Swansea University
Prifysgol Abertawe

R&D
RESEARCH & DEVELOPMENT
Abertawe Bro Morgannwg University Health Board

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol
Abertawe Bro Morgannwg
University Health Board

Human Samples in Research

Management and Retention of Records

Document Identifier		HTA-07-SOP-Management of Records	
AUTHOR	**Name and role**	Dr Lisa Wakeman HTA Governance Officer	
	Signature and date	Signed copy held in ABM UHB R&D Office	
APPROVER	**Name and role**	Professor Catherine Thornton Designated Individual	
	Signature and date	Signed copy held in ABM UHB R&D Office	
EFFECTIVE DATE:	01.05.18	**REVIEW DATE:**	01.05.20

Document History

Version	Review Date	Comment	Replaces	Reviewed by
2.0	21.09.15	Update to front page and footers. Text deletions for obsolete links	1.0	Lisa Wakeman
3.0	01.09.16	Post-licence grant review, amendment from acting designated individual reference; minor text amendments	2.0	Lisa Wakeman
4.0	18.04.18	Amendments to reflect revised HTA Codes of Practice and Standards. Amendments to reference to updated NHS guidance on records management	3.0	Lisa Wakeman

1. Purpose

It is essential that accurate and complete records of the collection, use, storage and disposal of human tissue are kept to comply with the licensing requirements of the Human Tissue Authority (HTA). Principal Investigators (PIs) and custodians of human tissue collections must ensure that their holdings are fully documented. The HTA require detailed annual submission of holdings of tissue held under a licence and HRA Research Ethics Committee approval which will be facilitated by robust record keeping. Regular audits of record content to check for completeness and accuracy of records should be undertaken and will form part of the Swansea University/Abertawe Bro Morgannwg University Health Board (ABM UHB) HTA audit schedule for collections held under the joint HTA licence. Where records of personal data and/or biological samples are involved, researchers should take into account data protection legislation and the terms of consent obtained for their use and retention.

The purpose of this Standard Operating Procedure (SOP) is to guide staff and students involved in research covered by the Human Tissue Act 2004 (HT Act) in understanding the requirement for, and use of robust procedures for the capture, maintenance, retention, archiving and destruction of records related to the use of human tissue in research. Guidance within this SOP is restricted to the management of records pertaining to the governance of tissue use rather than records of scientific data generated as part of a research study. Guidance is drawn from the HTA, Royal College of Pathologists and Medical Research Council.

2. Background

The HTA sets out Governance and Quality Standards for the use of human tissue for research purposes. The standards require that all aspects of an establishments work are supported by ratified documented policies and procedures as part of the overall governance process. Licensed establishments are required to implement a procedure for the management of documented procedures for the creation, amendment, retention and destruction of records.

Types of records include but are not limited to; administrative records, traceability records, paper and electronic documents, emails, audio and video recordings, CD-ROMs and actual human tissue samples.

Relevant material can only be stored either under approval of a recognised Research Ethics Committee (REC) or under a HTA licence.

Samples retained for audit or verification of completed research can be retained for 12 months following completion of analysis. After this period samples MUST be stored under a HTA licence unless there is continuing REC approval for the particular study or REC approval for further use is pending.

Consent is needed for the continued storage of specimens for any of the scheduled purposes set out in Schedule 1, part 1 of the Human Tissue Act 2004 which includes "Research in connection with disorders, or the functioning, of the human body".

A recognized REC is either:

• a Research Ethics Committee established under, and operating to, standards set out in the governance arrangements issued by the UK Health Departments

or:

• an ethics committee recognised by the UK Ethics Committee Authority (UKECA) to review clinical trials of investigational medicinal products under the Medicines for Human Use (Clinical Trials) Regulations 2004

3. Roles and Responsibilities

The HTA requires that the Designated Individual (DI) be responsible for ensuring that appropriate procedures and practices are in place for the management of records related to the use of human tissue in research and that these processes are adhered to.

The Person(s) Designated (PD) carries the role of directing others in relation to the HT Act. As part of this role they have the ability to reasonably assist the DI in implementing procedures to ensure compliance with the HT Act and HTA licensing requirements.

The Principal Investigator (PI) of each research project is responsible for ensuring that quality records are captured, maintained and destroyed in line with this SOP.

It is the responsibility of individual researchers to support the PI in ensuring that tissue related records are stored and archived securely and appropriately.

The HTA Governance Officer is responsible for ensuring that this SOP remains fit for purpose.

