Licence application report on compliance with HTA licensing standards
Assessment: **28 June 2023**

BioDock

HTA licensing number 22714

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

and

Application for a licence under the Human Tissue Act 2004

Licensable activities applied to be carried out by the establishment
'E' = Establishment applied to be licensed to carry out this activity and will carry it out.

Site	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Hub BioDock Nottingham Science and Technology Park				**E**	**E**		
Satellite BioDock – Harrimans Court				**E**	**E**		

Tissue types applied to be authorised for licensed activities

Applied to be authorised = Establishment to be authorised to carry out this activity and will carry it out.

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Progenitor Cell, Haematopoeitic, Cord Blood; Cord Blood				Applied to be authorised	Applied to be authorised		
Other; Cord Tissue				Applied to be authorised	Applied to be authorised		
Other; Dental Pulp				Applied to be authorised	Applied to be authorised		
Progenitor Cell, Hematopoietic; Peripheral Blood Stem Cells (PBSC)				Applied to be authorised	Applied to be authorised		
Progenitor Cell, Haematopoietic, Bone Marrow; Bone Marrow				Applied to be authorised	Applied to be authorised		
Mature Cell, T Cell (DLI) ; DLI*				Applied to be authorised	Applied to be authorised		

*DLI **-** donor lymphocytes for infusion

Licensed activities – Human Tissue Act 2004

Applied to be authorised = Establishment to be authorised to carry out this activity and will carry it out.

Area	Storage of relevant material which has come from a human body for use for a scheduled purpose
Hub **BioDock** **Nottingham Science and Technology Park**	Applied to be licensed
Satellite **BioDock – Harrimans Court**	Applied to be licensed

Summary of assessment findings

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

Although the HTA found that BioDock (the establishment) had met the majority of the HTA's standards, four minor shortfalls were found against standards for Governance and Quality, and Premises, Facilities and Equipment under the standards related to the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended). An additional six minor shortfalls were found against the standards assessed for activities that will be carried out under the Human Tissue Act 2004. The shortfalls were against standards for Consent, Governance and Quality, Traceability, and Premises, Facilities and Equipment.

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 application assessment.

Compliance with HTA standards

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

Minor Shortfalls

Standard	Assessment Finding	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.	The establishment's standard operating procedures (SOPs) do not contain sufficient detail to fully describe the processes that they relate to. For example: - The receipt procedure does not detail what action will be taken if on receipt it is discovered that samples have leaked indicating a thawing event in transit. - The disposal policy does not detail how the samples will be disposed of. - The Quarantine Procedure SOP does not detail whether clients are asked if samples are positive for microbial contamination nor how, if accepted, such samples will be handled.	**Minor**

Standard	Assessment Finding	Level of shortfall
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.	The establishment's risk assessments are limited in scope and do not cover all practices and processes relating to the quality and safety of the tissues.	**Minor**

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.	The establishment has not undertaken a premises risk assessment.	**Minor**

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.		
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.	The temperature monitoring SOP does not stipulate the upper and lower temperature limits, provide detail on how to challenge / test the alarms, or how to respond to an alarm out of normal business hours	**Minor**

Human Tissue Act 2004 standards

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in 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.	The establishment does not seek assurance that consent is in place for samples to be stored under the licence.	**Minor**

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.	The establishment's SOPs do not contain sufficient detail to fully describe the processes that they relate to. For example: - Does not describe limitations such as how long the relevant material may be stored for a scheduled purpose or ensure that the samples were collected under an appropriate licence or ethical approval. - The disposal policy does not detail how samples will be disposed of, or what information will be recorded. - Whilst the SOP for disposal of a sample explains how to locate samples for destruction, it does not provide detail on how to undertake the physical destruction of the sample.	**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's risk assessments do not cover all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.	**Minor**

T2 Bodies and human tissue are disposed of in an appropriate manner

b) The date, reason for disposal and the method used are documented.	The SOP for the disposal of samples does not require the date, reason for disposal and the method used to be documented.	**Minor**

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.	The establishment has not carried out an appropriate risk assessment of the premises.	**Minor**

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.	The temperature monitoring SOP does not stipulate the upper and lower temperature limits, provide detail on how to challenge / test the alarms, or how to respond to an alarm out of normal business hours	**Minor**

Advice

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

Number	Standard	Advice
1.	GQ2(a)	The proposed DI is advised to develop a separate quality manual to reflect the new licensing arrangements.
2.	GQ2(r)	The proposed DI is advised to ensure that any tissue and cells stored for human application are received from establishments that hold a current human application licence and are licensed for the range of tissues and cells to be stored.

