Inspection report on compliance with HTA licensing standards
Inspection dates: **21 and 23 September 2022**

BioVault

HTA licensing number 11063

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.
'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
BioVault	TPA	E	TPA	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.
Authorised* = Establishment is authorised to carry out this activity but is not currently carrying it out.

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Progenitor Cell, Haematopoietic, Bone Marrow; Bone Marrow		Authorised*		Authorised	Authorised*		
Progenitor Cell, Haematopoietic, PBSC; PBSC		Authorised		Authorised	Authorised		
Mature Cell, MNC; DLI		Authorised		Authorised	Authorised		
Progenitor Cell, Hematopoietic, Cord Blood; Cord Blood	Authorised	Authorised	Authorised	Authorised	Authorised	Authorised	Authorised
Umbilical Cord; Cord Tissue	Authorised	Authorised	Authorised	Authorised	Authorised	Authorised	Authorised
Musculoskeletal, Bone; Bone				Authorised	Authorised	Authorised	
Membrane, Fascia				Authorised	Authorised	Authorised	

Lata; Fascia Lata							
Musculoskeletal, Tendon & Ligament; Ligament						Authorised	
Musculoskeletal, Tendon & Ligament; Tendon				Authorised	Authorised	Authorised	
Musculoskeletal, Tendon & Ligament; Menisci						Authorised	
Musculoskeletal, Cartilage; Cartilage				Authorised	Authorised	Authorised	
Musculoskeletal, Bone; Cancellous Bone Particles				Authorised	Authorised	Authorised	
Skin						Authorised	
Musculoskeletal, Bone; DBM						Authorised	
Acellular bone						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 BioVault (the establishment) had met many of the HTA's standards that were assessed during the inspection, six major and five minor shortfalls were found against standards for Governance and Quality, and Premises, Facilities and Equipment.

The number and recurrent nature of the shortfalls identified during this site visit inspection is of concern to the HTA. Four shortfalls have been classified as major to reflect this and to ensure that the establishment takes immediate action to introduce and embed suitable practices for the conduct of the licensable activities.

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

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.		
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.	During the establishment's previous inspection in 2020, a shortfall was identified relating to the testing of UCB and UCT donors carried out by a third party on behalf of the establishment. The shortfall was closed on the basis of evidence submitted to the HTA indicating that documented procedures had been updated to address it. However, these procedures were not issued until the day before the current inspection took place. Instead, previous versions of these procedures, which did not contain the necessary updates had been re-issued. In addition to the above, the establishment uses an electronic spreadsheet to determine levels of cell recovery achieved during processing. This spreadsheet was not included in the establishment's document control system to ensure that the inputs are managed, protected, backed up and the formulae and functions produce accurate results.	**Major**

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.	Establishment procedures set out that in the event of a positive serology test result on the maternal blood sample, the sample must be retested. If the result of the second test is positive or conflicting, the procured tissue and cells will be designated as a biohazard and identified as such in the establishment's records and at the point of product release. In addition to this, the establishment's procedures set out that the establishment will request a new maternal sample for testing or require the client to arrange their own re-test and share the results. During the inspection an example was identified where the result of a serology test mandated under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) was positive. In this example, the establishment did not follow their own procedures for the management of positive serology results. In addition to this, the establishment did not seek expert advice to assure themselves that the testing algorithm used was appropriate, that the conclusions drawn from all the available results were robust and that no further testing was required to allow the sample to be stored in the clean storage tanks.	**Major**
n) The establishment ensures imports from third countries meet the standards of quality and safety set out in Directions 001/2021.	At the establishment's last inspection it was determined that one of the third country suppliers (3CSs) that aseptically processes tissue products did not meet requisite air particle monitoring requirements at rest and in operation. The shortfall was closed in 2021 on the establishment's assurance that, among other corrective actions, they would also undertake a risk assessment for tissue that had been aseptically processed prior to the	**Major**

