Inspection report on compliance with HTA licensing standards
Inspection dates: 16 and 21 June 2022

Royal Free Hospital

HTA licensing number 12406

Licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)
and
Licensed under the Human Tissue Act 2004

Licensable activities carried out by the establishment
Licensed activities – Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)
'E' = Establishment is licensed to carry out this activity and is currently carrying it out.
'E*' = Establishment is licensed to carry out this activity but is not currently carrying it out.
'SLA' = Service level agreement; the establishment is licensed for this activity but another HTA-licensed establishment carries out the activity on their behalf.

Site	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Royal Free Hospital	E*		E/SLA	E	E		

Tissue types authorised for licensed activities

Authorised = Establishment is authorised to carry out this activity and is currently carrying it out.
Authorised* = Establishment is authorised to carry out this activity but is not currently carrying it out.

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Cardiovascular, Vessels; Other Vessels	Authorised*		Authorised	Authorised	Authorised		

Licensed activities – Human Tissue Act 2004
The establishment is licensed for the storage of relevant material which has come from a human body for use for a scheduled purpose but is not carrying out this activity.

Summary of inspection findings
The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that the Royal Free Hospital (the establishment) had met many of the HTA's standards that were assessed during the inspection, four major and six minor shortfalls were found against standards for Governance and Quality, and Premises, Facilities and Equipment.

Six of the shortfalls (four major and two minors) relate to findings from the last inspection. The HTA is concerned that adequate steps were not taken to address these findings in the intervening period and to embed suitable practices at the establishment. A similar issue was identified in 2019 regarding shortfalls from the inspection conducted in 2017.

Concerns were discussed with the establishment as part of this inspection, the current DI has provided assurance that key personnel have been appointed to manage the activities under the licence and that the establishment is committed to meeting the regulatory requirements. Based on this assurance, the HTA has 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. However, in light

of the establishment's lack of progress with addressing shortfalls from previous inspections, the HTA will consider the need for regulatory action if appropriate action is not taken to meet the regulatory requirements in accordance with the timeframes detailed in Appendix 2.

Compliance with HTA standards

Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) standards

Major shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.	Although the establishment has a documented check for verifying that the correct accompanying paperwork is present with the vessels, the establishment does not document receipt checks, such as the integrity of the pots and labelling of the vessels. During the inspection, it was identified that the current version of the vessel log does not allow the establishment to capture the full panel of mandatory serology testing results. Recent vessel logs were incomplete, and vessel transfer forms were incorrectly completed. There is a risk of vessels being released from quarantine before verification is completed and recorded, or vessels not being released under concession. The HTA raised this issue as a major shortfall at the last inspection, however it has not yet been fully addressed.	**Major**
i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.		

GQ2 There is a documented system of quality management and audit.		
a) There is a quality management system which ensures continuous and systematic improvement.	The HTA raised a major shortfall against internal audits at the last inspection due to audits being limited in scope and not being undertaken in accordance with the predefined schedule. The establishment has completed a number of internal audits which are presented in annual audit reports. Multiple non-compliances were identified from different audit topics, and data is presented in such a way that makes it difficult to determine the root cause of any issues identified. Corrective and preventative action plans with completion deadlines are not put in place following audits to ensure continuous and systematic improvement within the quality management system. As a result of this, there are ongoing issues which have not been resolved from previous annual audits.	**Major**
b) There is an internal audit system for all licensable activities.		

GQ4 There is a systematic and planned approach to the management of records.		
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.	The establishment's quality manual states that equipment maintenance and service records are retained for the lifetime of the equipment plus two years. This is not aligned with the regulatory requirement to retain raw data for 10 years after the use, expiry date or disposal of tissues and/or cells. In addition to this, the quality manual states that traceability records will be held for 30 years from the time of initial entry. It does not explicitly require the establishment to retain these records for 30 years from the use, expiry date or disposal of tissues and/or cells. The HTA closed this same shortfall from the last inspection based on the establishment's assurance that the quality manual had been updated to reflect the regulatory requirements. However, it was identified during this inspection that this document had not been updated.	**Major**
i) The minimum data to ensure traceability from donor to recipient as required by Directions 001/2021 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.		

