

## HTA's standards for licensed Research establishments

### 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

C2 Information about the consent process is provided and in a variety of formats

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

### 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

GQ2 There is a documented system of quality management and audit

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

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

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

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

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

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

### Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

PFE 2 Environmental controls are in place to avoid potential contamination

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

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

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

### Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

D2 The reason for disposal and the methods used are carefully documented