Executive Licensing Panel Minutes

Centre 0352 (Future Health Biobank)

Renewal Inspection Report

Variation of Licenced Premises

Date:	18 May 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Richard Sydee (Chair) Dina Halai Dan Howard	Director of Finance and Resources Senior Scientific Policy Manager Chief Information Officer
Executive:	Bernice Ash	Secretary
Observers:	Catherine Burwood Dee Knoyle	Licensing Manager Committee Officer

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 four years.

1.2. The panel noted that Future Health Biobank is located in the Faraday Building on Nottingham Science Park and has held a storage only licence since September 2016.

1.3. The panel noted that the company does not provide treatment services but uses its cryostorage expertise to offer gamete and embryo storage services to other HFEA licensed centres, under long term service contracts or as part of a planned contingency response to an emergency. At the time of the inspection, the Person Responsible (PR) confirmed that no gametes or embryos have ever been stored at the centre.

1.4. The panel noted that centre holds a Human Tissue Authority (HTA) licence to allow processing, testing, storage, distribution and import/export of human tissues and cells for human application. The centre was last inspected by the HTA in September 2019 and three major and seven minor shortfalls were identified; the PR has confirmed that these have since been resolved. The centre is also regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA) and is accredited to ISO standard 9001:2015.

1.5. The panel noted that centre was due a renewal of licence inspection during the period of suspension of fertility treatments, due to Covid-19. In April 2020, the PR applied for a variation to extend the duration of the centre's current storage only licence by one year. The centre's initial 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.

1.6. The panel noted that, in March 2021, the PR applied to vary the centre's premises and this will also be for consideration at the meeting.

1.7. The panel noted that the centre's interim inspection occurred in April 2018 and a renewal inspection was scheduled to be undertaken by April 2020. However, due to the Covid-19 pandemic, a Desk Based Assessment and Risk Based Approach (DBA/RBA), was conducted. Following this, it was established that any items of concern identified 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.

1.8. The panel noted that a virtual inspection was conducted on 20 April 2021, which included videoconferencing with key members of staff.

1.9. The panel noted that at the time of inspection, there were no recommendations for improvement.

1.10. The panel noted that, as result of the UK's departure from the European Union (EU), a relicensing exercise is currently under way. This follows approval by the Licence Committee of a variation without application on 4 March 2021, meaning that new offer licences are being sent to all clinics, incorporating changes to some of the standard licence conditions. The varied licences will all come into effect on 1 July 2021, after the transition period ends on 30 June 2021.

1.11. The panel noted that the renewal for this centre is being considered during that relicensing period. However, since this renewal licence (if approved) will begin on 15 September 2021, the renewal licence will simply follow on in the normal way from the centre's current active licence, which by that date will be the new, varied, licence.

1.12. The panel noted that the inspection team recommends the renewal of the centre's storage only licence, for a period of four years, without additional conditions.

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 storage only licence for a period of four years, without additional conditions. The panel agreed that if no representations or any other information is received within 28 days, the final renewal licence should be issued.

3. Variation of Licenced Premises - Background

3.1. The panel noted that the centre submitted an application, on 12 March 2021, to vary the centre's licence to reflect a change of premises to add an additional unit of the Faraday Building to the existing storage only licence. Future Health Biobank now occupies units 10, 11 and 12 of the Faraday Building for the purpose of cryogenic storage of human material.

3.2. The panel noted that should the variation application be approved the centre's licensed premises address would change to the following address:

Nottingham Science Park
Units 10-12 Faraday Building
University Boulevard Nottingham
Nottinghamshire
NG7 2QP

3.3. The panel noted that, as for the centre's renewal inspection, the variation of premises inspection was conducted by virtual inspection on 21 April 2021. It was concluded that any items of concern identified were of relatively low risk and could be reviewed effectively using virtual technology rather than on-site inspection. An updated floor plan of the premises to be covered by the licence and photographic evidence demonstrating the suitability of the new unit for gamete and embryo storage had been provided.

3.4. The panel noted that, due to the relicensing exercise, the panel is asked to approve this variation of premises for the centre's current licence, and also for the new, varied, licence that will supersede it on 1 July 2021. The Licensing team will send the centre a varied licence for immediate use until 30 June 2021, and an updated offer licence for 1 July 2021 onwards, also reflecting the variation of premises, as requested.

