Executive Licensing Panel - minutes

Centre 0352 (Future Health Biobank) Initial Inspection Report – Storage Only Licence

Friday, 9 September 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Paula Robinson (Chair) David Moysen Jessica Watkin	Head of Business Planning Head of IT Policy Manager
Members of the Executive	Dee Knoyle Ian Brown	Secretary Head of Corporate Governance
External adviser		
Observers		

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

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

1. Background

1.1. Future Health Technologies Ltd is incorporated as a private limited company and is located at:

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

1.2. The company has processed and stored over 115,000 stem cell samples from over 75 different countries. Current services include umbilical cord stem cell banking, dental pulp stem cell banking, adipose stem cell banking and pre-natal and new born screening.

1.3. The Person Responsible (PR) submitted an initial application for a storage only licence on 9 May 2016. The company wishes to be licensed in the name of Future Heath Biobank and plans to provide gamete and embryo storage services to HFEA licensed centres, under long term service contracts or as part of a planned contingency response to an emergency.

1.4. The company already holds a Human Tissue Authority (HTA) licence to allow procurement, processing, testing, storage, distribution and import/export of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The company also processes and stores relevant material derived from the human body for use in scheduled purposes and is also regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA).

2. Consideration of application

2.1. The panel considered the papers which included an application form, inspection report and CV of the proposed Person Responsible (PR).

2.2. The panel noted the report of the inspection carried out on 19 July 2016.

2.3. The panel noted that the proposed PR, Mr Duncan Hind, holds academic qualifications in the field of biological sciences. The proposed PR also has more than two years' practical experience which is directly relevant to the activity to be authorised by the licence as required by the HFE Act 1990 (as amended) section 16(2)(c)(i) and (ii) (including acting in the capacity of PR). The proposed PR has successfully completed the HFEA PR Entry Programme.

2.4. The panel noted the suitability of the proposed (LH), Mr Roger James Dainty.

2.5. The panel noted the suitability of the premises for the conduct of licensed activities.

2.6. The panel noted that the inspectorate is satisfied that the activities to be carried out at the proposed centre are necessary or desirable in order to provide licensed storage services.

2.7. The panel noted that at the time of the inspection on 19 July 2016 the proposed centre was compliant.

2.8. The panel noted that the inspectorate considered that there is sufficient information available to recommend:

- the appointment of the proposed PR
- the appointment of the proposed Licence Holder
- the grant of a storage only licence for a period of four rather than two years, as would be usual for an initial licence, given the company has performed storage activities directly related to

those to be undertaken under the proposed HFEA licence, for over five years, in a manner compliant with HTA standards.

2.9. The panel noted that the inspectorate also recommended that an interim inspection is carried out during the first year to monitor the proposed centre's progress and performance.

3. Decision

3.1. The panel referred to its decision tree.

3.2. The panel noted that a storage only licence application form was not available and therefore the PR has completed a treatment and storage application form and used the free text entry boxes to make clear that only storage of gametes and embryos will be undertaken.

3.3. The panel noted that the inspectorate had received the supporting information required by General Directions 0008 and was satisfied that the fee had been paid.

3.4. The panel was satisfied that the proposed PR, Mr Duncan Hind will discharge his duty under section 17 of the HFE Act 1990 (as amended). The panel agreed to appoint Mr Hind as the Person Responsible when the new licence comes into effect, in accordance with section 18A of the HFE Act 1990 (as amended).

3.5. The panel was satisfied with the suitability of the proposed LH, Mr Roger James Dainty. The panel agreed to appoint Mr Dainty as the Licence Holder when the new licence comes into effect.

3.6. The panel was satisfied that the premises to be licensed (and those of relevant third parties) are suitable for the conduct of licensed activities based on evidence provided within the report.

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

3.8. The panel referred to its guidance on periods for which new or renewed licences can be granted, which states that an initial treatment/storage/non-medical fertility services licence would normally be granted for up to two years. This is because in granting an initial licence, there will be no history of compliance to support a longer licence. However in this case the company has performed storage activities directly related to those to be undertaken under the proposed HFEA licence, for over five years in a manner compliant with HTA standards and therefore does have a history of compliance.

