Site visit inspection report on compliance with HTA minimum standards

Royal Devon and Exeter NHS Foundation Trust

HTA licensing number 11012

Licensed for the

- **procurement, testing, storage and distribution of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007; and**
- **storage of relevant material which has come from a human body for use for a scheduled purpose**

6 July 2016

Summary of inspection findings

The HTA found the Designated Individual, the Licence Holder, and the premises to be suitable in accordance with the requirements of the legislation.

Although the HTA found that Royal Devon and Exeter NHS Foundation Trust (the establishment) had met the majority of the HTA standards, two minor shortfalls were found relating to the requirement for HTLV-1 testing to be performed on donors living in, or originating from, high prevalence areas. and the scope of the independent audits.

Particular examples of good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual 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.

Licensable activities carried out by the establishment

'E' = Establishment is licensed to carry out this activity.

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Bone	**E**		**E**	**E**	**E**		
Tendons				**E**	**E**		
Cartilage/ Chondral tissue	**E**		**E**				

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out at the Exeter Bone Bank which is situated at the Royal Devon and Exeter NHS Foundation Trust. The establishment has been in operation since the late 1980s and has held a licence since 2006. Activities carried out under the licence include procurement, donor testing, storage and distribution of allogeneic and occasionally autologous femoral heads for use at the establishment and distribution under an agreement to a local private hospital. The establishment also undertakes the procurement of chondral tissue as a starting material for an advanced therapy medicinal product (ATMP) that is then used by the establishment to treat damaged knee cartilage by autologous chondrocyte transplant (ACT).

Potential donors for femoral heads are identified from patients undergoing hip surgery and are given literature and a confidential personal medical and behavioral history form to read. If the patient indicates that they still wish to be a donor, staff at the establishment will hold a

further discussion with the patient to ask about previous medical conditions, travel and sexual history and prior receipt of allografts. The identification of potential donors and seeking consent for procurement is performed by one of three members of staff trained to take consent.

Theatre staff make up packs prior to the surgical procedure taking place to use when procuring. These include two unique labels, one to be used on the pot containing the procured femoral head and the second for the patient's clinical notes. A check is carried out to confirm that the patient has consented prior to the procurement of tissue. All paperwork is reviewed using a checklist at the back of the procurement form. A blood sample for mandatory serology screening is taken on the day of procurement. Femoral heads are procured in an operating theatre using aseptic techniques and under the control of an orthopaedic surgeon. Microbiology screening is performed on a bone chip and swab for each procured femoral head at the time of donation. These samples along with the blood sample are analysed at the microbiology laboratory within the establishment.

The procured femoral head is weighed in theatre and placed in a sterile pot which once sealed is then placed in a second outer pot. The outer pot is sealed and a label is affixed to the pot stating for single use only. The label also contains the following information: type of tissue, date of donation, identification number, size in grams and expiry date. Occasionally the procured femoral head may be stored for future autologous use on the donor, in such cases the pot is labelled "for autologous use". For any rhesus positive donors, the status is recorded in the donor's notes and the pots are also labelled. In cases where the recipient is a woman of childbearing age the establishment matches rhesus status, but in the event of status not being known only rhesus negative femoral heads are used. As a precaution to protect against loss of traceability if the label came off the pot, the unique identification number on the label is also written on the side and lid of the pot using a permanent marker. The femoral head is placed in a second outer pot and then placed in a -80°C freezer (A) which is used to store quarantined tissue. Details of the stored tissue are entered into the bone bank log book and femoral heads for autologous use are highlighted in green.

For donors that live locally to the establishment, after 180 days a letter is sent to them and their GP requesting a second blood sample for mandatory serology screening. Donors living further away from the establishment first receive a phone call to determine whether they are happy to proceed and if so, a bio-bottle is sent to the donor to take to their GP. Blood samples taken by the GP are then sent to the establishment for testing via the bio-bottle. Once the results of the second screen are obtained the results are entered onto the relevant paperwork as well as into the establishment's electronic database. The DI will review the serology and microbiology results and if all of the results are negative the femoral head will be removed from quarantine and placed in one of two other -80°C freezers. Freezer B is for the long term storage of Rhesus positive tissue and freezer C for Rhesus negative tissue and tissue marked for autologous use only.

The location of each femoral head is marked on a white board located next to the freezers. The femoral heads are stored on different shelves depending on their size. The contents of all freezers are reviewed monthly and are audited every quarter. Requests for femoral heads are made according to size and the issue of tissue is checked by two people and details of the recipient are entered in the bone bank log. The temperatures of the freezers are displayed digitally and are recorded manually by establishment staff from Monday to Saturday. In addition, for each of the freezers, there is a chart wheel and this is reviewed for any temperature deviations. The freezers are alarmed to the switchboard which will notify the bone bank staff both in and out of hours in the event of a deviation from the required storage temperature. Access to the bone bank is restricted and the freezers are locked.