4. Consideration of application

4.1. The panel considered the papers, which included an executive summary, application form and licensing minutes for the past four years.

4.2. The panel noted that, at the time of the of the DBA/RBA, conducted in April 2021, no areas of non-compliance were identified.

4.3. The panel noted that the information provided fulfils the requirements for this type of licence variation application, as defined in General Directions 0008.

4.4. The panel noted that the inspectorate recommends the approval of the application to vary the licence to reflect the change of premises to the following address:

Nottingham Science Park
Units 10-12 Faraday Building
University Boulevard Nottingham
Nottinghamshire
NG7 2QP

5. Decision

5.1. The panel was satisfied that the appropriate application had been submitted and that the application contained the supporting information required by General Directions 0008.

5.2. The panel was satisfied that the application fee was submitted to the HFEA in accordance with requirements.

5.3. The panel was satisfied that the premises are suitable for the conduct of licensed activities.

5.4. The panel endorsed the inspectorate's recommendation to change the centre's licensed premises to:

Nottingham Science Park
Units 10-12 Faraday Building
University Boulevard Nottingham
Nottinghamshire
NG7 2QP

5.5. The panel also approved this change of premises for the new, varied, licence that will supersede it on 1 July 2021. The Licensing team will send the centre a varied licence for immediate use until 30 June 2021, and an updated offer licence for 1 July 2021 onwards, also reflecting the approved variation of premises.

6. Chair's signature

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

Signature

Name

Richard Sydee

Date

24 May 2021

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this storage centre complies with essential requirements in providing a safe and high quality gamete and embryo storage service for 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: 20 April 2021

Purpose of inspection: Renewal of a licence for 'Storage Only' and variation to licensed premises.

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 April 2018, therefore an on-site inspection should usually be conducted by April 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.

Inspector: Louise Winstone

Date of Executive Licensing Panel: 18 May 2021

Centre name	Future Health Biobank
Centre number	0352
Licence number	L/0352/1/d
Centre address	Nottingham Science Park, Unit 10 and 11 Faraday Building, University Boulevard Nottingham, Nottinghamshire, NG7 2QP.
Person Responsible	Sarah Reddish
Licence Holder	Rachel Simpson
Date licence issued	16 September 2016
Licence expiry date	15 September 2021
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
Future Health Biobank is located in the Faraday Building on Nottingham Science Park and has held a 'Storage Only' licence since September 2016.

The company does not provide treatment services but uses its cryostorage expertise to offer gamete and embryo storage services to other HFEA licensed centres, under long term service contracts or as part of a planned contingency response to an emergency. At the time of the inspection, the Person Responsible (PR) confirmed that no gametes or embryos have ever been stored at the centre.

The centre holds a Human Tissue Authority (HTA) licence to allow processing, testing, storage, distribution and import/export of human tissues and cells for human application. The centre was last inspected by the HTA in September 2019 and the inspection identified three major and seven minor shortfalls. The PR has confirmed that these have since been resolved. The centre is also regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA) and is accredited to ISO standard 9001:2015.

The centre was due a renewal of licence inspection during the period of suspension of fertility treatments. In April 2020, the PR applied for a variation to extend the duration of the centre's current 'Storage Only' licence by one year. The centre's initial 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 centre also varied their licence in November 2017 to change the Licence Holder and the PR.

On 12 March 2021, the PR applied to vary the centre's premises to add an additional unit of the Faraday Building to the existing 'Storage Only' licence. Future Health Biobank now occupies units 10, 11 and 12 of the Faraday Building for the purpose of cryogenic storage of human material. An updated floor plan of the premises to be covered by the licence and photographic evidence demonstrating the suitability of the new unit for gamete and embryo storage has been provided.

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 that at the time of the inspection, no recommendations for improvement were made.

Recommendation to the Executive Licensing Panel

The executive recommends the renewal of the centre's 'Storage Only' licence for a period of four years without additional conditions and for the centre's licence to be varied to incorporate the additional unit of the Faraday Building. The centre's address is to be changed to:

Nottingham Science Park,
Units 10-12 Faraday Building,
University Boulevard Nottingham,
Nottinghamshire,
NG7 2QP.