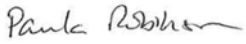
3.9. The panel endorsed the inspectorate's recommendation to grant a storage only licence for a period of four years, without additional conditions.

3.10. The panel also endorsed the inspectorate's recommendation to carry out an interim inspection during the first year to monitor the centre's progress and performance.

4. Chair's signature

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

Signature



Name

Paula Robinson

Date

16 September 2016

Initial Licence Inspection Report

Date of Inspection: 19 July 2016
Length of inspection: 5 hours

Inspection details:
The report covers the pre-inspection analysis, findings from a recent Human Tissue Authority (HTA) inspection, the HFEA inspection visit, information received with the new licence application and a desk based assessment of documentation submitted after the inspection visit.

Date of Executive Licensing Panel: 9 September 2016.

Purpose of the Inspection report
The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

The purpose of the inspection is to assess whether an application for a new licence will have in place processes and procedures to ensure that they will comply with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC) to ensure that centres will provide a quality service for patients. The report summarises the findings of the inspection. It is primarily written for the Executive Licensing Panel (ELP) which makes the decision about the centre's licence application

Centre details - proposed

Centre Name	Future Health Technologies Ltd.
Centre Number	0352
Centre Address	Nottingham Science Park, Units 10-11 Faraday Building, University Boulevard, Nottingham, NP7 2PQ
Person Responsible	Duncan Hind
Licence Holder	Roger James Dainty
Proposed date of licence issue	23 September 2016

TRIM: 2016/009578
2016-07-19 Initial licence report, centre 0352

Contents

Report to Licence Committee

Brief description of the centre:

An initial licence enquiry was received on 2 February 2016 from Mr Duncan Hind, the proposed Person Responsible (PR). The Executive provided appropriate advice and Mr Hind submitted an initial application for a storage only licence on 9 May 2016.

Future Health Technologies Ltd. is incorporated as a private limited company in the United Kingdom and is located in units 10 and 11 in the Faraday Building, a collection of business units on Nottingham Science Park. The company has processed and stored over 115000 stem cell samples from over 75 different countries. Current services include umbilical cord stem cell banking, dental pulp stem cell banking, adipose stem cell banking and prenatal and newborn screening.

The company wishes to utilise its cryostorage expertise to provide 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, hence their application for a 'storage only' licence.

The centre already holds a Human Tissue Authority (HTA) licence to allow procurement, processing, testing, storage, distribution and import/export of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The centre also processes and stores relevant material derived from the human body for use in scheduled purposes; thus the centre is also regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA).

Proposed activities of the Centre:

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓

Summary for licensing decision:

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- The proposed PR has submitted documentation in compliance with the requirements of General Direction 0008. The inspection team notes that the PR has applied for a 'storage only' licence using a treatment and storage licence application form. This is because a specific storage only licence application form is not available in the clinic portal. The proposed PR has also not ticked any licensed activities within the form

however the application form does have free text entry boxes which make clear that only storage of gametes and embryos will be undertaken.
- 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 will discharge his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) and equipment are suitable;
- the centre's proposed practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for an initial licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The centre has no critical, major or 'other' areas of non-compliance. The inspection team is satisfied that the proposed activities to be carried out at the centre are necessary or desirable in order to provide licensed storage services.

Recommendation to the Executive Licensing Panel:
The inspection team recommend that the ELP accept the application form submitted by the proposed PR as an application for a 'storage only' licence to undertake sperm, egg and embryo storage.

The inspection team considers that, overall, there is sufficient information to recommend:
- the appointment of the proposed PR
- the appointment of the proposed Licence Holder.
- the issue of a 'storage only' licence to the centre for a period of four rather than two years, as would be usual for an initial licence, given the centre has performed storage activities directly related to those to be undertaken under the proposed HFEA licence, for over five years in a manner compliant with HTA standards.

Details of 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.

The use of the HTA inspection report in evidence of compliance at this inspection:
The HTA undertook a routine inspection of the proposed centre on 26 November 2015 and the findings from that inspection have been used to inform this report. The inspection focussed on process and equipment validation, quality control testing and documentation, and the suitability of the premises, equipment and facilities. It identified three shortfalls to HTA Standards: one related to Governance and Quality and two within Premises and Facilities. On this inspection, the Designated Individual advised that these shortfalls had been addressed.