	implementation of the necessary air particle monitoring procedures and that were still in storage or had already been distributed to end users. At the time of the current inspection the establishment was unable to provide this risk assessment for review. Further to the above, the environmental monitoring carried out by another 3CS that aseptically processes tissue products imported by the establishment for end use, also does not meet the requisite air particle monitoring requirements. This is a recurrent issue that was identified on the previous inspection and the classification of this finding as a major shortfall reflects this.	
GQ4 There is a systematic and planned approach to the management 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.	During the review of the donor records an example was identified where time and temperature deviations during the transport of UCB and UCT to the establishment for processing had not been identified and documented in accordance with the establishment's procedures, nor had the units been marked for concessionary release. The establishment's receipt checks and audits are not sufficiently robust to identify tissue products received that do not meet required specifications. This is a recurrent issue that was identified during the previous inspection and it has not yet been fully addressed. The classification of the finding as a major shortfall reflects this.	**Major**

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 has previously undertaken validation work to demonstrate that serology test kits are reliable when used to analyse blood samples that had been exposed to high temperatures and / or extended shipping times of up to five days in transit. The shortfall was closed in February 2022 on the basis that for samples received outside of the validated testing kit parameters a new maternal blood sample would be requested within seven days of procurement. Also, as part of the validation work the establishment moved to the use of an alternative syphilis testing kit, which was proven to be more reliable for the testing of samples transported under the establishment's transport parameters. During the inspection two examples were identified where the UCB, UCT and maternal bloods for serological testing arrived at the establishment after being in transit for longer than five days. However, no additional maternal blood samples were requested to provide adequate assurance that the test results obtained using these samples were valid. In addition, an example was identified where a UCB unit and associated serology sample had been exposed to high temperatures during transit. The serology sample was tested using the previous syphilis test. The UCB unit was reviewed at the time of receipt and was marked for concessionary release. However, at the point of release to the end user there was no consideration of the reliability of the test results and whether any repeat testing was required.	**Major**

PFE2 Environmental controls are in place to avoid potential contamination.		
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.	The establishment does not carry out monitoring for fungal contaminants in the grade A environment during the processing of tissues and cells. In addition, since the last inspection the frequency of environmental monitoring was not carried out in accordance with the establishment's procedures. Examples were identified where quarterly air sampling at rest in the background, operator finger dabs, monthly operational particle counts, staff gowning validations and annual staff gowning validations, were missed. Although the establishment raised and documented these incidents, it did not implement effective corrective actions in order to prevent a recurrence.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 001/2021.	Although the establishment has an agreement with another licensed establishment for the mandatory serological testing of the maternal bloods this does not clearly set out the responsibilities of each party for the carrying out of this activity or for reporting of SAEARs within 24 hours of discovery.	**Minor**
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.	Although the establishment undertakes internal audits these do not include a review of raw data, such as temperature monitoring records and sessional environmental monitoring records.	**Minor**

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.	The establishment's procedures set out that on release of a UCB unit for end use a CD34 assay with an additional colony forming unit-granulocyte monocyte (CFU-GM) assay will be carried out, if required, to ensure the tissue quality and safety. However, these procedures do not clearly set out the parameters that will trigger the establishment to undertake a CFU-GM assay.	**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.	During the inspection several examples were identified where the temperature monitoring system issued an alarm. Although the alarms were acknowledged, staff at the establishment did not review records to identify that these events had resulted in the loss of temperature monitoring raw data.	**Minor**
GQ7 There are systems to ensure that all adverse events are investigated promptly.		
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.	The establishment's recall procedure sets out that an annual simulated recall will be held to ensure all staff properly undertake this procedure. There has not been an annual simulation exercise carried out since the last 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

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

Number	Standard	Advice
1.	GQ2a PFE2b	The establishment is considering downgrading one of its cleanroom areas to Grade D whilst deciding how to best use it for other projects. The DI is advised to document this through a formal change control process.
2.	GQ2c	The DI is advised to document the donor files and raw data reviewed as part of the establishment's independent audit and the combined vertical audit that is undertaken as a collaboration between the establishment and another licensed establishment for whom cells are processed in a dedicated area of the establishment's cleanroom suite.
3.	PFE2c	The DI is advised to review the form that captures the establishment's daily and monthly checks to ensure it remains suitable and is adhered to.