4. Procedure

4.1 Tissue Traceability Records

The HTA require that traceability is maintained for the storage and movement of all relevant material held under a licence. Traceability records should cover tissue from the point of collection, to receipt and to final destination whether entirely used in testing/processing, disposed of or transferred. Methods of record keeping can be

electronic or paper based and should be maintained securely in locked or password protected storage. The following traceability information should be kept in a record management system for each individual sample:

- Name of PI
- Project title
- Description of tissue labeling system (may be incorporated into local SOPs)
- Unique sample identification reference (no patient identifiable information)
- Tissue type
- Date of receipt
- Details of sample origin
- Consent details (if appropriate) and location of consent form
- Storage location
- Description of processes applied to sample and relevant dates of processing
- Details of transfers to temporary storage (outward and inward) including transfers between storage areas within the same laboratory/unit
- Details of use and movement of tissue (Material transfer agreements (MTA), transfer documentation, log books)
- Date and method of disposal (i.e. used up in testing, disposed of by incineration, transfer to another location etc.)
- Reason for disposal

The HTA stipulate that records that enable tissue traceability must be maintained at least until the tissue has been disposed of, used to extinction or otherwise brought outside of the regulatory framework, or will never be used again in research. Staff working under a HTA licence should also adhere to ABM UHB and Swansea University policies and procedures for records management.

4.2 Other Essential Records

The following records must be captured and maintained as required for the collection, storage, use and disposal of relevant material::

- Details of consent including:
    - Who gave consent
    - What the individual consented to
    - Whether the consent is project-specific or for wider research use
    - Restrictions of tissue use stipulated during consent
    - Assurances of consent if custody of consent records lies with another organization
- Project specific ethical approval - records of ethical approval from a recognized REC should be maintained, including all associated patient

information and consent documents and all amendments. The end date of approval should be recorded and monitored to ensure no breach of the HT Act once approval lapses due to retention of relevant material beyond the REC end date.

- Records of service inspections and instrument maintenance – retain for the lifetime of the instrument; minimum of eight years.

- Equipment maintenance logs - retain for the lifetime of the instrument; minimum of eight years.

- Risk assessments – review as required by risk assessment outcome.

- Adverse events and associated corrective and preventative actions.

- Human tissue-related health records - HTA-licensed NHS Trusts and Health Boards should adhere to the two-part Department of Health (DoH) document *Records Management Code of Practice for Health and Social Care 2016*, available on the Digital NHS website, which sets out the requirements for retention of all NHS records. The current position is that all NHS health records created as a result of work taking place in accordance with the Human Tissue Act 2004 are to be retained for 30 years however the retention period for the storage of relevant material stored under a research HTA licence is outwith the scope of the Code. In relation to information related to human samples the Code states:

    - *Just because the human material is not kept for long periods, does not mean that the information about the specimen or sample must be destroyed at the same time. The information about any process involving human material must be kept for continuity of care and legal obligations.*

- Research data and records - RCPATH guidance states that:

    - Confidential named patient data (documentation) collected in the course of investigation and held separately from patients' records should be destroyed or anonymised 6 months after the research has been completed, the data have been analysed and final publication of findings has been made. If further recourse to identifiable information is anticipated, it should be kept for as long as such a need may exist where this is permissible under data protection laws.

- Refrigerators and freezers records
    - Where used for long-term storage of human samples for research, summarised daily temperature data should be regarded as a type of internal quality control record and retained for at least eight years.
    - When a freezer is being used for potentially very long term storage, e.g. in biobanking, data summarised from daily temperature records should be kept for at least the lifetime of the equipment. The records of all affected individual samples should be annotated with, or linked accessibly to details of, any temperature deviation beyond 'normal' variance. These details should remain accessible as a component of the sample record, following transfer to a new freezer, for the lifetime of the specimen.
- Documented evidence of joint HTA licence core SOPs as being read and understood by all researchers using human tissue.
- Records of staff training
- Material transfer agreements
- Quality control records
- External quality assessment records
- Internal and external audit reports
- Disposal records (human tissue and documentation)
- Protocols for the use, calibration and maintenance of relevant equipment, together with associated risk assessments, must be clearly documented.
- Local SOPs and protocols for all routine methods that involve the collection, use, storage and disposal of human tissue, together with associated risk assessments, should be documented systematically, in plain language and ideally in a standard format to ensure clarity, consistency and accuracy. Where there is more than one approved technique for any given procedure within the organisation, clear records should be kept on which were used.
- Where procedures change, they should be version controlled and made obsolete in line with the Swansea University/ABM UHB core *HTA-01-SOP-SOPs* and the current version should be available and readily accessible to all staff, students and visiting workers.

4.3 Retention of specimens and records in the context of biosample banking for research

The information below is reproduced from the Royal College of Pathologists guidance document "The retention and storage of pathological records and specimens" (5th edition April 2015).