In this HFEA inspection report, the inspection team consider that the HTA inspection report provides suitable and appropriate evidence for compliance with HFEA requirements in many areas because:

- Many HTA standards, with which the centre has demonstrated compliance, are equivalent to HFEA standards, both sets of standard being derived from the European Union Tissues and Cells Directives.
- The HTA inspection was performed only eight months prior to this HFEA inspection, so findings are current. The proposed PR advised that practices and procedures relevant to the proposed HFEA licensed activities were unchanged from those reviewed at the HTA inspection.

1. Protection of patients and children born following treatment

Witnessing and assuring patient and donor identification (Guidance Note 18)

What the proposed centre does well.

Witnessing (Guidance note 18)
The centre plans to operate 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.

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 proposed centre but will operate to their own witnessing procedures.

The proposed 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 proposed centre could do better.
Nothing identified at this inspection.

Donor recruitment, assessment and screening (Guidance Note 11)
Payments for Donors (Guidance Note 13)
Donor assisted conception (Guidance Note 20)

What the proposed centre does well.

Screening of donors (Guidance notes 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 Directions 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 proposed centre could do better.
Not applicable

Patient selection criteria and laboratory tests

- Procuring, processing and transporting gametes and embryos (Guidance Note 15)
- Counselling (Guidance Note 3)
- Laboratory accreditation (Guidance Note 20)

What the proposed centre does well.

Procurement of gametes and embryos (Guidance note15)
The centre will not provide treatment or procure gametes or embryos, therefore these areas of practice are not relevant to this inspection.

Counselling (Guidance note 3)
The centre will not treat patients and the primary centres who initially store gametes and

embryos before transferring them to Future Health Technologies Ltd. will be responsible for making counselling available to gamete providers. Therefore this area of practice is not relevant to this inspection.

Laboratory accreditation (Guidance note 20)
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.

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

Good clinical practice

- Quality management system (Guidance Note 23)
- Traceability (Guidance Note 19)
- Validation (Guidance Note 15)
- Equipment and materials (Guidance Note 26)
- Premises – suitability of the premises and air quality (Guidance Note 25)
- Adverse incidents (Guidance Notes 27)
- Third party agreements (Guidance Note 24)
- Intracytoplasmic sperm injection (ICSI) (Guidance Note 21)
- Infection control
- Medicines management
- Pre-operative assessment and the surgical pathway

What the proposed centre does well.

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 on this inspection 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.

Traceability (Guidance note 19)
The HTA inspection report and discussions on this inspection confirm that the centre's procedures are compliant with HFEA traceability requirements. The primary centres will maintain storage records and control over the samples within the dewars, and thus the traceability of individual samples. The proposed centre will maintain the dewars and ensure the safe storage of samples within the dewars.

These requirements are important to ensure it is possible to:

- identify and locate gametes and embryos during storage;
- identify the donor of particular gametes or embryos;
- identify any person who has carried out any activity in relation to particular gametes or

embryos; and
- identify and locate all relevant data relating to products and materials coming into contact with the gametes or embryos and which may affect their quality or safety.

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 cryopreserved 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.

Equipment and materials (Guidance note 26)
Observations on inspection and the recent HTA inspection report 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 validated, designated for the purpose and are appropriately maintained in order to minimise any hazard to staff.

As Future Health Technologies Ltd. will receive stored material held within dewars from other HFEA licenced 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 to guide the response if equipment malfunctions.

Safety and suitability of premises and facilities (Guidance note 25)
The proposed centre comprises a reception area, offices and a large cryostore on the ground floor and further offices on the first floor, of units 10 and 11 within the Faraday building. A large liquid nitrogen reservoir is located immediately outside the centre, in a caged area adjacent to the cryostore. A further emergency liquid nitrogen reservoir is also adjacent to the centre in another caged area.

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 to ensure 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.

Adverse incidents (Guidance note 27)
The HTA inspection report and discussions with the proposed PR indicate that the centre's procedures for reporting adverse incidents will be 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.

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.

