Inspection report on compliance with HTA licensing standards
Inspection dates: **16-18 and 20 September 2024**

Robert Jones and Agnes Hunt Orthopaedic Hospital

HTA licensing number 11064

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.
'TPA' = Third party agreement; the establishment is licensed for this activity but another establishment (not licensed by the HTA) carries out the activity on their behalf.

Site	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Robert Jones and Agnes Hunt Orthopaedic Hospital	E		TPA	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			
Musculoskeletal, Tendon & Ligament; Tendons				Authorised			
Other, Bone Marrow (ATMP)	Authorised*		Authorised*				
Other, Cartilage (ATMP)	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.

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 Robert Jones and Agnes Hunt Orthopaedic Hospital (the establishment) had met many of the HTA's standards that were assessed during the inspection, one major and eight minor shortfalls were found against standards for Governance and Quality, and Premises, Facilities and Equipment. In addition to this, four minor shortfalls were identified against standards relating to

the storage of relevant material under the Human Tissue Act 2004 (HT Act). These shortfalls were against standards for Governance and Quality, and Premises, Facilities and Equipment.

At the time of the inspection, it was determined that the establishment had stored meniscus outside of the authorisations in place for the licence. The licence has subsequently been updated and the HTA will consider this breach of regulatory requirements outside the scope of this report.

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

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

Major Shortfalls

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.	The establishment's questionnaire used to gather relevant medical and social history information from femoral head donors requires updating to ensure that donors are robustly guided to note deferral criteria specified by Directions 001/2021, as set out in Annex A of the HTA's 'Guide to Quality and Safety Assurance of Human Tissues and Cells for Patient Treatment'. For example: • to gather information about a donor's travel history so that the potential risk can be assessed by a suitable expert, rather than requiring the donor to self-identify whether they have visited a high-	**Major**

	risk area; • to identify whether the donor has received grafts of cornea, sclera and dura mater; and, • to identify if the donor has been prescribed immunosuppressive medication that could affect the quality and safety of the graft or invalidate the mandatory serological assays undertaken as part of the donation process.	

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.		
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.	Mandatory serological testing is undertaken by a third party laboratory. Requirements within the establishment's current rolling agreement with the laboratory for raw data retention and the reporting of adverse events are not aligned with the requirements set out in Directions 001/2021. In addition to this, the establishment has not been able to provide a suitable agreement with the third party testing laboratory that undertakes confirmatory testing for the primary testing laboratory.	**Minor**
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.		
GQ2 There is a documented system of quality management and audit.		
b) There is an internal audit system for all licensable activities.	Internal audit reports, such as the 'HTA pre inspection check' of activities relating to cartilage procurement, do not capture sufficient detail about what was reviewed for each standard, to provide assurance that all licensable activities are subject to a regular programme of audit.	**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 has a comprehensive training record in place to record staff training in bone bank activities. However, the current system does not clearly define the minimum training requirement for each task and which elements must be supervised or witnessed prior to staff being authorised to undertake the task independently. During the inspection, examples were identified in which staff did not follow the establishment's documented procedures relating to femoral head procurement during a period when the Bone Bank Manager was absent. Incidents were also reviewed that arose from staff not following documented procedures for the management of serology samples. Related	**Minor**

	to this, the establishment does not have a system in place to document staff reading of procedures relevant to their tasks under the licence.	
k) The establishment is sufficiently staffed to carry out its activities.	Activities within the establishment's bone bank are managed and overseen on a day-to-day basis by the Bone Bank Manager, who undertakes the role on a part time basis two days per week, alongside other responsibilities that are not related to the bone bank. Many of the shortfalls identified during this inspection point to a lack of protected time and resource for the management and oversight of bone bank activities. Contingency arrangements during a period of planned staff absence were insufficient and resulted in a loss of traceability of bone procured under the licence, as described in the finding against standards GQ4a and f, below. Scheduled bone bank daily, weekly and monthly duties are frequently missed on days when the Bone Bank Manager is not available or focused on other tasks.	**Minor**
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.	The establishment occasionally exports cartilage to a third party for the manufacture of an autologous Advanced Therapy Medicinal Product (ATMP). In two examples that were reviewed during the inspection, it was identified that the establishment did not retain copies of the procurement records if the ATMP product was not successfully manufactured, although copies could be retrieved from the manufacturer. In addition to this, whilst preparing requested records in advance of the inspection, the establishment identified a small number of cases where records associated with femoral head procurement had not been retained.	**Minor**
f) There are procedures to ensure that donor documentation, as specified by Directions 001/2021, is collected and maintained.		