The establishment also stores tendons and other bone allografts in freezer C; these tissues are supplied by another HTA-licensed establishment. Receipt and end use of these allografts

is also recorded in the bone bank log book and on the whiteboard. Acellular products for end use are also stored by the establishment. As end use storage of these products is not currently licensable the systems used to manage the storage and traceability of such tissues were not reviewed as part of this inspection.

Kits for the procurement of cartilage are obtained from a company based in Germany which is authorized to manufacture autologous chondrocyte transplants (ACT) according to the German Medicines Act. Consent of the patient undergoing cartilage procurement is sought by the treating clinician in day surgery, who provides the patient with relevant information sheets. Procurement of femoral heads is undertaken in orthopaedic theatres equipped with laminar flow. Blood samples are taken at the time of procurement for mandatory serological testing. The inner box for shipping the cartilage biopsy to Germany is placed at -20°C for a minimum of ten hours before use. Cartilage biopsies are placed in transport vials containing liquid culture medium. These vials are stored at between 2°C - 8°C. Immediately following procurement, the blood samples and procured material are transported to Germany in a shipper for testing and processing, respectively. Donors are tested for HIV 1 and 2, Hepatitis B and C and syphilis. On the day of inspection, the establishment started testing all patients for HTLV-1. This testing is undertaken by the microbiology laboratory within the establishment. In the past year the establishment carried out five cartilage procurements.

The establishment is currently participating in a clinical trial for ACT. The ATMP will be manufactured by the same German company. As the same kits are being used in this clinical trial, to differentiate between the two ACT procedures, the shipper for the trial is a silver box and the liquid culture medium is clear. In addition, the register for these procurements is completed on white paper. A blue shipper and red liquid culture medium is used for the routine cartilage procurement. Details of the procurement is recorded on pink paper. To date, chondral tissue has been procured from one patient and the ATMP has been transplanted. Two further patients have been identified as qualifying to participate in the trial.

This was the fifth routine inspection of the establishment. The site visit included a visual inspection of the freezer storage area, the fridge and freezer storage for the ACT kits, a review of the establishment's documentation and roundtable discussions with the bone bank staff and the DI. The audit undertaken during the inspection included consent forms for procurement, testing and records relating to the subsequent use of the femoral heads. In addition, the location of two femoral heads stored in the quarantine freezer and a tendon stored in the release freezer was confirmed. The bone bank register was reviewed for a femoral head that was used and the information checked against the theatre log. Patient records for two chondral procurements, carried out both two weeks prior to and on the day of inspection, were reviewed. No discrepancies were found.

At the time of the inspection, relevant material was not being stored under this licence for use in a scheduled purpose as defined by the Human Tissue Act 2004. Consequently, the establishment's systems relating to the storage and use of such material were not assessed during this inspection.

Inspection findings

The HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

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

Governance and Quality

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 003/2010. 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 003/2010.	During the last inspection it was identified that the establishment's procedures relating to HTLV-1 testing of donors did not meet the requirements of Annex II of Directive 006/17/EC and the HTA's Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment - revised June 2015 which forms the annex to Directions 003/2010. To address this, the establishment implemented HTLV-1 testing for all donors of femoral heads. However, equivalent testing was not implemented for donors of cartilage tissue and alternate arrangements were not put in place to ascertain whether such testing was needed on a case-by-case basis. **Note: two weeks prior to the inspection the establishment risk assessed one patient to determine whether HTLV-1 testing was required. The establishment has subsequently decided to test all ACT patients for HTLV-1. This practice was confirmed on the day of inspection when one patient underwent cartilage procurement and a blood sample was sent for HTLV-1 testing at the Trust's laboratory.**	**Minor**
GQ2 There is a documented system of quality management and audit		
c) Independent audits at least every two years against all applicable HTA standards.	Although the establishment has conducted an independent audit since its last inspection, the scope of this audit did not extend to the activities associated with the procurement of chondral tissue. Consequently, the systems and practices relating to this programme have not been subject to independent audit against applicable HTA standards in the required timeframe.	Minor

