Executive Licensing Panel - minutes

Centre 0376 The Jack Copland Centre, Scottish National Blood Transfusion Service (SNBTS)

Initial Inspection Report – Storage Licence

Tuesday, 30 June 2020

HFEA Teleconference Meeting

Panel members	Claire Ettinghausen (Chair) Helen Crutcher Yvonne Akinmodun	Director of Strategy and Corporate Affairs Risk and Business Planning Manager Head of Human Resources
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers		

Declarations of interest

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

The panel had before it:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Background

1.1. The Jack Copland Centre, Scottish National Blood Transfusion Service (SNBTS) is located at:

52 Research Avenue North
Heriot-Watt Research Park
Edinburgh
EH14 4BE

1.2. The proposed Person Responsible (PR), Dr Sharon Zahra, submitted an application for a storage only licence in March 2020. The Jack Copland Centre is within the headquarters of the SNBTS in Edinburgh, Scotland, and this manages all tissue banking activity in Scotland.

1.3. The panel noted that The Jack Copland Centre (SNBTS) aims to provide centralised storage in Scotland for donated gametes, alongside gametes being stored for the purposes of fertility preservation. The proposed PR has confirmed that the centre will initially undertake storage of donated sperm and sperm being stored for the purposes of fertility preservation. Once this service has been established, the centre will then undertake storage of donated eggs and eggs being stored for the purposes of fertility preservation.

1.4. The panel noted that donor recruitment, donor assessment, gamete donation, procurement and testing will be undertaken at the four Scottish HFEA licensed 'Treatment and Storage' centres, these being Edinburgh Assisted Conception Unit (0201), Glasgow Royal Infirmary (0037), Aberdeen Fertility Centre (0019) and Ninewells Hospital (0004). Once donations have been quarantined and cleared for clinical use, the samples will be transferred to The Jack Copland Centre, (SNBTS) for storage. The Jack Copland Centre, (SNBTS) will be responsible for ongoing storage of the gametes, and distribution to the HFEA licensed centres in Scotland when required for use in treatment.

1.5. The panel noted that the centre is licensed by the Human Tissue Authority (HTA) for 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, and is also regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA) to allow blood collection, processing, testing and distribution.

1.6. A desk based assessment was performed on 1 May 2020.

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 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, a decision was taken by the HFEA to suspend all inspections until 31 August 2020, at which point prevailing circumstances will need to be reviewed before a further decision is taken with regard to inspection activities. This is in line with other national regulators.

2.3. The panel noted that this centre's application, for a storage only licence, was being reviewed during this time and an onsite inspection had been scheduled for April 2020. However, in view of the restrictions in place due to the Covid-19 pandemic, this inspection could not take place.

2.4. The panel noted that the executive determined that a desk-based assessment was appropriate for this application and is in keeping with the requirements of the HF&E Act 1990 (as amended). Photographic evidence and documents have been supplied by the centre in support of this

application and a video conference call with key staff has taken place. An onsite inspection will be performed when the current restrictions have been lifted and the centre is fully operational.

2.5. The panel noted that the HTA undertook a routine inspection of the proposed centre between 20 and 23 August 2018 and the findings from that inspection have also been used to inform the report. The HTA found that the Jack Copland Centre, (SNBTS) met the majority of the HTA standards. However, ten minor shortfalls were found in relation to 'Governance and Quality', 'Premises' and 'Facilities and Equipment'. Overall, the HTA assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection. Evidence has been provided to confirm that these shortfalls have now been addressed.

2.6. The inspection team considers that the HTA inspection report provides suitable and appropriate evidence for compliance with HFEA requirements because several HFEA and HTA requirements have been derived from the 'European Union Tissues and Cells Directives', which are considered as equivalent standards. Therefore, the inspection team considers that the findings of the HTA inspection in 2018 provides assurance that the centre is compliant with a number of HFEA requirements.

2.7. The panel noted that there were no areas of non-compliance, at the time of the desk based assessment, conducted on 1 May 2020.

2.8. The panel noted that the proposed PR, Dr Sharon Zahra, 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.

2.9. The panel noted the suitability of the proposed Licence Holder (LH), Professor Marc Turner.

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

2.11. 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 LH.

2.12. The panel particularly noted that the inspectorate recommended the grant of a storage only licence, for a period of four, rather than two years (which is usual for an initial licence). In making this recommendation, the executive has taken into consideration that the centre is also licensed by the HTA; it has performed storage activities directly related to those to be undertaken under the proposed HFEA licence for over ten years, in a manner compliant with HTA standards.

2.13. The panel noted that the anticipated start date, stated in the application form, is 1 December 2020 which is when the proposed PR anticipates first taking receipt of stored material. The executive recommends that the centre is issued a 'Storage only' licence immediately, following consideration of the application, and not from1 December 2020 as stated on the application form.

