impact on treatment numbers during 2020. Treatments for the centre's patients and the satellite service were temporarily suspended, from 6 -20 January 2021, due to the additional demands of the pandemic on hospital services and the need for staff to be redeployed.

1.5. The panel noted that, in 2020, the centre reported 9 cycles of partner insemination, with one pregnancy. This represents a clinical pregnancy rate which is comparable to 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 the centre followed professional body guidance to suspend all non-essential treatments in response to Covid-19 and is compliant with GD0014 Version 2 for resuming treatment services.

1.10. The panel noted that, the centre's interim inspection occurred in May 2018 and a renewal inspection was scheduled to be undertaken by May 2020. However, due to the Covid-19 pandemic, a DBA/RBA was conducted. Following this, it was established that any items of concern identified were of relatively low risk and could be reviewed effectively using virtual technology, rather than an on-site inspection. This process removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

1.11. The panel noted that a DBA, followed by a virtual inspection, was conducted on 9 June 2021, which included videoconferencing with key members of staff.

1.12. The panel noted that, at time of the inspection, there were two 'other' areas of non-compliance concerning infection control and patient support. Since the virtual inspection, the Person Responsible (PR) has provided evidence that actions have been taken to implement both recommendations made in the report, committing, where required, to audit the effectiveness of those actions within the required timescales.

1.13. The panel noted that the centre's success rates are consistent with the national average. The PR is encouraged to continue to use the Quality Management System (QMS) to best effect to monitor and improve their success rates and the quality of the service offered to patients.

1.14. The panel noted that the centre is well led and provides a good level of patient support.

1.15. 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 in the report being implemented in 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.

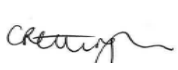
2.3. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR will discharge his duty under section 17 of the HFE Act 1990 (as amended).

2.4. The panel endorsed the inspectorate's recommendation to renew the centre's treatment (insemination using partner/donor sperm) 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. 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

Clare Ettinghausen

Date

31 August 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: 9 June 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.

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.

This centre was last inspected in May 2018, therefore an on-site inspection should usually be conducted by May 2020. However, following the DBA/RBA for this clinic, it was concluded that any items of concern identified during the DBA were of relatively low risk and could be reviewed effectively using virtual technology rather than on-site inspection. This removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

This inspection was therefore carried out by desk based assessment followed by a virtual inspection, which included videoconferencing with key members of centre staff.

Inspectors: Julie Katsaros (lead), Sara Parlett and Grace Lyndon

Date of Executive Licensing Panel: 24 August 2021

Centre name	Royal Derby Hospital
Centre number	0149
Licence number	L/0149/11/c
Centre address	Fertility Unit, Women's and Children's Services, Derby City General Hospital, Uttoxeter Road, Derby, Derbyshire, DE22 3NE, United Kingdom
Person Responsible	Mr Kanna Mannadiar Jayaprakasan
Licence Holder	Mr Saad Amer
Date licence issued	1 November 2016
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:

The Royal Derby Hospital is located in Derby and has held a licence with the HFEA since 1995.

The centre provides intra uterine insemination using partner/donor sperm treatments. Other licensed activities at the centre include the storage of gametes.

The centre also provides a satellite service for Care Nottingham, centre 0101.

The centre did not provide any cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 March 2021. 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. Treatments for both the centre's patients and the satellite service were temporarily suspended from 6 - 20 January 2021 due to the additional demands of the pandemic on hospital services and the need for staff to be redeployed.

The centre was due a renewal of licence inspection during the period of suspension of fertility treatments in 2020. In June 2020, the Person Responsible (PR) applied for a variation to extend the duration of the centre's current 'Treatment (insemination using partner / donor sperm) and storage' licence by one year.

The centre's current licence was issued for a period of four years, and following the grant of the licence variation, the centre's licence duration was extended to five years.

The current licence has also been varied to reflect the following change:

- 4 March 2021 – All centres: Variation of all licences without application (European Union (EU) Exit requirements).

Pregnancy outcomes

In 2020, the centre reported nine cycles of partner insemination with one pregnancy, which is in line with the national average.

Multiple births

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 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 the centre's 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, including two 'other' areas of non-compliance.

Since the inspection visit, the PR has provided evidence that actions have been taken to implement the following recommendations 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 compliance with infection prevention and control practices in accordance with statutory and best practice guidance and ensure that the findings of audits are followed up, recommendations implemented, and actions documented.
- The PR should ensure that the centre has a documented patient support policy in place, which outlines how the centre ensures that patients and their partners receive appropriate psychosocial support from all staff they encounter before, during and after treatment.

Recommendation to the Executive Licensing Panel

The centre has no critical or major of areas of non-compliance.

The inspection team notes that the success rates are consistent with the national average. The PR is encouraged to continue to use the QMS to best effect to monitor and improve their success rates and the quality of the service offered to patients.

The centre is well led and provides a good level of patient support.

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 0149 had not been issued with an importing (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018.

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 gametes 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 gametes are sourced from sperm banks and processes are 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 does not recruit donors, therefore this area of practice was not reviewed at this inspection.

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
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
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 gametes 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, or any material removed from them, 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 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 compliant with guidance.