Advice

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

No.	Standard	Advice
1.	GQ1b	The DI is advised to revise the relevant standard operating procedures (SOPs) or work instructions (WI) for the following: (i) For receipt of materials SOP, to specify what should be checked when allografts are received. (ii) WI 1, “Retrieving femoral heads”, makes reference to occasional circumstances when the retrieval team may be uncertain that bone may be procured for autologous use until the procedure has commenced. In such cases on advice of the bone bank coordinator, the femoral head is procured and then consent and mandatory testing undertaken once the patient has recovered from the anesthetic. The DI is advised to document, in the SOP, that a blood sample for serology testing must be taken within seven days of the procurement. (iii) WI 9,” Bone bank freezer”, contains details, in the event of a freezer failure, of the procedure of double bagging pots containing bone before transferring them to a working freezer. The DI should consider marking the bags as “not for use” and include this in the SOP. (iv) For WI 3 the title should be amended to read “Exclusion criteria for donors of organ and tissue” rather than “Exclusion criteria of organ and tissue for donors”.
2.	GQ1r	The DI is advised to amend the form supplied with distributed tissues. This should clearly state: (i) the storage restrictions. i.e. tissues should not be stored for more than 48 hours in unlicensed premises. (ii) that any serious adverse events and serious adverse reactions (SAEARS) should be reported to the establishment within 24 hours of discovery.
3.	GQ2b	There are procedures in place to document non-conformances and in some cases the action taken. The DI is advised to ensure that all actions taken are documented and to carry out checks to ensure that the corrective actions put in place are being followed.
4.	GQ4c	The DI is advised to ensure that any written errors should not be covered with correction fluid but instead scored out once, the correction written above and initialled and dated.
5.	GQ7a	The DI is advised to include in the SOP for the reporting of SAEARS, details of how to access the HTA’s online incident reporting portal.
6.	GQ8a	The majority of activities that take place under the licence have been risked addressed and systems have been put in place to mitigate the risks. However, the DI is advised to expand the risk assessments to include freezer failure and ACT-related activities such as checks for media expiry dates.
7.	PFE3b	Prior to accessing the freezer, staff from the bone bank will forewarn staff on the switchboard and then confirm whether the freezer alarm had sounded. The DI is advised to also test the switchboard’s response to unannounced freezer alarms to ensure that the correct notification procedure is being followed.

8.	PFE3b & PFE3c	Although the fridge and freezer used for the ACT activities are monitored this was not captured in an SOP. The DI is advised to document the procedures for fridge and freezer monitoring for the ACT-related activities.
9.	N/A	The DI is advised to ensure that all Persons Designate undertaking the procurement of cartilage tissue have access to the HTA's online incident reporting portal to report any SAEARS.
10.	N/A	During the inspection the DI sought advice about the use of small bone blocks retrieved from the femoral shaft during routine hip replacement surgery. These bone blocks are normally disposed of during surgery. However, surgeons at the establishment have identified these as ideal for spinal procedures. These blocks will be allocated unique identification numbers and bone chips and swabs will be sent for microbiological testing. The DI will ensure that these blocks will undergo the normal screening procedures which all tissues and donors are subject to and that they will be suitably labelled to ensure donor and recipient traceability. The DI has been advised to amend the consent form so that potential donors are fully informed of what is being donated.

Concluding comments

There were a number of good practices observed during the inspection. Even though the DI and the bone bank coordinator were new to their role, the bone bank was well run as evidenced by the commitment to minimize wastage by ensuring that the correct size femoral head is used and the carrying out of regular audits of the bone bank inventory. When a femoral head is used, a letter is sent to inform and thank the donor. An efficient colour coding system was in place to distinguish the two types of cartilage tissue procurements.

Two minor shortfalls were identified during the inspection relating to the absence of donor assessment for HTLV-1 testing and the scope of the independent audits. There are some areas of practice that may benefit from further improvement and the HTA has given advice and guidance to the DI with respect to these.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan 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.

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 shortfall identified during the inspection

Report sent to DI for factual accuracy: 28 July 2016

Report returned from DI: 18 August 2016

Final report issued: 22 August 2016

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: 24 August 2017

Appendix 1: 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

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 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 (Q&S Regulations) 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 Q&S Regulations 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 003/2010 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 003/2010 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.
f) There are procedures for tissue and / or cell procurement, which ensure the dignity of deceased 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 European directives on medical devices and in vitro diagnostic medical devices.
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 non EEA states meet the standards of quality and safety set out in Directions 003/2010.
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 003/2010.
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 003/2010, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 003/2010.
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 003/2010 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 003/2010.
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 003/2010.
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 003/2010.
c) In cases other than autologous donors, donor selection is carried out by authorised personnel and signed and reviewed by a qualified health professional.
d) There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.
e) Testing of donor samples is carried out using CE marked diagnostic tests.
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.
d) Where appropriate, there are procedures to ensure that the premises are of a standard that ensures the dignity of deceased persons.
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 003/2010.
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 003/2010.
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.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions.
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 standards
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
• Consent forms comply with the HTA's Code of Practice • Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose • If the establishment obtains consent, a process is in place for acquiring consent in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Where applicable, there are agreements with third parties to ensure that consent is obtained in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Consent procedures have been ethically approved
C2 Information about the consent process is provided and in a variety of formats
• Standard operating procedures (SOPs) detail the procedure for providing information on consent • Agreements with third parties contain appropriate information • Independent interpreters are available when appropriate • Information is available in suitable formats, appropriate to the situation

