Inspection report on compliance with HTA licensing standards
Inspection dates: **12 and 13 June 2024**

Royal Hallamshire Hospital

HTA licensing number 11030

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

Licensable activities carried out by the establishment

'E' = Establishment is licensed to carry out this activity and is currently carrying it out.

Site	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Royal Hallamshire Hospital	E		E	E	E		E
Satellite **Northern General Hospital**	E		E	E	E		

Tissue types authorised for licensed activities

Authorised = Establishment is authorised to carry out this activity and is currently carrying it out.

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Musculoskeletal, Bone; Bone	Authorised		Authorised	Authorised	Authorised		
Musculoskeletal, Cartilage; Cartilage (ATMP)	Authorised		Authorised		Authorised		Authorised
Musculoskeletal, Tendon & Ligament; Tendons				Authorised			

ATMP – Advanced Therapy Medicinal Product

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 Royal Hallamshire Hospital (the establishment) had met the majority of the HTA's standards that were assessed during the inspection, nine minor shortfalls were found against standards for Consent, Governance and Quality, and Premises, Facilities and Equipment. Following the inspection and prior to the publication of the final report, the establishment submitted evidence to the HTA that one of the shortfalls identified had been addressed.

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.

Compliance with HTA standards

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
C2 Information about the consent process is provided and in a variety of formats.		
a) The procedure on obtaining consent details what information will be provided to donors. As a minimum, the information specified by Directions 001/2021 is included.	The patient information and consent forms relating to chondrocyte and femoral head procurement do not include details of all the disease marker tests that will be performed.	**Minor**

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, instances where the establishment's standard operating procedures (SOPs) do not reflect current practice at the establishment were identified. For example: • The establishment's femoral head procurement SOP states that femoral heads must be frozen within three hours of procurement and if this is not the case, to re-swab the tissue for microbial contaminants. There is no validation data supporting these actions. However, these actions are not the establishment's current practice and therefore the establishment's approach to freezing of femoral heads is not aligned with the SOP. • The establishment's SOP governing the removal of femoral heads from storage for end use states that femoral heads can be removed and if not used within an hour, returned to the freezer for future use. This is not the establishment's current practice. • The establishment's receipt of tissue SOP includes reference to previous practices at the establishment, such as the use of a database which is no longer used. • The donor testing SOP does not include the timelines for when chondrocyte donors must undergo blood draw for serological testing.	**Minor**

GQ2 There is a documented system of quality management and audit.		
b) There is an internal audit system for all licensable activities.	The establishment's internal audit system does not include a review of raw data generated within the testing laboratory, such as temperature records.	**Minor**
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.	A review of temperature monitoring records for the storage area in the testing laboratory where agar microbial plates are stored and serological testing blood samples may be stored overnight found that there were gaps in the data as a result of the electronic monitoring system losing its connection.	**Minor**

<table>
<tr><th colspan="3">GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.</th></tr>
<tr><td>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.</td><td rowspan="3">An instance was identified where three chondrocyte donors did not undergo HTLV serological testing in accordance with the establishment’s procedures.

The treating clinician tested one of the donors for HTLV post donation and another clinician assessed the two remaining donors’ medical and social histories to determine if HTLV testing would have been required; they concluded that the tests would not have been needed.

The establishment had not reported these incidents through its incident reporting system and processes.

The establishment submitted sufficient evidence to address this shortfall before the report was finalised.</td><td rowspan="3">Minor

Fully Met</td></tr>
<tr><td>GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.</td></tr>
<tr><td>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.</td></tr>
</table>

GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.		
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.	During the 2022 HTA inspection an issue with temperature monitoring was identified and was subject to a corrective and preventative action (CAPA) plan. During the 2024 inspection, a review of the temperature monitoring data for the period between the identification of the shortfall and the implementation of the corrective and preventative action identified further periodic losses of data. Although the CAPA plan addresses the loss of data though a new electronic monitoring system, these further losses of data had not been reported through the establishment's incident reporting system, nor had a risk assessment of any potential impact of the stored tissue been documented.	**Minor**
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.	An ambient storage room in the testing laboratory that is used to store broth for microbiological analysis exceeded the maximum storage temperature for these consumables for an extended period between November 2022 and August 2023. This temperature excursion had not been identified by the establishment or laboratory staff.	**Minor**

PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.		
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.	The establishment undertook a validation of the transport box used to transport femoral heads between the hub and satellite site. This same box may also be used to distribute tissue to other local establishments for end use. Establishment procedures state that the box can be used for transport periods of up to 40 minutes. However, the establishment's validation exercise was for only 20 minutes meaning that the documents do not reflect the validated transport period or that the validated transport period is too short.	**Minor**
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.	At the time of the inspection, the establishment's temperature monitoring probes had not been serviced and calibrated within the correct timeframe. Additionally, the establishment's testing laboratory was not able to provide a calibration certificate for one of the temperature monitoring probes used in the laboratory storage areas.	**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.	GQ4(h)	The establishment's testing laboratory is considering the installation of new automated temperature monitoring equipment. The DI is advised to assure themselves that historic data on the current system remains accessible for the required 10 year period after use, expiry or disposal of tissue.
2.	GQ4(k)	The establishment no longer allows tissue to be returned from end users. However, the end user agreements currently state that tissue can be returned. The DI is advised to update and re-issue the end user agreements so that they reflect current practice. The DI is also advised to include a reminder to end users that tissue may not be stored by an end user for more than 48 hours without an appropriate HTA licence being in place.
3.	GQ5(a)	The establishment's donor exclusion criteria meet the requirements of the Regulations. The DI is about to undertake a review of the wording of the establishments exclusion criteria and the donor lifestyle questions. The DI is advised to ensure that the donor exclusion criteria as they are set out in Annex A of the Guide to Quality and Safety Assurance of Human Tissues and Cells for Patient Treatment are reflected appropriately in the new documents. In addition, the DI is advised to create a document containing all of the donor exclusion criteria so that donor responses to the questions can be recorded and maintained in the donor files. Finally, the DI is advised to revise the section of the donor form that records if any contra-indications to donation have been identified. Currently, this section is left blank if no contra-indications are identified. However, the DI is advised to require this field to be completed stating that there are no contra-

		indications so that an unintentionally blank field cannot be mistaken as meaning that there are no contra-indications to donation.
4.	GQ6(c)	The DI is advised to update the external tissue tracking sheet in the same way that the internal tracking sheets have been updated so that it includes space to add a recipient addressograph label to the sheet which may help with traceability of tissues.
5.	GQ7(a) & GQ8(b)	The DI is advised to undertake risk assessments more frequently when investigating incidents in addition to investigating and putting in place measures to mitigate the risk of reoccurrence. This may support the incident investigation process and look at wider areas of activity relating to minor incidents.
6.	PFE3(a)	The establishment's testing laboratory undertakes a manual temperature measurement as a back-up to the electronic system. The establishment is advised to record maximum and minimum temperatures rather than a single record from the time of measurement for the back-up records so that if they were used, any deviations from the expected range would be identified. Separately and in addition, the establishment has recently implemented a new electronic temperature monitoring system in the areas where tissues, reagents and consumables are stored. The DI is advised to find out how long data will be stored for each probe in the event that a probe losses its connection with the base station. This will help the DI to determine if there may have been a loss of data should any of the probes loose their connection.
7.	PFE3(a)	The establishment maintains procurement kits at the satellite premises for staff to use even though procurement only very rarely occurs at this location. An ambient store room is used to store Hartman's solution which is used to rinse procured tissue. The temperature of the storage room can become high and therefore, the DI is advised to consider storing a small stock of the Hartman's solution in the freezer room which is actively cooled with air-conditioning. This may mean that the risk of the Hartman's solution exceeding its maximum storage temperature would be reduced.

8.	PFE5(a)	The DI is advised to continue with their plans to temperature-map the establishment's freezers.
9.	PFE5(c)	The establishment undertakes planned alarm tests and also records alarm events caused through re-stocking or cleaning. In addition to this, the DI is advised to undertake alarm tests outside of normal working hours to assure themselves that alarms are responded to as expected. The DI is also advised to review and update as necessary the list of contacts that switchboard use when responding to temperature excursion alarms out of hours.

Background

The establishment procures femoral heads from hip replacement patients and stores these for allogeneic end use in other orthopaedic procedures. The establishment also procures chondrocytes which are then exported for manufacture into an ATMP. In addition, the establishment may purchase other orthopaedic tissues from other HTA-licensed establishments for end use in specified surgeries.