2.14. The panel noted that a Covid-19 self assessment tool has been developed by the HFEA for storage only centres to complete to ensure the services that they provide are safe. This has been shared with the proposed PR, who has committed to completing this and submitting it for review by the executive prior to taking receipt of stored material. It is not considered necessary to complete this now, as it will be several months before the clinic will be accepting material and it is likely that guidance may change.

3. Decision

3.1. The panel referred to its decision tree.

3.2. The panel was satisfied that the appropriate application form was submitted.

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, Dr Sharon Zahra, will discharge her duty under section 17 of the HFE Act 1990 (as amended). The panel agreed to appoint Dr Sharon Zahra 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, Professor Marc Turner The panel agreed to appoint Professor Marc Turner as the Licence Holder when the new licence comes into effect.

3.6. The panel was satisfied that the premises to be licensed are suitable for the conduct of licensed activities based on the 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.

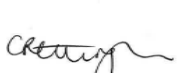
3.8. The panel referred to ‘guidance on periods for which new or renewed licences can be granted’ which states that an initial treatment/storage/non-medical fertility services licence would normally be granted for up to two years. However, the panel noted the recommendation, by the executive, to issue this initial licence for four years and was satisfied with this recommendation

3.1. The panel agreed to grant the licence for storage only, for a period of four years, with no 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.

4. Chair’s signature

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

Signature



Name

Clare Ettinghausen

Date

6 July 2020

Initial Licence Report

Purpose of the inspection report

This is a report of a desk-based assessment carried out to determine whether an application for a new licence will meet essential requirements. 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 desk-based assessment: 1 May 2020

Purpose of desk-based assessment: Application for a HFEA 'Storage' licence

Assessment details: The report covers the findings from a desk-based assessment of submitted documentation and communications received from the centre.

Inspector: Louise Winstone (lead) and Karen Conyers.

Date of Executive Licensing Panel: 30 June 2020

Centre name	The Jack Copland Centre, Scottish National Blood Transfusion Service (SNBTS)
Centre number	0376
Centre address	52 Research Avenue North, Heriot-Watt Research Park, Edinburgh, EH14 4BE.
Proposed Person Responsible	Sharon Zahra
Proposed Licence Holder	Marc Turner

Contents

Section 1: Summary report

Brief description of the centre:

The proposed Person Responsible (PR) has applied for a HFEA 'Storage' licence for 'The Jack Copland Centre, SNBTS', which is within the headquarters of the SNBTS in Edinburgh, Scotland. The SNBTS manages all tissue banking activity in Scotland.

The Jack Copland Centre, SNBTS aims to provide centralised storage in Scotland for donated gametes and gametes being stored for the purposes of fertility preservation. The proposed PR has confirmed that the centre will initially undertake storage of donated sperm and sperm being stored for the purposes of fertility preservation. Once this service has been established, the centre will then undertake storage of donated eggs and eggs being stored for the purposes of fertility preservation.

Donor recruitment, donor assessment, gamete donation, procurement and testing will be undertaken at the four Scottish HFEA licensed 'Treatment and Storage' centres, these being Edinburgh Assisted Conception Unit (0201), Glasgow Royal Infirmary (0037), Aberdeen Fertility Centre (0019) and Ninewells Hospital (0004). Once donations have been quarantined and cleared for clinical use, the samples will be transferred to The Jack Copland Centre, SNBTS for storage. The Jack Copland Centre, SNBTS will be responsible for ongoing storage of the gametes, and distribution to the HFEA licensed centres in Scotland when required for use in treatment.

The Jack Copland Centre, SNBTS is licensed by the Human Tissue Authority (HTA) for 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, and is also regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA) to allow blood collection, processing, testing and distribution.

Summary for licensing decision

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, a decision was taken by the HFEA to suspend all inspections until 31 August 2020, at which point prevailing circumstances will need to be reviewed before a further decision is taken with regard to inspection activities. This is in line with other national regulators.

This centre's application for a HFEA 'Storage licence' was being reviewed during this time and an onsite inspection had been scheduled for April 2020. However, in view of the restrictions in place due to the Covid-19 pandemic, this inspection could not take place.

Paragraph 2(1) of Schedule 3B of the HF&E Act 1990 (as amended) provides that "Where a person –

(a) makes an enquiry to the Authority which concerns the making of a relevant application by that person, or
(b) has made a relevant application to the Authority which the Authority has not yet considered,

the Authority may arrange for a duly authorised person to inspect any of the premises mentioned in sub-paragraph (3)."

The use of the word 'may' indicates that it is at the Authority's discretion whether to perform an onsite inspection. The executive has determined that a desk-based assessment was appropriate for this application and is in keeping with the requirements of the HF&E Act 1990 (as amended). Photographic evidence and documents have been supplied by the centre in support of this application and a video conference call with key staff has taken place. An onsite inspection will be performed when the current restrictions have been lifted and the centre is fully operational.