4.	PFE4a	The DI is advised to review the procedure on product issue and distribution and the related form, to ensure that as part of the checks carried out prior to releasing UCB or UCT establishment staff also carry out a review of the relevant raw data in addition to the summary data.
5.	PFE5a	The DI is advised to implement a 'return to use' form for equipment that has undergone maintenance. The DI is further advised to include within the form a checkbox to prompt staff to ensure that service records provided by maintenance contractors are properly stored within the establishment's governance systems rather than within individual staff email accounts.
6.	N/A	The establishment will be winding down UCB and UCT processing in the coming months. However, new processing activities may arise. The DI is advised to consider any staffing and licensing implications as part of the decision-making process to introduce new activities or add new tissue products under the licence. The DI is also advised to update the relevant procedures and risk assessments to reflect this decision-making.

Background

BioVault is licensed for procurement, processing, storage, testing, distribution, import and export of UCB and UCT. In the coming months the establishment will cease procurement, testing and processing activities associated with these tissue types but retain the activities of storage, distribution and export.

The establishment also provides a processing service for peripheral blood stem cells (PBSCs), bone marrow (BM) and peripheral blood lymphocytes for donor lymphocyte infusion (DLI), which have been procured under another establishment's HTA licence. PBSCs, BM and DLIs are processed by Biomedical Scientists from the second establishment under an agreement with BioVault. The establishment also currently imports several tissue products from two 3CS for end use in the UK, some of which are received and stored at the establishment's premises prior to release for end use.

Since the previous inspection there has been a change to the CLHc and changes to the establishment's 3CSs. There have been no other significant changes to the licence arrangements or the activities carried out under the licence.

The establishment has been licensed by the HTA since July 2006. This was the establishment's eighth inspection; the last inspection took place in March 2020.

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

A review of selected documentation relevant to the establishment's licensable activities and quality management system was undertaken, including a review of policies and procedural documents, temperature monitoring records, environmental monitoring records, audits, maintenance records, risk assessments, agreements and incident records.

Visual inspection

A review of the facilities was conducted at the establishment, including areas where receipt, processing and storage of the tissue products takes place.

Audit of records

Representative records were reviewed. These included:

- a review of records relating to six UCB and associated UCT samples from six clients. Two of these procurement events took place in the UK and four took place overseas. These records included documents related to consent; receipt and acceptance checks; processing, including environmental monitoring; donor testing; storage; end use; and disposal, where applicable. Additionally the inspection team reviewed an example of a letter sent to a client in an instance where there were conflicting serology testing results;

- the processing records of a femoral head, a meniscus, two tendons and a dermis product from both 3CSs. These records included documents relating to donor consent, mandatory serology and sterility testing, environmental monitoring or terminal sterilisation certificates, and certificates of donor eligibility, as appropriate;
- a traceability audit of a tendon product currently in -80°C storage and deemed suitable for release to end-users; and,
- a traceability audit of three imported bone products currently in storage at room temperature.

Meetings with establishment staff
Discussions were held with the establishment's DI, the Chief Executive Officer, the Technical Manager and the Laboratory Supervisor.

The establishment is also licensed for the storage of relevant material for use in a Scheduled Purpose. This activity was not reviewed as part of this inspection.

Report sent to DI for factual accuracy: 2022-11-10

Report returned from DI: 2022-11-25

Final report issued: 2023-01-23

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 HT Act 2004, 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.
n) The establishment ensures imports from third countries meet the standards of quality and safety set out in Directions 001/2021.

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.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 001/2021.
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
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.

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.