	Whilst this was identified and addressed through the establishment's incidents systems, it highlighted a lack of suitable staff to oversee licensable activities in the bone bank in the absence of the Bone Bank Manager.	
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 undertakes environmental monitoring during the preparation of reagents used in cartilage procurement. However, printouts from the non-viable particle monitors on thermal printer paper are not routinely photocopied to ensure the data is retained for the duration required by Directions 001/2021.	**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's approach to the management of samples collected for mandatory serological testing, including those collected in the community at least 180 days after femoral head donation, has not been reviewed to ensure that it is aligned with the requirements set out in the relevant test kit inserts. In addition to this, the establishment has collected samples for mandatory serological testing in relation to autologous cartilage procurement the day before procurement, rather than on the day or up to seven days after procurement, as required by Directions 001/2021.	**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	During the inspection, examples were identified where storage areas were not continuously monitored to ensure any deviations from required ranges	**Minor**

taken to minimise risk of damage, theft or contamination.	could be identified and suitable actions taken. Examples included: • areas where broth bottles and swabs used to undertake sterility testing during femoral head procurement are stored prior to use; and, • refrigerators used to store media used during the procurement of cartilage as an ATMP starting material.	

Human Tissue Act 2004 standards

Standard	Inspection findings	Level of shortfall
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.	During the inspection, it was found that research tissue bank (RTB) standard operating procedures (SOPs) did not always contain sufficient procedural details for staff or reflect all current practices. The establishment confirmed that several SOPs had passed their review period without being reviewed due to staff resourcing issues. Examples where RTB SOPs required updating to provide further guidance to staff included: • to provide detailed instructions to staff on responding to out of hours alarms from temperature monitoring systems;	**Minor**

	• to formalise a procedure for challenging alarm systems, such as for temperature monitoring and liquid nitrogen systems, ensuring staff respond in a timely manner; and, • to align with establishment practice, such as in relation to the minimum age of donors from whom tissue stored within the Biobank will be procured.	
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits covering licensable activities.	Although an audit of tissue stored under the licence was undertaken shortly before the inspection, prior to this, stocks had not been audited for several years.	**Minor**
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.	The establishment did not have risk assessments in place covering all aspects of tissue storage under the HT Act. For example, the establishment has not provided a risk assessment covering the risks: • associated with tissue being stored in areas accessible to staff who do not work under the licence; • associated with the storage of tissue samples prior to retrospective consent being sought from donors; and • applicable to tissue stored in liquid nitrogen, such as insufficient liquid nitrogen supply, or failure to respond to alarms.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue		

c) Storage conditions are monitored, recorded and acted on when required.	Temperature probes used to monitor critical storage environments were out of calibration at the time of the inspection.	**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 – activities under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)

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

Number	Standard	Advice
1.	General	The DI is advised to update the licence to remove procurement and testing of bone marrow (ATMP) as this activity is no longer undertaken under the licence.
2.	GQ1b	The DI is advised to update the establishment's Quality Manual to reference the governance arrangements in place for cartilage procurement and associated donor testing undertaken under the licence in relation to the hospital's own ATMP manufacturing process.
3.	GQ1j	The DI is advised to implement a process to regularly review the use of a research grade reagent during the procurement of cartilage for ATMP manufacture to determine if an appropriate clinical grade reagent has become available.
4.	GQ2b	The DI is advised to review audit schedules to ensure all aspects of activities under the licence, including those undertaken by third parties, are scheduled for review. The DI is further advised to develop a

		checklist for the audit of activities at the testing laboratory so that the pathway of sterility and serology samples from receipt at the laboratory to the reporting of results is reviewed, and this review can be evidenced. This audit should include associated reviews of records such as equipment maintenance records, temperature records, and training records.
5.	GQ3k	In addressing the shortfall under standard GQ3k, the DI is advised to review the suitability of current reporting structures to ensure activities within the bone bank are appropriately resourced and to support the Bone Bank Manager in escalating issues and implementing agreed changes relevant to activities under the licence.
6.	GQ4j	During the inspection it was identified that the establishment had not recorded the lot number of heparin coming into contact with tissues and cells during bone marrow procurement. The relevant trial has now ceased. The DI is advised to undertake a review to ensure that all consumables and reagents coming into contact with tissues and cells that may be used in human application are documented.
7.	GQ5d	The establishment occasionally procures and exports cartilage as a starting material for an ATMP manufactured by a third party. Both parties undertake serological testing for mandatory serological markers, although only the establishment undertakes testing for markers of HTLV infection. The DI is advised to implement a procedure for the documented review of results provided by the third party manufacturer, to ensure that any differences in the results held by either party are identified and investigated in a timely manner.

