

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

**Licensing standards**



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## Consent

### **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 (as amended) (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 001/2021 is included.
- b. If third parties act as procurers of tissues and / or cells, the third-party agreement details what information will be provided to donors. As a minimum, the information specified by Directions 001/2021 is included.
- c. Information is available in suitable formats and there is access to independent interpreters when required.

- d. There are procedures to ensure that information is provided to the donor or donor's family by trained personnel.

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

- a. Staff involved in obtaining consent are provided with training on how to take informed consent in accordance with the requirements of the HT Act 2004 and Code of Practice on Consent.
- b. Training records are kept demonstrating attendance at training on consent.

## **Governance and Quality**

**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 Medical Devices Regulation 2002 (SI 2002 618, as amended) (UK MDR 2002) and United Kingdom Conformity Assessed (UKCA).
- k. There is a procedure for handling returned products.
- l. There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
- m. The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
- n. The establishment ensures imports from third countries meet the standards of quality and safety set out in Directions 001/2021.
- o. There is a complaints system in place.
- p. There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
- q. There is a record of agreements established with third parties.
- r. Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 001/2021.
- s. Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
- t. There are procedures for the re-provision of service in an emergency.

**GQ2 There is a documented system of quality management and audit.**

- a. There is a quality management system which ensures continuous and systematic improvement.
- b. There is an internal audit system for all licensable activities.
- c. An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.

- d. Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results.

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

- a. There are clearly documented job descriptions for all staff.
- b. There are orientation and induction programmes for new staff.
- c. There are continuous professional development (CPD) plans for staff and attendance at training is recorded.
- d. There is annual documented mandatory training (e.g. health and safety and fire).
- e. Personnel are trained in all tasks relevant to their work and their competence is recorded.
- f. There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
- g. There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
- h. There is a system of staff appraisal.
- i. Where appropriate, staff are registered with a professional or statutory body.
- j. There are training and reference manuals available.
- k. The establishment is sufficiently staffed to carry out its activities.

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

- a. There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
- b. There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.

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

**GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.**

- a. Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 001/2021.
- b. The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 001/2021.

- c. In cases other than autologous donors, donor selection is carried out by authorised personnel and signed and reviewed by a qualified health professional.
- d. There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.
- e. Testing of donor samples is carried out using UKCA or CE marked diagnostic tests, in line with the requirements set out in Directions 001/2021.
- f. Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code.

**GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.**

- a. There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
- b. An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
- c. The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.
- d. The requirements of the Single European Code are adhered to as set out in Directions 001/2021 (Northern Ireland only).

**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**

**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 001/2021.
- c. There are procedures for cleaning and decontamination.
- d. Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.

**PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.**

- a. Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
- b. There are systems to deal with emergencies on a 24-hour basis.
- c. Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
- d. There is a documented, specified maximum storage period for tissues and / or cells.

**PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.**

- a. There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 001/2021.
- b. There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
- c. There is a system to ensure that traceability of tissues and / or cells is maintained during transport.
- d. Records are kept of transportation and delivery.
- e. Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.
- f. There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
- g. Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.
- h. Packaging and containers used for transportation are validated to ensure they are fit for purpose.
- i. Primary packaging containing tissues and / or cells is labelled with the information required by Directions 001/2021.
- j. Shipping packaging containing tissues and / or cells is labelled with the information required by Directions 001/2021.

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

- a. Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
- b. Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.
- c. Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.
- d. New and repaired equipment is validated before use and this is documented.
- e. There are documented agreements with maintenance companies.

- f. Cleaning, disinfection and sanitation of critical equipment is performed regularly, and this is recorded.
- g. Instruments and devices used for procurement are sterile, validated and regularly maintained.
- h. Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.
- i. Staff are aware of how to report an equipment problem.
- j. For each critical process, the materials, equipment and personnel are identified and documented.
- k. There are contingency plans for equipment failure.

## **Disposal**

### **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.