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.		
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.	The establishment currently records a daily spot check of the vessel fridge temperature using the display on the fridge. Although the establishment confirmed that the area is manned 24-hours a day, regular omissions of data were seen in the temperature records, sometimes up to five consecutive days. The current process does not provide adequate assurance that vessels have been stored within the required temperature range prior to release. The HTA raised a minor shortfall against the storage environment for vessels at the last inspection. This was closed based on the establishment's assurance that a continuous temperature monitoring system had been put in place which would allow the temperature to be monitored electronically, and any excursions would trigger alerts and notify the relevant staff. However, the establishment confirmed during this inspection that the continuous temperature monitoring system was not being used.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.	During the inspection, it was identified that some of the procedures did not reflect current practice. For example, the establishment described taking a copy of the vessel transfer form and securing the transport box with a cable tie prior to distribution, but these instructions are not included in the current standard operating procedure (SOP). A similar issue was identified at the last inspection, and it appears that the establishment's procedures have not all been updated to reflect current practice.	**Minor**
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 001/2021.	The establishment was unable to provide a copy of the agreement with the testing laboratory at the last inspection; this was raised as a minor shortfall. Although the agreement was subsequently provided, it does not meet the requirements set out in Directions 001/2021. For example, the agreement does not include the reporting requirements for serious adverse events. *See advice item 2, below.*	**Minor**

GQ2 There is a documented system of quality management and audit.		
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.	An independent audit was completed one day before the site visit inspection. The audit was limited in scope and whilst it included a brief review of the establishment's procedures, there was insufficient evidence to demonstrate that it was carried out against all of the applicable HTA standards.	**Minor**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.		
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.	The establishment confirmed that personnel are trained in tasks relevant to their work. However, their competency was not recorded on the competency forms created by the establishment. In one example, the Persons Designated (PD) training had been recorded, however the content of the training was not sufficiently described.	**Minor**

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.		
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 001/2021.	The establishment uses an external laboratory for confirmatory testing for mandatory infectious disease markers such as HTLV, HIV and HBsAg. However, the establishment was unable to provide assurance that the external laboratory is working in accordance with the requirements of Directions 001/2021.	**Minor**

GQ7 There are systems to ensure that all adverse events are investigated promptly.		
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.	The current SOP for serious adverse events and reactions (SAEARs) reporting does not set out the establishment's responsibilities for reporting incidents within 24-hours of discovery, or what to do in the absence of the DI. There is also a reference to staff working under Post Mortem licences using this SOP, despite the fact that incidents in the Post Mortem sector are reported through a different pathway. Similarly, the Quality Manual does not clearly delineate the SAEARs reporting pathways between the Organ, Donation and Transplantation sector and the Human Application sector.	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

Advice

The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	GQ1c, GQ2a	The DI is advised to add target completion dates for any actions raised during governance meetings, and ensure these are reviewed at the next meeting to drive continuous and systematic improvement. The DI is further advised to ensure minutes of governance meetings are written up and circulated in a timely manner and put a system in place so that any immediate actions agreed during meetings are shared with colleagues who were unable to attend.
2.	GQ1r, GQ4h	The wording of the agreement with the testing laboratory is such that the regulatory requirement for the retention of raw data would no longer be met after 2022. The DI is advised to update the agreement to

		ensure the laboratory meets the regulatory requirements to retain raw data for 10 years after the use, expiry date or disposal of tissues and/or cells.
3.	GQ4b	Examples of overwriting, scribbling out of records and sections being left blank were seen on some of the establishment's records. The DI is advised to provide training on Good Documentation Practice to the relevant members of staff.
4.	GQ4k	The DI is advised to consider strengthening the wording of end user agreements to ensure that the vessel transfer forms are completed by the end users and returned to the establishment in a timely manner.
5.	GQ3e, GQ7a	The establishment described an event where the vessel fridge alarm was activated, however this was not recorded in the establishment's internal incidents. As this event was not reported, there was limited information to understand what happened. The DI is advised to provide training on incident reporting and include as much detail in the reports as possible so that it is clear what happened and document whether there was any impact on the quality and safety of the vessels in storage at the time. The establishment has recently appointed a new DI and PDs under the licence. The DI and PDs are advised to sign up to the HTA portal, and familiarise themselves with how to report a SAEAR.
6.	GQ8a	The establishment currently transcribes paper records into electronic format for the temperature and vessel logs. The DI is advised to risk assess whether transcription errors may be introduced during this practice, and introduce risk mitigating steps, if necessary.
7.	PFE2a, PFE5k	The DI is advised to update the relevant SOP to include how to segregate quarantine vessels from cleared for release vessels in the event that the contingency fridge is required to minimise the risk of vessels being mixed-up.
8.	PFE5a	The DI is advised to challenge the vessel fridge alarm on a regular basis to ensure the systems are fully functioning and that relevant members of staff respond appropriately. These challenges and responses should be documented within the establishment's governance system.