Advice – activities under the Human Tissue Act 2004

Number	Standard	Advice
8.	GQ1d	Whilst activities falling within the scope of the establishment's human application sector licence are discussed in regular meetings, it was confirmed that there have been no regular meetings to discuss issues around the RTB. Currently, activities related to the RTB have halted due to the lack of ethical approval, but the DI is advised to ensure that matters related to the RTB are regularly discussed, and to ensure that regular meetings resume once activities have restarted.
9.	GQ3a	The DI is advised to review staffing arrangements in place for activities under the HT Act to ensure there is sufficient resource available to support the necessary governance and oversight required under the regulatory framework. For example, the RTB hosted under the licence is located in the pathology unit. At the time of inspection there were several vacant staff positions resulting in limited trained staff available to oversee the RTB. During a period of staff absence the ethical approval for the RTB lapsed, RTB related SOPs were not reviewed in line with establishment policies, and SOPs were not updated to reflect current practices. Additional trained staff in the unit would support the oversight of activities, and act as a contingency during staff absences.
10.	T1c	The establishment maintains a number of traceability spreadsheets for the tracking of samples stored under the HT Act, which may each need to be updated to reflect, for example, the disposal of a tissue sample. The DI is advised to review current systems giving consideration to whether a consolidation of information captured in different spreadsheets would simplify the process and minimise a risk that information held in different spreadsheets may become inconsistent over time.
11.	PFE3a	During the inspection a freezer used to store samples under the HT Act was found to contain a build up of ice. The DI is advised to review maintenance schedules to ensure all freezer locations are listed and subject to routine de-icing, and to record these de-icing activities within the establishment's records.

12.	PFE2c	The DI is advised to add signs to each freezer used to store tissue under the licence to ensure the contents and required temperature range are clear to staff who are responsible for the oversight of stored samples, and for responding to alarms.
13.	NA	The DI is advised to remove or update expired copies of the establishment's licence that were on display in the research freezer storage area.

Background

The Robert Jones and Agnes Hunt Orthopaedic Hospital operates a bone bank and a cellular therapy unit which is jointly regulated by the HTA and the Medicines and Healthcare products Regulatory Agency (MHRA) as a manufacturer of ATMPs. In addition to being licensed for procurement, testing, and storage under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended), the establishment is licensed for the storage of relevant material for a scheduled purpose under the Human Tissue Act 2004 (HT Act).

Whilst the majority of samples stored for research have project-specific approval from recognised research ethics committees (RECs), the establishment also maintains a research tissue bank (RTB) storing relevant material under the HT Act. Samples in the RTB are primarily obtained from patients undergoing treatment at the hospital, and the establishment had ethical approval to retrospectively seek consent for samples that had been collected for diagnostic use. At the time of inspection the ethical approval had lapsed and the establishment had made the decision to halt the service, with no tissue being provided for research purposes. Samples stored for research use are stored at -80°C, in vapour phase liquid nitrogen (LN2), and at ambient temperatures.

The establishment has been licensed by the HTA since August 2006. This was the establishment's nineth inspection; the last inspection took place in July 2022.

Since the last inspection, the role of Designated Individual (DI) has transferred to a new post holder, who is a Consultant Orthopaedic Surgeon. The establishment has also been authorised to undertake the licensable activity of Export to enable the export of cartilage as a starting material for the manufacture of an ATMP. The establishment is no longer undertaking procurement of bone marrow for ATMP manufacture; the last procurement events took place in 2023.

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

The inspection included a review of procedural documents relating to licensed activities, equipment servicing and maintenance records, audits, risk assessments, reported incidents, meeting minutes, temperature monitoring for the storage units, and staff training records. The review of records associated with premises and equipment in the ATMP manufacturing facility was limited on this occasion as the inspection coincided with an MHRA inspection of the same facility.

Visual inspection

The inspection team undertook a review of the premises where tissue stored under the licence is procured, received, and stored. The pathway for serology samples collected for mandatory testing was reviewed, and areas used to store reagents and consumables were visited. In addition to this, the inspection team visited the third party testing laboratory that undertakes sterility and serological testing on behalf of the establishment.

The inspection included a review of various areas within the premises where the establishment stores relevant material under the HT Act, including research laboratories and the liquid nitrogen storage area.

Audit of records

Records were reviewed for three femoral head procurements, one bone marrow aspirate procurement and seven cartilage procurements.

In addition to the records for material stored for human application, records associated with nine different samples stored under the HT Act were also reviewed as part of a traceability audit. This included a physical check of samples stored at the establishment, and a review of both paper-based and electronic records for samples stored for specific projects and samples stored in the RTB.

Meetings with establishment staff
The inspection team met with the DI and Persons Designated undertaking human application and research activities under the licence. The team also met with representatives of the third party testing laboratory.

Report sent to DI for factual accuracy: 07 November 2024

Report returned from DI: 21 November 2024

Final report issued: 28 January 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.
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.
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.
d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results.
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.
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.

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.
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.
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.

g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.
i) Primary 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) Consent forms are available to those using or releasing relevant material for a scheduled purpose.
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.