- Consent procedures have been ethically approved

C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent

- Standard operating procedures (SOPs) detail the consent process
- Evidence of suitable training of staff involved in seeking consent
- Records demonstrate up-to-date staff training
- Competency is assessed and maintained

Governance and quality system standards

GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process

- Policies and procedures are in place, covering all activities related to the storage of relevant material for research in connection with disorders, or the functioning, of the human body
- Appropriate risk management systems are in place
- Regular governance meetings are held; for example, health and safety and risk management committees, agendas and minutes
- Complaints system

GQ2 There is a documented system of quality management and audit

- A document control system, covering all documented policies and standard operating procedures (SOPs).
- Schedule of audits
- Change control mechanisms for the implementation of new operational procedures

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Qualifications of staff and training are recorded, records showing attendance at training
- Orientation and induction programmes
- Documented training programme, (e.g. health and safety, fire, risk management, infection control), including developmental training
- Training and reference manuals
- Staff appraisal / review records and personal development plans are in place

GQ4 There is a systematic and planned approach to the management of records

- Documented procedures for the creation, amendment, retention and destruction of records
- Regular audit of record content to check for completeness, legibility and accuracy
- Back-up / recovery facility in the event of loss of records
- Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)

GQ5 There are documented procedures for distribution of body parts, tissues or cells

- A process is in place to review the release of relevant material to other organisations
- An agreement is in place between the establishment and the organisation to whom relevant material is supplied regarding the tracking and use of material and eventual disposal or return

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- There is an identification system which assigns a unique code to each donation and to each of the products associated with it
- An audit trail is maintained, which includes details of when and where the relevant material was acquired, the consent obtained, the uses to which the material was put, when the material was transferred and to whom

GQ7 There are systems to ensure that all adverse events are investigated promptly

- Corrective and preventive actions are taken where necessary and improvements in practice are made
- System to receive and distribute national and local information (e.g. HTA communications)

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- Documented risk assessments for all practices and processes
- Risk assessments are reviewed when appropriate
- Staff can access risk assessments and are made aware of local hazards at training

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- A risk assessment has been carried out of the premises to ensure that they are appropriate for the purpose
- Policies in place to review and maintain the safety of staff, authorised visitors and students
- The premises have sufficient space for procedures to be carried out safely and efficiently

- Policies are in place to ensure that the premises are secure and confidentiality is maintained

PFE 2 Environmental controls are in place to avoid potential contamination

- Documented cleaning and decontamination procedures
- Staff are provided with appropriate protective equipment and facilities that minimise risks from contamination
- Appropriate health and safety controls are in place

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

- Relevant material, consumables and records are stored in suitable secure environments and precautions are taken to minimise risk of damage, theft or contamination
- Contingency plans are in place in case of failure in storage area
- Critical storage conditions are monitored and recorded
- System to deal with emergencies on 24 hour basis
- Records indicating where the material is stored in the premises

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- Documented policies and procedures for the appropriate transport of relevant material, including a risk assessment of transportation
- A system is in place to ensure that traceability of relevant material is maintained during transport
- Records of transportation and delivery
- Records are kept of any agreements with recipients of relevant material
- Records are kept of any agreements with courier or transport companies

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Records of calibration, validation and maintenance, including any agreements with maintenance companies
- Users have access to instructions for equipment and receive training in use and maintenance where appropriate
- Staff aware of how to report an equipment problem
- Contingency plan for equipment failure

Disposal Standards
D1 There is a clear and sensitive policy for disposing of human organs and tissue
• Documented disposal policy • Policy is made available to the public • Compliance with health and safety recommendations
D2 The reason for disposal and the methods used are carefully documented
• Standard operating procedures (SOPs) for tracking the disposal of relevant material detail the method and reason for disposal • Where applicable, disposal arrangements reflect specified wishes

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 HT Act 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 shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions,

   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:

(1) A notice of proposal being issued to revoke the licence

(2) 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.

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

(5) 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** or the **HTA Directions**;

or

A shortfall which indicates a breach in the relevant Codes of Practices, the HT Act and other relevant professional and statutory guidelines;

or

A shortfall which indicates a failure to carry out satisfactory procedures 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.

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 both the draft and final inspection report. You 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
- follow up at next desk-based or site-visit inspection.

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