- There is no maximum retention time for biosamples (including their linked clinical information and biological data) stored with consent for research use, unless otherwise specified as a condition of the donor's consent. (*N.B relevant material may only be retained under recognized REC approval or a HTA licence).*

- Operational records kept to ensure that equipment, facilities and processes work appropriately, and that faults and remedial actions are recorded, should be kept in the same way as those kept for clinical governance in relation to diagnostic specimens.

- It is particularly important, as far as possible, to link specimens with details of their pre-analytical handling, such as warm/cold ischaemic times, methods of freezing and frozen storage, duration of fixation, processing schedule and any non-standard details of preservation (alternative fixatives, cold storage of paraffin blocks, etc.).

- If biosamples issued for research are not exhausted by an end-user and are returned to the biobank, records should be cumulated to document their movements and the conditions of storage while under the custodianship of the researchers.

- A material transfer agreement (MTA) will be in place between the biobank and the researcher or researcher's institution and this should include definition of the storage conditions for any biosample that will be returned. This MTA, with linked details of the studies and biosamples to which it relates, should be kept by the biobank for at least as long as any of the included biosamples remains available for further study. The researcher should keep an equivalent record in relation to their study in accordance with their institution's requirements for research records retention. If the end-user is required by the MTA to dispose of, rather than return to the biobank, any surplus material from the biosample at the end of their study, they must keep auditable records of the date and method of disposal, for a minimum period of time compliant with their institution's requirements.

- The biobank should keep records of internal and external quality assurance performance and audits for at least 12 years. This is particularly important for those banks not housed physically in clinical laboratory premises subject to

regular inspection by bodies such as CPA or UKAS. Alternative or additional regulatory review may be required by the Human Tissue Authority, other accreditation bodies and research funding organisations.

- A biobank will keep the biosamples and records of any adopted sub-collection for the same length of time and, as far as possible, to the same standard, as their ongoing collections. Such legacy collections may arise, for example, following closure of another biobank or adoption (with appropriate consent and ethical approvals) of biosamples after the completion of a specific research project or clinical trial.

4.5 Security of Records

Records relating to human tissue that contain confidential or protected personal information must be kept secure at all times and accessible only to authorized individuals. NHS records should be held securely in line with the requirements of the *Records Management Code of Practice for Health and Social Care 2016* document.

Paper records – must be stored in a locked facility when not in use. When in use they must be under the direct supervision of the research team.

Electronic records – must be password protected and passwords should be restricted to authorized individuals. Passwords should be changed regularly and personal computers should be password locked when unattended. Records should be kept on Health Board or University network drives to ensure that they are backed-up regularly and not subject to loss due to damage to individual PCs.

Patient and personal identifiable information should not be sent by email unless sending between email addresses within NHS Wales (@wales.nhs.uk)

Individuals using Swansea University IT systems should abide by the organizations Computing Regulations, back-up requirements and security policy.

Patient identifiable information must not be held on personal devices and must not be removed from the secure storage environment.

Individuals using ABM UHB IT systems should retain evidence of attendance at mandatory Health Board Information Governance training sessions and be familiar with the organizational Health Records / Records Management Strategy and comply with all IT Health Board policies listed below:

- Data protection and Confidentiality Policy
- Email Policy
- Fax Policy
- Health Records Policy

- Access to Health Records Policy
- Health Records Tracking Policy
- Information Security Policy
- Internet Access Policy
- Minimum Retention and Destruction Policy

Staff and students remotely accessing human tissue-related electronic records should ensure that they are viewed securely and privately.

Staff and students should take reasonable steps to protect the security of their usernames and passwords, including not making them available for use to other individuals.

Personal identifiable information related to the use or storage of human tissue should not be held on personal removable storage devices (e.g. USB devices, mobile phones, cameras, personal digital assistants (PDA), CDs). Encrypted removable media must be used whenever patient identifiable data is handled outside the Health Board. Patient identifiable information must never be copied to personal computers in the home. Further information and guidance can be obtained in the policies listed above and from the Health Board Information Governance Department.

4.5 Transfer of Records

Where a unit is due to close or where programmes end and programme leaders or PIs transfer or retire, arrangements must be made in advance to support the retention and management of samples and data. This may include the transfer of custodianship to another individual within the unit or to another organisation and arrangements should detail provisions for access and eventual destruction. Where this occurs, the Designated Individuals of the new and existing organisation should be notified. Transfer of samples to another organisation must be done under a material transfer agreement in line with *HTA-05-SOP-Transportation*.

4.6 Archiving

Paper documents relating to human tissue from patients or participants within ABM UHB can be archived by the Health Board, either stored on site in locked cabinets within a secure unit or off site archive with a commercial archiver. The R&D Department archivist and Quality Assurance Officer have access to onsite and off site storage. The R&D department should be contacted for details of these facilities.

