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

Addenbrooke's Hospital

HTA licensing number 11072

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

'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
Addenbrooke's Hospital			TPA	E	E		

Tissue types authorised for licensed activities

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

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Cardiovascular, Vessels; Other Vessels			Authorised	Authorised	Authorised		
Cardiovascular, Valves; Heart Valves				Authorised*			
Membrane, Amniotic; Amniotic Membrane				Authorised			
Musculoskeletal, Bone; Bone				Authorised			
Musculoskeletal, Cartilage; Cartilage				Authorised			
Musculoskeletal, Tendon &				Authorised			

Ligament; Ligaments							
Musculoskeletal, Tendon & Ligament; Menisci				Authorised			
Neuronal; Nerves				Authorised*			
Skin; Skin				Authorised*			

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 Addenbrooke's Hospital (the establishment) had met the majority of the HTA's standards that were assessed during the inspection, five minor shortfalls were found against standards for Governance and Quality, 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 inspection.

Compliance with HTA standards

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of quality management and audit.		
b) There is an internal audit system for all licensable activities.	The establishment has not undertaken an appropriate audit of the third-party testing laboratory to provide an assurance that testing meets the requirements of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) (Q&S Regs) and Directions 001/2021.	**Minor**
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.	The last independent audit was undertaken in 2019.	**Minor**
GQ4 There is a systematic and planned approach to the management of records.		
k) There are documented agreements with end users to ensure they record and store the data required by Directions 001/2021.	Vessels are sometimes distributed to other establishments. No end user agreements are in place to ensure that these establishments record and store the data required by Directions 001/2021, or report any serious adverse events or reaction associated with the distributed vessels to Addenbrooke's Hospital.	**Minor**

Standard	Inspection findings	Level of shortfall
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.	Serology testing of cadaveric liver donors is conducted under the licensing framework of The Quality and Safety of Organs Intended for Transplantation Regulations 2012, and test results are uploaded to NHSBT's Transplant Path system (previously Electronic Offering System). Vessels that are procured with the liver may be used in the patient who received that liver or could, potentially, be used instead in another recipient. Where vessels, referred to as accessory vessels, are being stored for more than 48 hours for use in a patient other than the recipient of the associated liver, donor serology testing of the donor's blood sample must be performed in accordance with the requirements of the Q&S Regs. The establishment routinely sends blood samples for all donors of accessory vessels for serology testing. During the review of records associated with vessels that had been used clinically, one example was seen where the mandatory serology tests had not been conducted by the testing laboratory.	**Minor**

<table>
<tr><th colspan="3">PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.</th></tr>
<tr><td>a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.</td><td rowspan="3">Serum samples for mandatory serology testing, quality control reagents and test kit consumables are stored in refrigerators at the third-party testing laboratory. The continuous temperature monitoring probes have been out of calibration since 5 December 2023. While the establishment identifies a new supplier for the provision of a continuous temperature monitoring system it has implemented weekly monitoring of each refrigerator. This provides some assurance that, at the time of mapping, the individual unit is within the specified parameters. However, this does not provide an assurance that there have been no temperature deviations between mapping events. The establishment has been unable to provide a risk assessment reflecting the current scenario where the probes for all refrigerators are out of calibration for an extended time.

In addition, serum samples are stored in a specific refrigerator prior to transfer to long-term frozen storage. The refrigerator has frequent temperature excursions both at the upper and lower limits of the pre-defined ranges. These excursions have exceeded the acceptable sporadic readings defined in the third-party laboratory’s “Operation of ‘realtime-online’ Monitoring System” standard operating procedure. Probe buffering has been implemented to reduce the deviations, both in frequency and range, although it has not eliminated them. The laboratory is continuing to refine the probe buffering process. Whilst it has been verbally confirmed that this procedural change is occurring under a change control process, the testing laboratory has been unable to provide any supporting documentation as the final method has not yet been verified.</td><td rowspan="3">Minor</td></tr>
<tr><td>PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.</td></tr>
<tr><td>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.</td></tr>
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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.	GQ4a	Temperature monitoring data for the bone allograft freezers is recorded using wheel charts. The DI is advised to ensure whenever there is a temperature deviation that this is investigated, and the chart annotated.
2.	GQ4b	When correcting errors in documentation, the DI is advised to ensure that staff cross through, initial, and date the error, and do not use correction fluid.
3.	GQ4h	The DI is advised to scan paper records that may be susceptible to loss or fading over time to ensure the data is maintained in line with the requirements for maintaining tissue traceability.
4.	GQ4i	The DI is advised to update the tissue log books to ensure the reader is clear that records of traceability must be retained for 30 years from the use, disposal or expiry of the tissue.
5	GQ6b	To ensure a robust audit trail, the DI is advised to document, in the vessels register, the date and time when vessels are distributed and received by establishments.