Background
The establishment has been licensed by the HTA since March 2007. This was the establishment's eighth inspection; the last inspection took place in December 2019.

At the time of this inspection, two major shortfalls and one minor shortfall were still unmet from the previous inspection. A number of shortfalls from the previous inspection were closed based on the establishment's assurance that the agreed actions had been completed. However, it became apparent that these actions were not followed through; these shortfalls have been reflected in the findings above.

The establishment has recently appointed a new DI and LH. There have been no other significant changes to the activities carried out under the licence since the previous inspection.

Description of inspection activities undertaken
The HTA's regulatory requirements are set out in Appendix 1. The following areas were covered during the inspection:

The inspection team carried out a site visit followed by a virtual regulatory assessment (VRA). The site visit took place at the Royal Free Hospital in the theatres where the vessel fridge is located. The inspection team also visited the Ophthalmology department where the establishment proposes to store amniotic membrane in the future; the HTA is awaiting further information from the establishment before this activity can commence.

Traceability audits were carried out for two vessels in storage at the time of inspection. Records related to the receipt and serological testing were reviewed. Some of the recent vessel logs were reviewed prior to this inspection by the previous inspector as this was part of an open shortfall from the last inspection. Therefore, it was only possible to carry out a limited traceability audit for recently received vessels and the last two distribution events (*see major shortfall GQ1g and GQ1i*).

The inspection was facilitated by the DI, who is a Consultant in Hepato-Pancreatic-Biliary (HPB) surgery and Organ Retrieval and Liver Transplant Surgeon, the Head of Quality and Licensing (PD), Transplant Coordinator (PD), Theatre Senior Sister (PD), Lead Nurse in HPB, and an Organ Perfusion Practitioner. The inspection team also held discussions with an Associate Professor in Infection regarding the testing activities, and the Consultant Ophthalmologist involved in the end use of amniotic membrane.

Some of the policies, procedures and documents relating to the licensable activities were reviewed prior to the inspection by the inspection team. A review of documentation was also carried out on-site which included records relating to equipment servicing, vessel fridge temperatures, staff training and competency, and agreements.

Round table discussions with the establishment's staff covered topics such as training and competency, record management, risk assessments, governance meetings, agreements, reported incidents, recall, change controls and audits.

Report sent to DI for factual accuracy: 19 July 2022

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 05 August 2022

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 8 March 2023

Appendix 1: The HTA's regulatory requirements

The HTA must assure itself that the DI, Licence Holder, premises and practices are suitable.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as ‘Critical’, ‘Major’ or ‘Minor’. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the Human Tissue Act 2004, Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended), or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant direct risk of causing harm to a recipient patient or to a living donor,

   or

   A number of ‘major’ shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered ‘critical’.

   A critical shortfall may result in one or more of the following:

   - A notice of proposal being issued to revoke the licence
   - Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall.

A shortfall in the carrying out of licensable activities which poses an indirect risk to the safety of a donor or a recipient

or

A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the safety of a donor or a recipient;

or

A shortfall which indicates a major deviation from the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) or the HTA Directions;

or

A shortfall which indicates a failure to carry out satisfactory procedures for the release of tissues and cells or a failure on the part of the designated individual to fulfil his or her legal duties;

or

A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall by adversely affecting the quality and safety of the tissues and cells.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

A shortfall which cannot be classified as either critical or major and, which can be addressed by further development by the establishment.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk-based review or at the time of the next on-site inspection.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with the final inspection report. Establishments must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.

Appendix 3: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Human Tissue (Quality and Safety for Human Application) Regulations 2007 Standards (as amended)

Governance and Quality

Standard
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.
i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
j) There are procedures detailing the critical materials and reagents used and where applicable, materials and reagents meet the standards laid down by the Medical Devices Regulation 2002 (SI 2002 618, as amended) (UK MDR 2002) and United Kingdom Conformity Assessed (UKCA).

k) There is a procedure for handling returned products.
m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 001/2021.
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
t) There are procedures for the re-provision of service in an emergency.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.
b) There are orientation and induction programmes for new staff.
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.

d) There is annual documented mandatory training (e.g. health and safety and fire).
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
h) There is a system of staff appraisal.
i) Where appropriate, staff are registered with a professional or statutory body.
j) There are training and reference manuals available.
k) The establishment is sufficiently staffed to carry out its activities.
GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.
c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.
e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
f) There are procedures to ensure that donor documentation, as specified by Directions 001/2021, is collected and maintained.