The proposed PR in the licence application form stated 'No' in response to: 'Is it intended that a third party will procure, test or process gametes and embryos on your behalf or supply your centre with goods or services that may affect the quality and safety of gametes and/or embryos'. The PR confirmed that this answer was provided in error and that third party agreements are in place with all providers of goods and services.

Intracytoplasmic sperm injection (ICSI) (Guidance note 21)
The centre will not provide treatment or process gametes or embryos, therefore this area of practice is not relevant to this inspection.

Infection control
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
The centre will not provide treatment or process gametes or embryos, therefore this area of practice is not relevant to this inspection.

Pre-operative assessment and the surgical pathway
The centre will not provide treatment or process gametes or embryos, therefore this area of practice is not relevant to this inspection.

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

Multiple Births (Guidance Note 7)

What the proposed centre does well.

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

What the proposed centre could do better
Not applicable.

Staff engaged in licensed activity

- Person Responsible (Guidance Note 1)
- Staff (Guidance Note 2)

What the proposed centre does well.

Person Responsible (Guidance note 1)
The proposed PR has academic qualifications in the field of biological sciences (a BSc (hons) in Genetics and Microbiology), and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence, as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii). The PR has successfully completed the HFEA PR Entry Programme.

Two referees have attested to the suitability of the character of the applicant for the post of PR.

Staff (Guidance note 2)
The proposed Licence Holder is a Fellow of the Institute of Science and Technology and is a Director of Future Health Technologies Ltd.

The HTA inspection report and discussions with staff on inspection, indicate that the centre has suitably qualified and competent staff, in sufficient number, to carry out the proposed 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 proposed centre could do better.
Nothing identified at this inspection.

Welfare of the Child (Guidance Note 8) and Safeguarding

What the proposed 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
The centre will not treat patients, therefore this area of practice is not relevant to this inspection.

What the proposed centre could do better.
Not applicable.

Embryo Testing

- Preimplantation genetic screening (Guidance Note 9)
- Embryo testing and sex selection (Guidance Note 10)

What the proposed centre does well.

Preimplantation genetic screening (Guidance note 9)
Embryo testing and sex selection (Guidance note 10)
These areas of practice are not applicable to this inspection.

What the proposed centre could do better.
Not applicable.

2. Patient Experience

Treating patients fairly

- Treating patients fairly (Guidance Note 29)
- Confidentiality and privacy (Guidance Note 30)
- Complaints (Guidance Note 28)
- Provision of costed treatment plans (Guidance Note 4)
- Egg sharing arrangements (Guidance Note 12) – *if applicable*
- Surrogacy (Guidance Note 14) – *if applicable*

What the proposed centre does well.

Treating patients fairly (Guidance note 29)
The centre will not treat patients therefore this area of practice is not relevant to this inspection.

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 Human Fertilisation and Embryology Act 1990 (as amended). Paper and electronic documents are secure and staff who will have access to HFEA data or material will either be named on the licence or will work under the direction of the PR.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek client feedback and to be responsive to complaints from clients and staff. This is important to ensure that the centre uses feedback and any complaints as an opportunity to learn and improve their services.

Provision of costed treatment plans (Guidance note 4)
The centre will not treat patients therefore this area of practice is not relevant to this inspection.

Egg [and sperm] sharing arrangements (Guidance note 12; General Directions 0001)
The centre will not offer egg and sperm sharing services therefore this area of practice is not applicable to this inspection.

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

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

Information

- Information to be provided prior to consent (Guidance Note 4)
- Information about storage of embryos (including cooling off periods)
- Information about Intracytoplasmic sperm injection (Guidance Note 21)
- Information about preimplantation genetic testing (Guidance Notes 9 & 10) –
- Information about legal parenthood (Guidance Note 6)

What the proposed centre does well.

Information (Guidance note 4; CH(11)02)
The centre will not treat patients therefore this area of practice is not applicable to this inspection.

The centre will provide sufficient, accessible and up-to-date information to prospective primary centres to enable them to make informed decisions about the options for storage offered by the centre. The primary centres will be responsible for informing patients regarding the storing of their gametes and embryos at the proposed centre.

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

Consent

- Consent to treatment, storage, donation, training and disclosure of information (Guidance Note 5)
- Consent to legal parenthood (Guidance Note 6)

What the proposed centre does well.