The establishment has been licensed by the HTA since October 2008. This was the establishment's eighth inspection; the last inspection took place in June 2022.

There have been no significant changes to the licence arrangements or 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:

Review of governance documentation

Various governance documents and related items were reviewed during the inspection. These included staff training records, temperature monitoring records relating to the stored tissues, consumables and reagents, transport box validation, and equipment

maintenance records. SOPs relating to donor selection and testing, procurement, receipt of purchased tissue, transport and returning bone to the freezer were also reviewed in addition to a discussion taking place with a member of staff responsible for donor selection and seeking consent. Further discussions also took place with establishment staff regarding four incidents, their investigation and any corrective or preventative actions put in place following the investigations. Discussions were held regarding the internal audit of chondrocyte procurement. The most recent independent audit carried out by a non-tissue bank member of staff was reviewed. Governance meetings and general escalation of any issues were also discussed. Finally, agreements with the ATMP manufacturer and an example of an end user agreement were also reviewed.

Visual inspection

The inspection included visits to both the hub and satellite sites. At each of these premises, all areas where tissue is receipted and stored were visited which included reviews of maintenance dates as attached to the freezers by the engineer. Areas where all consumables and reagents used in licensable activity were also visited. Finally, the testing laboratory used by the establishment was visited during the inspection of the satellite premises.

Audit of records

During the inspection records relating to three femoral head procurements, four chondrocyte procurements and one purchased tissue were reviewed. The review included records such as:

- Femoral Heads - donor consent, procurement records including items coming into contact with the tissue, testing results from procurement and 180 day re-testing, microbiological sterility testing results and issue paperwork.
- Chondrocytes - donor consent, ATMP manufacturer serology results, establishment’s HTLV serological testing results, and records of no contraindications for donation confirmation.
- Purchased tissue - Tissue ID and storage location changes.

Meetings with establishment staff

Meetings with various establishment staff, including the DI, took place throughout the inspection.

Report sent to DI for factual accuracy: 19 July 2024

Report returned from DI: 30 July 2024

Final report issued: 29 August 2024

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: 3 February 2025

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)

Consent

Standard
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act), the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) and as set out in the HTA's Codes of Practice.
a) If the establishment acts as a procurer of tissues and / or cells, there is an established process for acquiring donor consent which meets the requirements of the HT Act 2004 the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) and the HTA's Codes of Practice.
b) If there is a third-party procuring tissues and / or cells on behalf of the establishment the third-party agreement ensures that consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) and the HTA's Codes of Practice.
c) The establishment or the third party's procedure on obtaining donor consent includes how potential donors are identified and who is able to take consent.
d) Consent forms comply with the HTA Codes of Practice.
e) Completed consent forms are included in records and are made accessible to those using or releasing tissue and / or cells for a Scheduled Purpose.

C2 Information about the consent process is provided and in a variety of formats.
a) The procedure on obtaining consent details what information will be provided to donors. As a minimum, the information specified by Directions 001/2021 is included.
b) If third parties act as procurers of tissues and / or cells, the third-party agreement details what information will be provided to donors. As a minimum, the information specified by Directions 001/2021 is included.
c) Information is available in suitable formats and there is access to independent interpreters when required.
d) There are procedures to ensure that information is provided to the donor or donor's family by trained personnel.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.
a) Staff involved in obtaining consent are provided with training on how to take informed consent in accordance with the requirements of the HT Act 2004 and Code of Practice on Consent.
b) Training records are kept demonstrating attendance at training on consent.

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.
e) There are procedures for tissue and / or cell procurement, which ensure the safety of living donors.
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.
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
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.
j) Records are kept of products and material coming into contact with the 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 is in place to ensure raw data and records of traceability are maintained for 10 or 30 years respectively, as required.
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 001/2021.
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.
c) In cases other than autologous donors, donor selection is carried out by authorised personnel and signed and reviewed by a qualified health professional.
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.
d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

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.
b) Where processing of tissues and / or cells involves exposure to the environment, it occurs in an appropriate, monitored environment as required by Directions 001/2021.
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.
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
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.
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
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.
g) Instruments and devices used for procurement are sterile, validated and regularly maintained.
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.