		The DI is advised to implement a procedure to inform the HTA of any unlicensed establishments that request storage of tissues and cells for human application.
3.	GQ1(a) Human Tissue Act Standards	Prior to receiving any samples for storage, the establishment receives a completed and authorised declaration form indicating the type of storage required and specifying storage requirements for each sample type to be stored. As part of the site visit, examples of completed declaration forms were reviewed for samples that will be transferred to the establishment's HTA licence should it be approved. The proposed DI is advised to review the declarations to ensure that there is no ambiguity in the questions asked on the form. For example, the form should clearly ask if: - The relevant material to be stored needs to be held under a HTA licence. - Appropriate consent is in place to store the samples for a scheduled purpose. - There are any limitations on the storage and / or release of the relevant material. Currently the form asks the client to specify how long the material should be initially stored. It does not ask how long the donor has consented for the relevant material to be stored.
4.	GQ2(a) Human Tissue Act Standards	The proposed DI is advised to increase the scope of audits undertaken to ensure that they cover activities related to relevant material stored for a scheduled purpose. In addition, the proposed DI is advised to include horizontal process audits to ensure that SOPs accurately reflect practices and to identify areas for improvement.
5.	T1(c) Human Tissue Act Standards	The proposed DI is advised to implement a process for recording any limitations on storage and use of cells, and to record the end date of any approvals from recognised Research Ethics Committee (rREC) approved studies. This will help ensure that, if the future relevant material is returned to the client or a third party for storage, assurance is sought that the receiving establishment holds an appropriate HTA licence.

6.	N/A	Tissue and cells may be returned to clients. The proposed DI is advised to review the list of personnel authorised to request and receive the tissues or cells to ensure that this list is up to date.

Background

BioDock (the establishment) has applied to be licensed for the storage and distribution of tissue and cells under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended). In addition, the establishment has also applied for a licence under the Human Tissue Act 2004 for the storage of relevant material for use for scheduled purposes.

BioDock is a trading name of Future Health Technologies Ltd and these activities are currently taking place under Future Health Technologies Ltd's HTA licence. BioDock has now applied to be an independent biorepository with a hub and satellite arrangement. All material intended for Human Application will be stored in client-specific liquid nitrogen vessels. The vessels may be provided by the client or supplied by the establishment. All material stored for scheduled purposes will be stored separately and different equipment, such as cryocarts, will be used to handle this material.

Description of activities undertaken during the assessment

The HTA's regulatory requirements are set out in Appendix 1. A desk-based assessment of the documents submitted as part of the licence application was conducted.

Documentation was reviewed relating to the licensable activities. This included procedures, agreements with third parties, and risk assessments.

Visual inspection

The visit included a visual inspection of the hub areas where the establishment proposes to undertake the licensable activity. This comprised the areas where liquid nitrogen tanks containing tissues and cells are housed and the -80◦C freezer room where relevant material is currently being stored. The temperature monitoring and temperature excursion alert systems were reviewed. In addition, service records for temperature probes, validation records for cryoshippers, agreements with courier companies and staff training records

were reviewed.

A visit to the proposed satellite site was also undertaken.

Meetings with establishment staff

The assessment included a meeting with the following staff: proposed DI, general manager and quality manager.

Report sent to proposed DI for factual accuracy: 25 July 2023

Report returned from proposed DI: 16 August 2023 (No factual accuracy or request for redaction comments were made by the DI)

Final report issued: 16 August 2023

Completion of corrective and preventative actions (CAPA) plan

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

Date: 9 April 2024

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 (HA)

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

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

Appendix 3: Human Application Standards

The HTA standards applicable to this establishment are shown below; those not assessed 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

Governance and Quality

Standard
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.

i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
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.
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.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 001/2021.

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.
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.
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.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
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.
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
e) There are procedures to ensure that the premises are secure, and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.

PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24-hour basis.
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
a) There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 001/2021.
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.
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.
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
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.

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.
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.