Consent (Guidance note 5)
The centre will not take consent therefore this area of practice is not applicable to this inspection.

Disclosure of information, held on the HFEA Register, for use in research (Guidance note 6)
The centre will not provide any patient identifying information to the HFEA register, therefore this area of practice is not applicable to this inspection.

Consent to legal parenthood (Guidance Note 6)
The centre will not treat patients therefore this area of practice is not applicable to this inspection.

What the proposed centre could do better.
Not applicable.

3. Protection of gametes and embryos

Legal Requirements [Human Fertilisation and Embryology Act 1990 (as amended)]

- Licensed activities only take place on licensed premises
- Only permitted embryos are used in the provision of treatment services
- Embryos are not selected for use in treatment for social reasons
- Embryos are not created by embryo splitting
- Embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman
- Embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies
- Embryos which are or have been stored are not given to a person, other than in the course of providing treatment services, unless that person is a person to whom a licence applies
- No money or other benefit is given or received in respect of the supply of gametes or embryos unless authorised by the Authority

What the centre does well.

Licensed activities only take place on licensed premises
The proposed licensed premises are suitable for all activities specified in the initial licence application.

Embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies
The centre will receive and store embryos, kept within locked dewars, from other HFEA licensed centres in accordance with written agreements discussed elsewhere in this report.

Embryos which are or have been stored are not given to a person, other than in the course of providing treatment services, unless that person is a person to whom a licence applies
Embryos will only be returned to the PR of a primary HFEA licensed centre, in accordance with written agreements discussed elsewhere in this report.

Only permitted embryos are used in the provision of treatment services
Embryos are not selected for use in treatment for social reasons
Embryos are not created by embryo splitting
Embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman
No money or other benefit is given or received in respect of the supply of gametes or embryos unless authorised by the Authority
The centre will not treat patients therefore these areas of practice are not applicable to this inspection.

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

Storage of gametes and embryos

- Storage of gametes and embryos (Guidance Note 17)
- Screening of patients (Guidance Note 17)

What the centre does well.

Screening of patients (Guidance note 17)
It is important that centres appropriately screen gamete providers to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

The centre will not be treating patients and patients storing gametes and embryos will be screened by the primary centre. The proposed centre will however have procedures for ensuring that the providers of gametes from which cryopreserved material is derived, have been screened before the material is received at the centre and placed into storage. Such procedures will 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 will be the same as those used for storing material under the centre's HTA licence, which were considered compliant at the centre's last HTA inspection. These procedures are therefore compliant with HFEA requirements and 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 recording of storage consent 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.

Distribution and / or receipt of gametes and embryos

- Distribution of gametes and embryos (Guidance Note 15)
- Receipt of gametes and embryos (Guidance Note 15)
- Import/Export of gametes and embryos (Guidance Note 16)

What the proposed centre does well.

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The HTA inspection report and discussions with centre staff 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 note15)
The HTA inspection report and discussions with centre staff 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 Directions 0006)
The centre will not import or export gametes or embryos, therefore this area of practice is not relevant to this inspection.

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

Use of embryos for training staff (Guidance Note 22)

What the proposed 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 applicable to this inspection.

What the proposed centre could do better.
Not applicable.

4. Good governance and record keeping

Record keeping
Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre will not keep any HFEA patient records. Gamete and embryo storage records may be kept at the centre in certain situations and the proposed PR discussed secure, safe and confidential options for undertaking this activity.

The ongoing compliance of the centre's QMS with HTA standards provides good evidence that document control processes will be compliant with HFEA requirements. All documents viewed on inspection were version controlled and regularly reviewed.

Obligations and reporting requirements (Guidance note 32 ; General Direction 0005)
The centre will not undertake patient treatment therefore this area of practice is not applicable to this inspection.

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

Areas of proposed practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of potential non compliance. Each area is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

‘Critical’ area of non compliance

A ‘critical’ area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services. A ‘critical’ area of non-compliance requires immediate action to be taken by the Person Responsible.

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

‘Major’ area of non compliance

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

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

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

‘Other’ areas of practice that requires improvement

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

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

Additional information from the Person Responsible