Human Samples in Research

Acceptance of Sample Collections under the Swansea University Research HTA Licence 12651

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1. Purpose

The purpose of this SOP is to direct researchers who wish to store human tissue under the HTA human tissue research licence (ref 12651).

2. Background

The Human Tissue Act 2004 regulates the storage of human tissue for research. Human Tissue included under the Act is termed "Relevant Material" – refer to *HTA-RES-Quality Manual* for details of materials that fall under the definition of relevant material.

Collections of relevant material are often established during a NHS Research Ethics Committee (REC) approved research study. Where appropriate and valid consent to store the samples for future studies is in place then researchers may wish to retain collections of relevant material at the end of a REC approved study.

Samples may only be stored for a NHS REC approved study until the end date that was stated by the researcher on the IRAS form. Once this date is reached, the researcher has certain options to ensure that the material is handled in compliance with the Human Tissue Act 2004:

1. If the study is incomplete, the REC end date should be extended. Extension of NHS REC approval is considered to be a non-substantial amendment and must be submitted to REC on the Annual Progress Report form when due.
   NB: any organization that stores or provides human samples for the study (e.g hospital or health board) must be notified of the new end date before the initial end date is reached to avoid any breach of the Human Tissue Act due to lack of clarity around study status.

2. Apply to NHS REC to use the samples in a new study – application must take place before the end date of the current study lapses. Original patient consent must allow for storage for future use. Review of patient consent to assess that the consent is appropriate must be documented in the new study file.

3. Dispose of the samples. A disposal log must be completed and stored in the study file.

4. Apply to transfer the sample collection to the HTA research licence for use for a future study. Any future use of legacy samples may be subject to further REC approval. Application to store under the licence should be made in good time before the end of the study to allow assessment and agreement by the DI to be obtained before REC approval lapses.

Collections may also be transferred in from other licenced premises where a staff member joins the University or Health Board.

This SOP sets out the requirements to apply to store a collection under the HTA licence 12651 and the requirements for ongoing compliance during the storage period and further use of the samples.

This SOP also provides guidance for management of samples in the instances of retirement or departure of staff who are responsible for tissue collections.

3. Roles and Responsibilities

This SOP applies to all Swansea University and ABM UHB staff and students who collect, use or store human tissue for the purpose of research in connection with disorders, or the functioning, of the human body. This SOP also applies to individuals responsible for external sample collections who wish to apply to hold their samples on university or Health Board premises under HTA licence 12651.

The study Chief Investigator is responsible for ensuring that at the end of a REC approved study, the samples are handled in line with the Human Tissue Act 2004.

The DI is responsible for assessing whether the tissue collection is suitable for acceptance under the HTA licence.

The HTA Governance Officer is responsible for ensuring this SOP remains fit for purpose and for supporting the DI in the adoption and management of collections held under the licence.

Persons Designate are responsible for assisting the Designated Individual by recording and auditing collections within their area and any additional tasks delegated by the DI as required to maintain compliance with the HTA standards.

4. Procedure

Researchers may apply to store a sample collection under the research HTA licence. Storage under the licence requires compliance with the HTA Quality Management System. This includes, but is not limited to:

- Sample management and full traceability
- HTA Site file management
- Storage unit management and maintenance (fridge/freezer/nitrogen)
    - Temperature monitoring
    - Temperature alarm management and testing
    - Cleaning / decontamination / defrosting
    - Out of hours contact arrangements
    - Security

- Risk assessment and review
- Contingency planning and review
- Sample audit
- Internal audit and actions
- HTA inspection attendance and follow up actions

Please consult HTA-15-SOP-Maintenance and Monitoring Fridges and Freezers and relevant organisational health and safety policies for more detailed information on storage unit management.

4.1 Application requirement

Researchers may apply to store retrospective samples under the HTA licence by completing *HTA-09-FORM-HTA licence storage application* and returning to the HTA Governance Officer together with the following documents:

- A copy of the full IRAS application form, along with any amendments to NHS REC approval
- NHS REC letter
- NHS R&D approval letter if applicable
- Blank Copy of the participant information sheets and consent forms used to collect the samples (all versions)
- Comprehensive auditable anonymised list of the samples in electronic format – including reference to any consent opt-outs (i.e. where the donor has requested that their sample is not used in certain types of research e.g. genetic or animal research)
- Material Transfer Agreement if samples are to be transferred in from an external organisation
- Copy of HTA training certificate for all individuals responsible for the samples.