		In addition, the DI is advised to put in place a procedure to ensure that establishments receiving vessels are immediately informed of any unexpected donor findings.
6.	PFE3c	Bone allografts are stored in a temperature monitored freezer located near the operating theatre. Although the Cambridge Movement Surgical Hub (CMSH) is staffed 24 hours a day, the establishment is advised to implement a process for periodically challenging the temperature alarm system to ensure that responsible staff respond appropriately and as expected. The alarm for the freezer in CMSH is triggered when the temperature rises to -50°C, whereas in the main hospital the alarm is set at -41°C. Since the same staff will respond to temperature alarms, the DI is advised to standardize the temperature settings to avoid any delays in responding to alarms.
7	N/A	The DI is advised to consider appointing a Person Designated (PD) at the third-party testing laboratory to facilitate both communication with the laboratory and oversight of the licensed testing activity.

Background

The establishment has been licensed by the HTA since October 2006. This was the establishment's eighth inspection; the last inspection took place in April 2022.

Since the previous inspection, a new hub has been built on the Trust's campus to expand the capacity of the hospital's main theatre. This hub, known as the Cambridge Movement Surgical Hub (CMSH), provides additional elective surgery capacity focused on orthopaedic surgery.

Although licensed for the storage of heart valves, skin and nerves, the establishment only requests these tissues for immediate use.

The third-party testing laboratory has had its UKAS accreditation suspended. The Trust has undertaken a risk assessment and taken the decision to continue to use the laboratory to meet clinical needs. The laboratory also conducts serology testing of donors of accessory vessels stored under the Q &S Regs.

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 a selection of 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, audits, maintenance records, risk assessments, staff training records and incidents.

Visual inspection

A visual inspection of areas, including CMSH, where the storage of tissue takes place was undertaken. In addition, a visual inspection of the third-party testing laboratory and its sample, reagent, and consumable storage areas was also undertaken.

Audit of records and other documentation

Relevant records for the tissue types listed below were reviewed in conjunction with establishment staff:

- Three amnion products.
- Three vessels, including one that was marked for disposal.
- One tendon, one frozen irradiated ground bone, one fresh frozen femoral head and one Achilles tendon all stored at the main hospital site.
- One femoral head and one posterior tibialis stored at CMSH.

The records reviewed included log books where the receipt and end use of the bone allografts, amnion and vessels were registered. Where samples were present at the establishment there was a traceability audit both from the physical storage location to records, and vice versa. In addition, for the vessels, records related to testing for the mandatory serological markers and microbiological sterility testing results were reviewed.

Meetings with establishment staff
Discussions were held with establishment staff including the DI, PD for Orthopaedics, the PD and staff for the Eye Clinic/Ophthalmology department, the Compliance Manager, Head of Quality Assurance and Compliance, and a staff member at the third-party testing laboratory. Discussions were held regarding temperature monitoring, equipment maintenance, audit activity and incidents/non-conformances. Three incidents were discussed including investigation findings and any corrective actions put in place to prevent similar incidents in the future.

Report sent to DI for factual accuracy: 18 July 2024

Report returned from DI: 15 August 2024

Final report issued: 16 August 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

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

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

1. **Critical shortfall:**

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

   or

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

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

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

2. Major shortfall:

A non-critical shortfall.

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

or

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

or

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

or

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

or

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

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

3. Minor shortfall:

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

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by

the HTA either by desk-based review or at the time of the next on-site inspection.

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

Follow up actions

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

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

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

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

Appendix 3: HTA standards

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

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

Governance and Quality

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

i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
k) There is a procedure for handling returned products.
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 001/2021.
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
t) There are procedures for the re-provision of service in an emergency.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.

c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.
b) There are orientation and induction programmes for new staff.
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.
d) There is annual documented mandatory training (e.g. health and safety and fire).
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
h) There is a system of staff appraisal.
i) Where appropriate, staff are registered with a professional or statutory body.
j) There are training and reference manuals available.
k) The establishment is sufficiently staffed to carry out its activities.
GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.

b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.
c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.
e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
f) There are procedures to ensure that donor documentation, as specified by Directions 001/2021, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 001/2021.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 001/2021 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
j) Records are kept of products and material coming into contact with the tissues and / or cells.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 001/2021.
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 001/2021.
d) There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.
e) Testing of donor samples is carried out using UKCA or CE marked diagnostic tests, in line with the requirements set out in Directions 001/2021.
f) Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.

c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
e) In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall.
f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken.
g) Establishments distributing tissue and / or cells provide information to end users on how to report a serious adverse event or reaction and have agreements with them specifying that they will report these events or reactions.
h) Establishments distributing tissues and / or cells have systems to receive notifications of serious adverse events and reactions from end users and notify the HTA.
GQ8 Risk assessments of the establishment’s practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
e) There are procedures to ensure that the premises are secure, and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24-hour basis.

c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
a) There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 001/2021.
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.
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.