g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 001/2021.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 001/2021 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 001/2021.
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 001/2021.
d) There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.
e) Testing of donor samples is carried out using UKCA or CE marked diagnostic tests, in line with the requirements set out in Directions 001/2021.
f) Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.

b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
e) In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall.
f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken.
g) Establishments distributing tissue and / or cells provide information to end users on how to report a serious adverse event or reaction and have agreements with them specifying that they will report these events or reactions.
h) Establishments distributing tissues and / or cells have systems to receive notifications of serious adverse events and reactions from end users and notify the HTA.
GQ8 Risk assessments of the establishment’s practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.

b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
e) There are procedures to ensure that the premises are secure, and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.

b) There are systems to deal with emergencies on a 24-hour basis.
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
a) There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 001/2021.
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.
d) Records are kept of transportation and delivery.
e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.
i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions 001/2021.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions 001/2021.
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
b) Critical equipment is maintained and serviced in accordance with the manufacturer’s instructions.
c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.

d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly, and this is recorded.
h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.
i) Staff are aware of how to report an equipment problem.
j) For each critical process, the materials, equipment and personnel are identified and documented.
k) There are contingency plans for equipment failure.

Disposal

Standard
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.
a) The disposal policy complies with HTA's Codes of Practice.
b) The disposal procedure complies with Health and Safety recommendations.
c) There is a documented procedure on disposal which ensures that there is no cross contamination.
D2 The reasons for disposal and the methods used are carefully documented.
a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal.
b) Disposal arrangements reflect (where applicable) the consent given for disposal.

Human Tissue Act 2004 standards

Consent

Standard
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice.
b) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice.
c) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice.
d) Written information is provided to those from whom consent is sought, which reflects the requirements of the HT Act and the HTA's Codes of Practice.
e) Language translations are available when appropriate.
f) Information is available in formats appropriate to the situation.
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent
a) There is suitable training and support of staff involved in seeking consent, which addresses the requirements of the HT Act and the HTA's Codes of Practice.
b) Records demonstrate up-to-date staff training.
c) Competency is assessed and maintained.

Governance and Quality

Standard

GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.
b) There is a document control system.
c) There are change control mechanisms for the implementation of new operational procedures.
d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff.
e) There is a system for managing complaints.
GQ2 There is a documented system of audit
a) There is a documented schedule of audits covering licensable activities.
b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills
a) Qualifications of staff and all training are recorded, records showing attendance at training.
b) There are documented induction training programmes for new staff.
c) Training provisions include those for visiting staff.
d) Staff have appraisals and personal development plans.
GQ4 There is a systematic and planned approach to the management of records
a) There are suitable systems for the creation, review, amendment, retention and destruction of records.
b) There are provisions for back-up / recovery in the event of loss of records.

c) Systems ensure data protection, confidentiality and public disclosure (whistleblowing).
GQ5 There are systems to ensure that all adverse events are investigated promptly
a) Staff are instructed in how to use incident reporting systems.
b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made.
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.
b) Risk assessments are reviewed regularly.
c) Staff can access risk assessments and are made aware of risks during training.

Traceability

Standard
T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail
a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it.
b) A register of donated material, and the associated products where relevant, is maintained.
c) An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom.
d) A system is in place to ensure that traceability of relevant material is maintained during transport.
e) Records of transportation and delivery are kept.

f) Records of any agreements with courier or transport companies are kept.
g) Records of any agreements with recipients of relevant material are kept.
T2 Bodies and human tissue are disposed of in an appropriate manner
a) Disposal is carried out in accordance with the HTA's Codes of Practice.
b) The date, reason for disposal and the method used are documented.

Premises, facilities and equipment

Standard
PFE1 The premises are secure and fit for purpose
a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose.
b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained.
c) There are documented cleaning and decontamination procedures.
PFE2 There are appropriate facilities for the storage of bodies and human tissue
a) There is sufficient storage capacity.
b) Where relevant, storage arrangements ensure the dignity of the deceased.
c) Storage conditions are monitored, recorded and acted on when required.
d) There are documented contingency plans in place in case of failure in storage area.
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored
a) Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept.
b) Users have access to instructions for equipment and are aware of how to report an equipment problem.

c) Staff are provided with suitable personal protective equipment.