4.7 Disposal of Records

The disposal of traceability records should be carried out in such a way that the confidentiality of the data is maintained. Paper records containing patient information should be destroyed using the ABM UHB confidential waste containers. Records held

electronically should be deleted in line with ABM UHB and Swansea University IT procedures.

Documentation of the destruction of records, including a study reference, description and date of destruction should be maintained and retained by the principal investigator, so that the organisation is aware of those records that have been destroyed and are therefore no longer available.

5. References

Abertawe Bro Morgannwg Health Records Policy

Records Management Code of Practice for Health and Social Care 2016
https://digital.nhs.uk/article/1202/Records-Management-Code-of-Practice-for-Health-and-Social-Care-2016

Medical Research Council. Good Research Practice, July 2012. MRC, London.

www.mrc.ac.uk/research/research-policy-ethics/good-research-practice

Medical Research Council: Human Tissue and Biological Samples for Use in Research: Operational and Ethical Guidelines, November 2014. MRC, London.

www.mrc.ac.uk/news-events/publications/human-tissue-and-biological-samples-for-use-inresearch

NHS Health Research Authority (encompasses the National Research Ethics Service, NRES).

www.hra.nhs.uk

The Royal College of Pathologists April 2015; The retention and storage of pathological records and specimens (5TH edition)

http://www.rcpath.org/Resources/RCPath/Migrated%20Resources/Documents/G/G031_RetentionAndStorage_Apr15.pdf

6. Risk Assessment

A risk assessment for this HTA governance SOP is not required.

7. Definitions

Chief Investigator (CI) – The individual who takes overall responsibility for the design, conduct and reporting of a study if it is at one site; or if the study involves

researchers at more than one site, the Chief Investigator takes responsibility for the design, management and reporting of the study, co-ordinating the investigators who take the lead at each site.

Consent – Process by which an individual confirms willingness to participate in a particular procedure. The individual must have been informed of all aspects of the procedure that are relevant to the decision to participate. The individual must be competent to take the particular decision and be acting voluntarily.

Designated Individual (DI) – The person who is authorised and who supervises activities under a licence issued by the Human Tissue Authority.

Electronic Record Management System - A system that manages electronic records throughout their lifecycle, from creation and capture through to their disposal or permanent retention, and which retains their integrity and authenticity while ensuring that they remain accessible.

Human Tissue – Any and all constituent parts of the human body formed by cells.

Human Tissue Act 2004 - Legislation that regulates the removal, storage and use of human tissue, defined as material that has come from a human body and consists of, or includes, human cells. The HT Act covers England, Wales and Northern Ireland. Consent is the fundamental principle of the legislation and underpins the lawful removal, storage and use of body parts, organs and tissue. Different consent requirements apply when dealing with tissue from the deceased and the living. The Human Tissue Act lists the purposes for which consent are required (Scheduled Purposes).

Human Tissue Authority – The governing body set up to regulate activities that come under the HT Act. The HTA is a watchdog that supports public confidence by licensing organisations that store and use human tissue for purposes such as research, patient treatment, post-mortem examination, teaching, and public exhibitions.

HTA Codes of Practice - Provide guidance and lay down expected standards for each of the sectors regulated by the HTA (e.g. research) and under the HT Act. They are designed to support professionals by giving advice and guidance based on real-life experience.

HTA Standards - Core standards in four key areas that must be met for an organisation to obtain an HTA licence, relating to the provisions in the HT Act and the regulatory requirements: Consent; Governance and Quality Systems; Premises, Facilities and Equipment; Disposal.

Material Transfer Agreement – A contract governing the transfer of human material between organisations, where the recipient intends to use the material for their own research.

Person Designate – A person to whom the licence applies and to whom the authority conferred by the licence extends. Each School operating under an HTA Licence should have at least one Person Designate.

Principal Investigator – A Principal Investigator is the primary individual responsible for the preparation, conduct, and administration of a research grant, cooperative agreement, training or public service project, contract, or other sponsored project in compliance with applicable laws and regulations and institutional policy governing the conduct of sponsored research.

Quality Management System - Centralised governance framework policies, procedures, training, provision of advice and guidance, documentation and data records relating to all aspects of acquisition, storage, use and disposal of human samples.

Records - Information created, received, documented and maintained as evidence and information by an organization or person, in pursuance of legal obligations or business transactions.

Retention - An agreed period of time during which record(s) are retained within the records management system, at the expiration of which the record(s) are confidentially destroyed or transferred to archives for permanent retention.

Standard Operating Procedure (SOP) – Detailed, written instructions to achieve uniformity of performance of a specific function.

8. Appendices

None