#  Human Tissue Act – Licensing Standards: Research Sector

| Consent Standards |
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| C1 | Consent is obtained in accordance with the requirements of the Human Tissue Act (2004) and as set out in the HTA’s Codes of Practice |
|  | * Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA’s Codes of Practice
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| * Consent forms are available to those using or releasing relevant material for a scheduled purpose
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| * Where applicable, there are agreements with third parties to ensure consent is obtained in accordance with the requirements of the HT Act and the HTA’s Codes of Practice
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|  | * Written information is provided to those from whom consent is sought, which reflects the requirements of the HT Act and the HTA’s Codes of Practice.
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|  | * Language translations are available when appropriate.
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|  | * Information is available in formats appropriate to the situation.
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| C2 | Staff involved in seeking consent receive training and support in the essential requirement of taking consent |
|  | * There is suitable training and support of staff involved in seeking consent, which addresses the requirement of the HTA Act and the HTA’s Codes of Practice.
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|  | * Records demonstrate up-to-date staff training
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|  | * Competency is assessed and maintained
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| Governance and Quality Systems Standards |
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| GQ1 | All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process |
|  | * Ratified, documented and up to date policies and procedures are in place covering all licensable activities
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| * There is a document control system.
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| * There are change control mechanisms for the implementation of new operational procedures.
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| * Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff.
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| * There is a system for managing complaints.
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| GQ2 | There is a documented system of audit |
|  | * There is a documented schedule of audits covering licensable activities.
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| * Audit findings include who is responsible for follow-up actions and the timeframes for completing these.
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| GQ3 | Staff are appropriately trained in techniques relevant to their work and are continuously updating their skills |
|  | * Qualifications of staff and training are recorded, including records showing attendance at training
 |
| * There are documented induction training programmes for new staff.
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| * Training provisions include those for visiting staff.
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| * Staff have appraisals and personal development plans.
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| GQ4 | There is a systematic and planned approach to the management of records |
|  | * There are suitable systems for the creation, review, amendment, retention and destruction of records.
 |
| * There are provisions for back-up/recovery in the event of loss of records.
 |
| * Systems ensure data protection, confidentiality and public disclosure (whistle-blowing).
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| GQ5 | There are systems to ensure that all adverse events are investigated promptly |
|  | * Staff are instructed in how to use incident reporting system.
 |
| * Effective corrective and preventative actions are taken where necessary and improvements in practice are made.
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| GQ6 | Risk assessments of the establishments practices and processes are completed regularly and are recorded and monitored  |
|  | * There are documented risk assessments for all practices and processes requiring compliance with the HT Act and HTA’s Codes of Practice.
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| * Risk assessments are reviewed regularly.
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| * Staff can access risk assessments and are made aware of risks during training.
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| Traceability |
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| T1 | A coding and records system facilitates the traceability of bodies and human tissue, 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.
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| * A register of donated material, and the associated products where relevant, is maintained.
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| * An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom.
 |
|  | * A system is in place to ensure that traceability of relevant material is maintained during transport.
 |
|  | * Records of transportation and delivery are kept.
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|  | * Records of any agreements with courier or transport companies are kept.
 |
|  | * Records of any agreements with recipients of relevant material are kept.
 |
| T2 | Bodies and human tissue are disposed of in an appropriate manner |
|  | * Disposal is carried out in accordance with the HTA’s Codes of Practice.
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|  | * The date, reason for disposal and method used are documented.
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| Premises, Facilities and Equipment Standards |
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| PFE1 | The premises are secure and fit for purpose |
|  | * An assessment of the premises has been carried out to ensure that they are appropriate for the purpose.
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| * Arrangement are in place to ensure that the premises are secure and confidentiality is maintained.
 |
| * There are documented cleaning and decontamination procedures.
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| PFE2 | There are appropriate facilities for the storage of bodies and human tissue |
|  | * There is sufficient storage capacity.
 |
| * Where relevant, storage arrangements ensure the dignity of the deceased.
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| * Storage conditions are monitored, recorded and acted on when required.
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| * There are documents contingency plans in place in case of failure in storage area.
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| PFE3 | Equipment is appropriate for use, maintained, validated and where appropriate monitored.  |
|  | * Equipment is subject to recommended calibration, validation, maintenance, monitoring and records are kept.
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| * Users have access to instructions for equipment and are aware of how to report an equipment problem.
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| * Staff are provided with suitable personal protective equipment.
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