The HTA undertook a routine inspection of the proposed centre between 20 and 23 August 2018 and the findings from that inspection have also been used to inform this report. The HTA found that the Jack Copland Centre, SNBTS met the majority of the HTA standards, however ten minor shortfalls were found in relation to 'Governance and Quality', 'Premises' and 'Facilities and Equipment'. Overall, the HTA assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection. Evidence has been provided to confirm that these shortfalls have now been addressed.

The inspection team considers that the HTA inspection report provides suitable and appropriate evidence for compliance with HFEA requirements because several HFEA and HTA requirements have been derived from the 'European Union Tissues and Cells Directives', which are considered as equivalent standards. Therefore, the inspection team considers that the findings of the HTA inspection in 2018 provides assurance that the centre is compliant with a number of HFEA requirements.

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, Standard Licence Conditions (SLCs), and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has been submitted by the individual designated 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 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 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 ELP is asked to note that at the time of the desk-based assessment there were no areas of practice that required improvement.

Recommendation to the Executive Licensing Panel

The inspection team considers that there is sufficient information available to recommend:

- the appointment of the proposed Licence Holder;
- the appointment of the proposed PR; and
- the issue of a 'Storage only' licence to the centre for a period of four rather than two years (which is usual for an initial licence). In making this recommendation, the executive has taken into consideration that the centre is also licensed by the HTA and has performed storage activities directly related to those to be undertaken under the proposed HFEA licence for over ten years in a manner compliant with HTA standards.

The executive notes the anticipated start date in the application form is 1 December 2020 which is the date that the proposed PR anticipates first taking receipt of stored material. The executive recommends that the centre is issued a 'Storage only' licence immediately following consideration of this application and not 1 December 2020 as stated on the application form.

A Covid-19 self assessment tool has been developed by the HFEA for Storage only centres to complete to ensure the services that they provide are safe. This has been shared with the proposed PR, who has committed to completing this and submitting it for review by the executive prior to taking receipt of stored material. It is not considered necessary to complete this now, as it will be several months before the clinic will be accepting material and it is likely that guidance may change.

Centre 0376 has not applied for an Importing Tissue Establishment (ITE) import certificate, 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 donors 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 plans to operate a business model where they will take receipt of cryopreserved gametes from other HFEA licensed centres (the 'supplying' centres) for central storage and distribution.

The centre's proposed procedures for double checking the identification of samples received and subsequent distribution for clinical use are compliant with HFEA requirements. This ultimately ensures that patients receive treatment using the correct gametes.

What the centre could do better
Nothing identified.

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)
It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes.

The 'supplying' centres will be responsible for undertaking the recruitment, assessment and screening of gamete donors prior to procurement and storage. This centre's proposed procedures for ensuring that gamete donors have been appropriately screened prior to accepting the cryopreserved material for storage is compliant with HFEA requirements.

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 assessment.

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 assessment.

What the centre could do better
Nothing identified.

Suitable premises and suitable practices

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

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in an appropriate environment that is fit for purpose.

The centre's proposed procedures 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. It will not process them therefore HFEA requirements related to air quality are not relevant to this inspection.

Laboratory accreditation (Guidance note 25)
The 'supplying' centres will use SNBTS for the majority of donor screening tests. SNBTS laboratories and other laboratories used by the 'supplying' centres 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 services provided.

Infection control (Guidance note 25)
The centre will not provide treatment or process gametes or embryos, therefore this area of practice is not relevant to this assessment.

Medicines management (Guidance note 25)
The centre will not provide treatment services therefore this area of practice is not relevant to this assessment.

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

Multiple births (Guidance note 7; General Direction 0003)
These requirements are not relevant to the centre's proposed activities.

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

Transport and distribution of gametes (Guidance note 15; General Direction 0009)
The centre's proposed procedures for the transport, distribution and recall of gametes are compliant with HFEA requirements. This is important to ensure that all gametes sent to other licensed centres within or outside the UK are:

- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- shipped in a container/package which is validated, properly secured and ensures that the gametes are maintained in the specified conditions.

Receipt of gametes (Guidance note 15)
The centre's proposed 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 have enough accompanying 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 proposed PR has confirmed that they do not anticipate undertaking any import or export of gametes, therefore this area of practice is not relevant to this assessment.

Traceability (Guidance note 19)
Information received from the centre confirms that 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;
- identify the donor and recipient of particular gametes;
- identify any person who has carried out any activity in relation to particular gametes; and
- 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)

Information received from the centre confirms that the centre has a QMS in place 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 proposed third party agreements are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
These requirements are not relevant to the centre's proposed activities.