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)
The centre operates a business model where they will take receipt of locked storage dewars from other HFEA licensed centres (the 'primary' centres) and then store them in a compliant manner. Both receipt and subsequent dispatch of dewars will be witnessed. Under this business model, the centre will not access samples within the dewars. All such manipulation will be the responsibility of staff from the primary centres, who will visit the centre and operate to their own witnessing procedures.

The centre is compliant with HTA requirements related to witnessing, suggesting that if any manipulation of individual samples were to be necessary, it will be done in a compliant manner.

The inspection team are confident that the centre's procedures will be compliant with HFEA witnessing requirements. This ultimately ensures that patients receive treatment using the correct gametes or embryos.

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

Donor selection criteria and laboratory tests

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

What the centre does well

Screening of donors (Guidance note 11)
The centre will not recruit donors, therefore this area of practice is not relevant to this inspection.

Payments for donors (Guidance note 13; General Direction 0001)
The centre will not recruit donors, therefore this area of practice is not relevant to this inspection.

Donor assisted conception (Guidance note 20)
The centre will not treat people with donated gametes or embryos, therefore this area of practice is not relevant to this inspection.

What the centre could do better
Not applicable.

Suitable premises and suitable practices

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

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are suitable. At the time of the last on-site inspection, the centre's premises were clean and appeared well maintained and suitable for the proposed licensed activity. 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 will only store and distribute gametes and embryos. It will not process them so HFEA requirements related to air quality were not reviewed on this inspection.

Laboratory accreditation (Guidance note 25)
The primary centres will be responsible for undertaking the diagnosis and investigation of gamete providers whose gametes or embryos are subsequently transferred for storage at the proposed centre. Therefore, this area of practice is not relevant to this inspection.

Infection control (Guidance Note 25)
The centre will not provide treatment or process gametes or embryos, therefore prevention and control of infection to patients is not relevant to this inspection.

Medicines management (Guidance Note 25)

The centre will not provide treatment or prescribe medicines, therefore this area of practice is not relevant to 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 are not relevant to this inspection.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
The centre will not provide treatment, therefore this area of practice is not relevant to this inspection.

Multiple births (Guidance note 7; General Direction 0003)
The centre will not provide treatment, therefore this area of practice is not relevant to this inspection.

Procurement of gametes and embryos (Guidance note 15)
The centre will not provide treatment or procure gametes or embryos, therefore these areas of practice are not relevant to this inspection.

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

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

Receipt of gametes and embryos (Guidance note 15)
The HTA inspection report and findings from the previous inspection indicate that the centre's procedures for the receipt of cryopreserved gametes and embryos will be compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from primary centres if the gametes and embryos are appropriately labelled and have enough information to permit the gametes and embryos to be stored in a way that does not comprise their quality and safety.

Imports and exports (Guidance note 16; General Direction 0006)
The centre will not import or export gametes or embryos, therefore this area of practice is not relevant to this inspection.

Traceability (Guidance note 19)
The HTA inspection report and findings from the previous inspection confirm that the centre's procedures are compliant with HFEA traceability requirements. The primary

centre's will maintain storage records and control over the samples within the dewars, and thus the traceability of individual samples. The centre will maintain the dewars and ensure the safe storage of samples within the dewars.

These requirements are important to ensure that the centre has the ability:

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

Quality management system (QMS) (Guidance note 23)
The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

The HTA inspection report and observations made on previous inspections confirm that the centre has a QMS in place that is compliant with HFEA requirements. The QMS is well designed to meet the requirements of the HFEA.

Third party agreements (Guidance note 24)
The centre has third party agreements in place for service provision which are compliant with HTA and thus HFEA requirements. No HFEA centres have made a contract with the proposed centre to store gametes and embryos, however a template agreement, to be developed with centres contracting storage services, has been assessed by the inspection team to be compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not have transport and satellite agreements in place therefore this area of practice is not relevant to this inspection.

Equipment and materials (Guidance note 26)
The recent HTA inspection report and observations during the last on-site inspection indicate that the centre uses equipment and materials that are compliant with HFEA requirements. All of the equipment and materials which will be used in HFEA licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

The centre will receive stored material held within dewars from other HFEA licensed centres, these dewars will have undergone validation under the supervision of the PR of the primary centre, under the conditions of their HFEA licence.