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)
No surgical procedures are performed at this centre and therefore this area of practice is not relevant.

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 the patient's 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 (Guidance note 15; General Direction 0009)
The centre does not distribute gametes and therefore this guidance note is not relevant.

Receipt of gametes (Guidance note 15)
The centre's procedures for the receipt of gametes 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 does not import or export gametes and therefore this guidance note was not inspected.

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 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 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 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:

Infection control (Guidance Note 25)
On inspection the following issues were noted:

- The centre provided the inspection team with cleaning audits undertaken in 2020 and 2021, which identified several dusty areas within the centre but the date of completion of corrective actions was not present. Staff working at the centre were not able to confirm if these findings had been followed up and actioned.

SLC T2.

Department of Health: Health Building Note 00-09: Infection control in the built environment (2013) section 3.105.
See recommendation 1.

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 perform embryo testing, therefore these guidance notes are not relevant.

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. No patients have provided feedback in the last 12 months. 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 will be followed up at the next inspection.

A new system of patient feedback which specifically enables the feedback for fertility patients to be identified within the Trust's feedback questionnaire, was introduced in 2019 and the centre is currently trying to roll out an automated text messaging system to enable more patients to provide feedback to the centre. The centre's own patient survey results were reviewed. A total of 31 patients provided feedback to the centre over the last year, the majority of which was positive.

On the basis of this feedback and discussions with staff during 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 their partners 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 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 broadly 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 providing relevant consent and prior to consenting to legal parenthood.

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre does not offer egg or sperm sharing, therefore this guidance note is not relevant.

Surrogacy (Guidance note 14)
The centre does not offer treatments involving surrogacy arrangements, therefore this guidance note is not relevant.

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

Patient support (Guidance note 3)
The centre does not have a documented patient support policy in place.

SLC T2, HFEA CoP (9th edition) guidance note 3, section 3.14.

See recommendation 2.

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

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.

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At the last inspection in May 2018, legal parenthood consenting processes were found to be robust.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of a recent legal parenthood consenting audit. 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.

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 process or store embryos, therefore this section is not relevant.

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 compliant with HFEA requirements. These measures ensure that the gametes are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes in accordance with the consent of the gamete providers.

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

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 with HFEA requirements with the exception noted in the 'QMS' section of this report.

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 May 2018, recommendations for improvement were made in relation to two 'major' 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 identified.			

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
None identified.			

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
1. Infection control On inspection the following issues were noted: • The centre provided the inspection team with cleaning audits undertaken in 2020 and 2021, which identified several dusty areas within the centre but the date of completion and signature was not present. Staff working at the centre were not able to confirm if these findings had been followed up and actioned. SLC T2.	The PR should ensure compliance with infection prevention and control practices in accordance with statutory and best practice guidance and ensure that the findings of audits are followed up, recommendations implemented and actions documented. The PR should confirm, when responding to the report, that the areas identified in the centre's infection control audits have been addressed. The PR should also review the cleaning schedules and infection control practices to ensure compliance with this recommendation by 9 September 2021.	The issues that were identified in the audit had been addressed and the actions documented (the document attached). The cleaning of the premise is done every day with issues identified in the audits (like dust) is generally addressed the next day. The environemental audit (including infection control and cleaning) is undertaken by the fertility unit team every month and the cleaning audit by the ISS (Trust team) is undertaken in addition. The cleaning audit score has always been in the 90s (well above the benchmark/ pass level of 85%). The ISS will continue to monitor the dust levels (initially monthly for three months before going	The executive notes the PR's response and confirmation that the areas identified in the centre's infection control audits have been addressed. The executive notes the PR's response to the section in the non-compliance relating to the sharps bins and accepts his explanation with regard to the findings, therefore this element of the infection control non-compliance has been removed from the report. No further action beyond submission of the audit report due 9 December 2021.

Department of Health: Health Building Note 00-09: Infection control in the built environment (2013) section 3.105.	Three months after this review, the PR should conduct an audit of the centre's cleaning and infection control practices to ensure ongoing compliance with this recommendation. A summary report of this audit with corrective actions taken should be provided to the centre's inspector by 9 December 2021.	back to three monthly audits if all OK) and corrective actions would be undertaken regularly. With regard to sharp bins, it is a routine practice that temperory closure of sharp bins until the bin is full, when it is closed fully. In the photograph showed to the inspection team, it was purposely done to show the inspection team that the bin is not full.	
2. Patient support The centre does not have a documented patient support policy in place. SLC T2. HFEA CoP (9th edition) guidance note 3, section 3.14. Clinic focus October 2019.	The PR should ensure that the centre has a documented patient support policy in place, which outlines how the centre ensures that patients and their partners receive appropriate psychosocial support from all staff they encounter before, during and after treatment. The inspection team acknowledges that the PR acted promptly on the findings and shortly after the inspection provided the inspection team with a comprehensive patient	Already actioned as the report acknowledged.	The executive acknowledges the PR's immediate actions to fully address this inspection finding. No further action required.

	support policy, therefore no further action is required.		

Reponses from the Person Responsible to this inspection report
Thank you very much for the inspection report acknowledging compliance of our practices with HFEA regulations except the couple of issues (areas for improvement) raised above. We have clarified with action plans on these.