Equipment and materials (Guidance note 26)
The centre proposes using equipment and materials that are compliant with HFEA requirements. All of the equipment and materials that will be used in licensed activity are designated for the purpose and will be appropriately maintained in order to minimise any hazard to patients, donors 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 proposed storage and handling procedures have been validated in compliance with HFEA requirements. This ensures that these processes are effective and do not render the cryopreserved gametes clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's proposed procedures for reporting adverse incidents are compliant with HFEA requirements. The centre will report adverse incidents to the HFEA and will investigate all incidents that occur.

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.

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The proposed PR has complied with HFEA requirements during the application process and in preparing the centre for licensed activity.

The proposed PR has academic qualifications in the field of medicine and 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 quality and safety 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 and have access to appropriate training and development. 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, other regulators and partner clinics.

Staff (Guidance note 2)
Information received from the centre indicates 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. The centre does have access to a nominated registered scientist, within the UK, to advise on and oversee scientific activities.

The proposed Licence Holder is suitably qualified and experienced to undertake the role.

What the centre could do better
Nothing identified.

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 assessment.

Safeguarding
The centre will not treat patients therefore this area of practice is not relevant to this assessment.

What the centre could do better
Nothing identified.

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)** These requirements are not relevant to the centre's proposed activities.
What the centre could do better Nothing identified.

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 applicable to this assessment.

What the centre could do better
Nothing identified.

Treating donors fairly

Counselling
Egg and sperm sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating donors fairly (Guidance note 29)
This will remain the responsibility of the 'supplying' centres therefore this area of practice is not relevant to this assessment.

Patient support (Guidance note 3)
This will remain the responsibility of the 'supplying' centres therefore this area of practice is not relevant to this assessment.

Counselling (Guidance note 3)
The centre will not treat patients, the primary centres will be responsible for making counselling available for patients and prospective donors. Therefore this area of practice is not relevant to this assessment.

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
These requirements are not relevant to the centre's proposed activities.

Surrogacy (Guidance note 14)
These requirements are not relevant to the centre's proposed activities.

Complaints (Guidance note 28)
The centre's proposed procedures are compliant with HFEA requirements to seek client ('supplying' 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 proposed 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.

Information

What the centre does well

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

What the centre could do better
Nothing identified.

Consent and Disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5;6)
It is important to ensure that patients and donors have provided all relevant consents before carrying out any licensed activity.

This centre will not be obtaining consent from patients or donors therefore this area of practice is not applicable to this assessment. The 'supplying' centres will be responsible for ensuring valid and effective consent is in place from the gamete provider(s) prior to donation, procurement and storage. This centre will retain a copy of all donor and patient consents and undertake regular audits to ensure that the samples are being stored according to the gamete provider's consent.

Legal parenthood (Guidance note 6)
The centre will not treat patients therefore this area of practice is not applicable to this assessment.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre will not be required to submit any patient or donor identifying information to the HFEA Register as this will be the responsibility of the 'supplying' centres. Therefore this area of practice is not applicable to this inspection.

What the centre could do better
Nothing identified.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well
These requirements are not relevant to the centre's proposed activities.

What the centre could do better
Nothing identified.

Screening of patients
Storage of gametes

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 'supplying' centres will be responsible for undertaking screening of gamete providers prior to procurement and storage. This centre's proposed procedures for ensuring that gamete providers have been appropriately screened prior to accepting the cryopreserved material for storage is compliant with HFEA requirements.

Storage of gametes (Guidance note 17)
The centre's proposed procedures for storing gametes are compliant with HFEA requirements and will ensure that gametes will be stored appropriately to maintain their quality and safety.

The 'supplying' centres will be responsible for ensuring valid and effective consent is in place prior to gamete donation and storage. The PR has confirmed that the 'supplying' centres will retain responsibility for management of a 'bring forward' system to ensure that samples are only stored in accordance with the gamete provider's consent.

What the centre could do better
Nothing identified.

Use of embryos for training staff (Guidance note 22)

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 applicable to this assessment.

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

4. Information management

Record keeping Obligations and reporting requirements
What the centre does well **Record keeping and document control (Guidance note 31)** The centre's proposed procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care. **Obligations and reporting requirements (Guidance note 32; Direction 0005)** The centre's proposed procedures for submitting information about the receipt and distribution of gametes 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.

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 are given, as well as the timescales in which these improvements should be carried out.

Critical area of non-compliance

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

Area of practice and reference	Action required and timescale	PR Response	Executive Review
None noted.			

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 represent a major area of non-compliance.

Area of practice and reference	Action required and timescale	PR Response	Executive Review
None noted.			

‘Other’ areas of practice that require improvement

An ‘other’ area 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 constitutes a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale	PR Response	Executive Review
None noted.			

Further response from the Person Responsible to this inspection report
Dear Louise and Karen, Thank you for this report - we look forward to being fully licensed and able to collaborate further with both the HFEA and the clinical units we will be working with. Best wishes Sharon