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 storage procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient. The centre has

validated its storage processes using stored HTA regulated material and associated critical parameter monitoring data.

Adverse incidents (Guidance note 27)
The HTA inspection report and observations made during previous inspections indicate that the centre's procedures for reporting adverse incidents are compliant with HFEA requirements.

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
Nothing identified at this inspection.

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 biological sciences and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme.

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.

As a storage only centre, the centre will not require access to a nominated registered medical practitioner, within the UK, to advise on or oversee medical activities.

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 will not treat patients, therefore this area of practice is not relevant to this inspection.

Safeguarding (Guidance Note 25)
The centre will not treat patients, therefore this area of practice is not relevant to this inspection.

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)
This area of practice is not relevant to this inspection.

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

2. The experience of patients

Patient feedback

What the centre does well
The centre does not provide licensed treatment to patients, therefore this area of practice is not relevant to this inspection.

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 does not treat patients therefore this area of practice is not relevant to this inspection.

Patient support (Guidance note 3)
The centre does not treat patients therefore this area of practice is not relevant to this inspection.

Counselling (Guidance note 3)
The centre does not treat patients and, if gamete and embryo storage is to occur in future, the primary centres who store the material before it is transferred to Future Health Biobank will have responsibility to make counselling available to the gamete providers. Therefore, this area of practice is not relevant to this inspection.

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre does not offer egg and sperm sharing services therefore this area of practice is not relevant to this inspection.

Surrogacy (Guidance note 14)
The centre does not offer a surrogacy service therefore this area of practice is not relevant to this inspection.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek client (HFEA primary centre) feedback and to be responsive to client complaints. This is important to ensure that the centre uses client 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 confidentiality is maintained and understood by staff, in relation to the HF&E Act 1990 (as amended).
What the centre could do better Nothing identified at this inspection.

Information

What the centre does well **Information (Guidance note 4** The centre does not treat patients therefore this area of practice is not relevant to this inspection.
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) and Legal parenthood (Guidance note 6)** The centre does not take consent therefore this area of practice is not relevant to this inspection. **Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)** The centre does not provide any patient identifying information to the HFEA register, therefore this area of practice is not relevant to this inspection.
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
This area of practice is not relevant to this inspection.

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

Screening of patients and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 15)
It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos. The centre is not responsible for the screening of patients; this is the responsibility of the primary centre. The centre does however have procedures for ensuring that the providers of gametes from which cryopreserved material has been derived, have been screened before the material is placed into storage. Such procedures ensure compliance with HFEA screening requirements is maintained.

Storage of gametes and embryos (Guidance note 17)
The storage of gametes and embryos is an important service offered by off-site storage facilities to primary centres and can provide a safe and secure storage option in an emergency or as part of a longer term planned off-site storage strategy.

The centre's procedures for storing gametes and embryos are HTA compliant and compliant with HFEA requirements. These measures will ensure that gametes and embryos will be stored appropriately to maintain their quality and safety. The centre will only store gametes and embryos in accordance with the consent of the gamete providers, however the taking of storage consent is and will be the responsibility of the primary centre. The centre aims to operate to a business model in which the monitoring of storage consent expiry dates and any manipulation of the cryopreserved samples will remain the responsibility of the primary centre.

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)
No embryos will be processed at the centre or made available for training so this area of practice is not relevant to this inspection.

What the centre could do better

Nothing identified at 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 does not currently keep any HFEA patient records, however, ISO 9001:2015 certification of the centre's QMS and HTA licensing provide good evidence that document control processes are compliant with HFEA requirements. **Obligations and reporting requirements (Guidance note 32; General Direction 0005)** The centre will not undertake patient treatment therefore this area of practice is not relevant to this inspection.
What the centre could do better Nothing identified at this inspection.

Section 3: Monitoring of the centre's performance

Following the interim inspection in April 2018, recommendations for improvement were made in relation to 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 does not provide treatment to patients so has no success rates to monitor through the risk tool.

Areas of practice requiring action

This 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.		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 partially compliant with requirements.

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

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
None identified.		None	

Responses from the Person Responsible to this inspection report
I confirm that this report is factually accurate.