For prospective collections where the intention is to store the samples (including samples from healthy volunteers) please contact the HTA Governance Officer or DI to discuss before any approvals are sought.

4.2 Staff Changes

4.2.1 Staff departure or retirement

In the event that a member of staff who has responsibility for an existing tissue collection which is stored under the HTA licence leaves the organisation the following guidance should be followed:

4.2.1.1 Identify a staff member who is willing to assume the responsibility for the collection. This includes ongoing compliance with the HTA quality management system.

4.2.1.2 Submit the following by email to the HTA Governance Officer:

- Collection reference number
- Request to change of name along with written or forwarded email confirmation from the new individual of acceptance of the role
- Job title for new individual
- Contact details for new individual
- HTA training certificate for the new individual

Where there is no alternative member of staff to assume responsibility for the collection the HTA Governance Officer must be notified for escalation to the DI and relevant HTA Committee

4.2.2 New staff members

New staff joining the Health Board or University who wish to bring existing collections into the organisation must obtain agreement from the DI to do so.

To apply to transfer such collections to the HTA licence researchers must submit the *HTA-07-FORM-HTA licence storage application* together with the documentation listed in section 4.1.

4.2.3 Imported collections

To import samples from outside England, Wales or Northern Ireland (including transfer from Scotland) for storage under the HTA licence, researchers should follow *HTA-06-SOP-Import and Export* and following authorisation to import, submit *HTA-07-FORM-HTA licence storage application* together with the documentation listed in section 4.1.

4.3 Review of applications

All applications to store samples under the licence will be reviewed by the DI. Where the decision is not straightforward the opinion of the relevant HTA Committee will be sought.

A summary of applications and decisions will be presented to the Swansea University HTA Sub-Committee and the ABM UHB HTA Committee

4.4 Review of access of licenced samples for new studies

Where a researcher wishes to access samples in a stored licenced collection, (including those that they are responsible for) to conduct a new research study the researcher should consider whether the original consent obtained is sufficient for the new study and determine whether further NHS REC approval is required using:

http://www.hra-decisiontools.org.uk/ethics/

Where additional NHS REC is required a copy must be submitted to the HTA Governance Officer.

In all cases, a copy of the protocol must be submitted to the HTA Governance Officer who will liaise with the DI for authorisation for the project to proceed.

Research on samples held under the licence must not proceed until authorisation from the DI is received.

NB: Where the resources of ABM UHB or any other NHS organisation are required to deliver the project (e.g. Pathology access or support) then the relevant Research and Development Department(s) must be consulted for assessment and agreement of capacity and capability and negotiation of agreements.

5. References

HTA Code of Practice E: Research

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

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/use-tissue-research/

6. 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.

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

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 independent regulator established by the HT Act to protect public confidence by ensuring human tissue is used safely and ethically, and with proper consent. The HTA licenses and inspects organisations that collect, store and use human tissue for the Scheduled Purposes, for which appropriate consent is required (unless exemptions apply).

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.

Relevant Material – Any material, other than gametes, removed from the body which consists of or includes human cells. In the HT Act references to relevant material from a human body do not include:

- embryos outside the human body
- hair and nail from the body of a living person
- cell lines or any other human material created outside the human body

- serum, plasma, DNA and RNA

Research - A study that addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body. Research attempts to derive new knowledge and includes studies that aim to generate hypotheses, as well as studies that aim to test them or develop practical applications of new knowledge.

Scheduled Purposes - The activities relating to the removal, storage and use of human organs and other tissue that require consent, listed in Schedule 1 of the HT Act, e.g. research in connection with disorders or the functioning of the human body.

Standard Operating Procedure – Detailed, written instructions to achieve uniformity of the performance of a specific function which an integral part of a quality management system. In the context of research using human samples, SOPs document all the processes that affect the quality and safety of those samples (e.g. acquisition, storage, transfer and disposal).

Storage – Maintaining the tissue under appropriate controlled conditions.