



Records Management Policy

Document History

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Scope of Records Management Policy

This document provides details of the records management policy for the Biorepository, detailing the policies and procedures in place for the collection, retention, accuracy and destruction of sample records.

Records management:

- Meticulous record keeping is essential. Clear records management and quality management systems must be established and disseminated to personnel involved in HT Act activities.
- The system to manage policies for the creation, retention and destruction of records must be in place together with a system to ensure the accuracy of records.
- Activities must be supported by approved and documented policies and procedures. Standard operating procedures (SOP) must be written, authorised and made available to all personnel under the direction of the DI and, a system of SOP document control established.
- A coding and record system to facilitate the traceability of bodies, body parts, tissue and cells is requisite. Documentation should confirm the basis under which material leaves the Biorepository (for use or destruction).
- Stored human tissue or cells should be coded to enable full tracking of samples as appropriate according to their nature and origin. All samples within the Biorepository must be readily identifiable, and easily traceable.
- It is the responsibility of the Biorepository to ensure that human tissues or cells received are eligible for storage. Where such samples are covered by the HTA, it should be evident that they have the potential for future use, as specified by the protocol and information sheet, and with evidence of appropriate documentation (consent, protocol, ethics opinion, as indicated, and where appropriate as guided by the HTA Codes of Practice: E for Research).
- Clear record systems must be in place to ensure that all adverse events are recorded and actioned as appropriate.
- Provisions for the maintenance of appropriate and secure systems to ensure confidentiality and privacy in the recording, storage and release of data must be in place.
- Recovery plans for computer back-up of files available from information Systems must be implemented.
- All personal information must be stored, handled and disposed of in accordance with the Data Protection Act (1998) and the University of Sheffield Data protection Policies

Further Information:

Human Tissue Authority Code of Practice: E

<https://www.hta.gov.uk/sites/default/files/Code%20E.pdf>

Human Tissue Authority Codes of Practice: Standards and Guidance:

<https://www.hta.gov.uk/sites/default/files/Code%20E%20Research%20Standards%20and%20Guidance.pdf>

Information Commissioner's Office:

<https://ico.org.uk/>

University of Sheffield Policy statement

<https://www.sheffield.ac.uk/govern/data-protection>

Sheffield Teaching Hospitals Data Protection Principles

http://www.sth.nhs.uk/clientfiles/File/dpa_post_pn235.pdf

5. Associated Documents

	Document	Document Reference
1	SOP: Change Control	BIO:SOP:14
2	Change Control form	BIO:FORM:07
3		
4		
5		
6		
7		