Human Tissue in Research

HTA-CORE-SOP-Acceptance of Collections

1. Purpose

The purpose of this standard operating procedure (SOP) is to guide researchers who wish to store human tissue, defined as relevant material by the Human Tissue (HT) Act 2004 under Swansea University's Human Tissue Authority (HTA) research licence (ref 12651).

2. Scope

There are a few different situations where a tissue collection would need to be accepted, transferred, and stored under the University's HTA Research licence:

A. Collections of relevant material established during an NHS Research Ethics Committee (REC) approved research study, with evidence of appropriate and valid consent to store the samples for the future after the end date submitted to IRAS.

B. Collections transferred from other premises held under their HTA licence, when a new staff member joins Swansea University (SU).

C. Retirement or departure of staff who was responsible for tissue collection held under our HTA licence and custodianship is to be reassigned to another staff member.

D. Creation of a Research Tissue Bank (Biobank / Biological Repository).

E. International import/export of relevant material from outside England, Wales, or Northern Ireland, not covered by a REC-approved study, including imports from Scotland.

3. Responsibilities

This SOP applies to all SU staff and students who collect, use or store human tissue for research. This SOP also applies to external collaborators responsible for external sample collections who wish to apply to hold their samples on SU premises under HTA licence 12651.

The Chief Investigator/Principle Investigator (CI/PI) 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 (HT Act).

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

The Human Tissue Governance Officer (HTGO) 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 (PD) are responsible for assisting the DI by supporting staff in their local area to maintain compliance with the HTA standards and reporting on any evidence of non-compliance.

4. Procedure

4.1. Application for Storing Collection Under HTA Licence

Before a tissue collection can be accepted, transferred and stored under the SU licence the CI/PI must complete the HTA-FORM-Licence Storage Application and submit it to the HTGO for review by the DI.

The 'Licence Storage Application' will list several supporting documents that you will need to submit with the application also for review by HTGO and DI.

A list of supporting documentation to be submitted with the application are:

- A copy of the full IRAS application form, along with any amendments to NHS REC approval (if applicable).
- A copy of the NHS REC letter (if applicable).
- A copy NHS R&D approval letter (if applicable).
- Copy of participant information sheets, and blank consent forms used to collect the samples (all versions).
- Location of original signed consent forms (if applicable).
- 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 and GCP certificate for all individuals responsible for the samples.

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 SU HTA Sub-Committee.

4.1.1 Use of a collection once accepted under the HTA licence.

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/

If NHS REC approval is **not** needed you must then submit your new study and protocol through SU Internal Ethics for approval.

Research on samples held under the licence must not proceed until the new study has received ethical approved.

4.2 Acceptance of collection and end date of NHS REC-approved study

Samples may only be stored for REC-approved studies until the end date that was submitted via the IRAS portal by the CI.

The CI has four options available to them to ensure that the material is handled in compliance with the Human Tissue Act 2004 following the end date of their study.

As best practice, all available options should be considered during the planning stage of a study but as a minimum actioned at least 2 months before the end date of the study.

Options:

1. The REC end date should be extended if the study is incomplete. The extension of REC approval is a non-substantial amendment. To extend your study contact Research Governance.

Note: *Any organisation that stores or provides human samples for the study (e.g hospital or health board) must be notified of the new study end date before the original end date is reached to avoid any breach of the HT Act due to lack of clarity around study status.*

2. Dispose of the samples. A disposal log must be completed and archived in the study file (HTA-FORM-Disposal Record).

3. Submit a new IRAS application for REC approval to use the samples in a new study. (Original patient consent must allow for storage for future use).

4. Apply to transfer the sample collection to SU's HTA research licence for use in a future study. The HTA-FORM-Licence Storage Application together with the documentation listed in section 4.1 must be sent to the HTGO and DI to obtain an agreement to do so. Any future use of legacy samples may require further REC approval depending on the original consent provided.

Application to store under the licence must be submitted before the end of the study to allow assessment and agreement by the DI to be obtained before REC approval lapses.

Any human tissue stored under SU's HTA research license **must adhere to all** quality management systems described in the University's HTA CORE SOPs to ensure compliance with the HTA standard.

All collections stored under the HTA research license will be audited internally and externally by the HTA.

Any non-compliance identified could potentially put the research licence at risk. If an HTA audit identifies major shortfalls in compliance, SU will be issued a fine and the licence potentially be revoked . All HTA research activated at SU would legally be required to stop.

4.3 New Staff Members

New staff joining SU who wish to transfer their existing tissue collections (relevant material) to SU, under our HTA licence from their previous organisation must submit the HTA-FORM-Licence Storage Application together with the documentation listed in section 4.1 to the HTGO and DI to obtain an agreement to do so.

If you are a new staff member joining SU with an active NHS REC-approved study, which you would like to continue at SU, please first contact Research Governance to discuss your study and agree on potential amendments to your IRAS application that might be needed.

4.4 Staff Departure or Retirement

If a member of staff who has responsibility for an existing tissue collection held under the HTA licence leaves the organisation, the following guidance should be followed.

1. The departing staff member should identify another staff member who is willing to assume the responsibility for the collection. This will include ongoing compliance with the HTA quality management system.

2. Request to change name of the custodian by email to the HTGO, along with written or forwarded email confirmation from the new individual of acceptance of the role. Include in the email:

- A completed HTA-FORM-Licence Storage Application with updated information of the new custodian and storages facilities.
- HTA training and GCP certificates of the new custodian.

Where there is no alternative member of staff ready to assume responsibility for a collection the HTGO must be notified for escalation to the DI and relevant HTA Committee.

If a member of staff who has responsibility for an active NHS-approved study is leaving for any reason and will not be involved in delivery in the future, the CI must log into their IRAS portal and permanently transfer it to a different member of staff. Please contact Research Governance if you are planning to continue the study at a different organisation.

4.5 Creation of a Research Tissue Bank

A Research Tissue Bank (RTB) or biobank is a collection of human tissue or other biological material, which is stored for potential research use beyond the life of a specific project with ethical approval or for which ethical approval is pending.

A RTB can be created and held under SU's HTA licence, if the collection was collected under an NHS-approved study and the consent included broad generic consent for future storage for the creation of research related or unrelated to the original study.

Although HRA approval is not required to establish a RTB at a licenced premises, SU recommends that staff voluntarily submit for ethical review of their arrangements for the collection, storage, use and distribution of tissue via IRAS.

Obtaining ethical approval for a tissue bank may offer benefits such as facilitating programmes of research without a need for individual project-based ethical approval.

There are standard conditions which should be followed after REC favourable opinion has been issued or for non-REC studies after HRA Approval has been issued. For research tissue banks, RTB Conditions of Approval should be used.

For more information contact the HTGO.

4.6 Imported Collections from Outside UK

To import samples from outside England, Wales or Northern Ireland for storage under the HTA licence, researchers should follow HTA-CORE-SOP-Transportation, complete the HTA-FORM-Importation Justification and submit to the HTGO.

Research tissue banks based in **Scotland** do not need a HTA licence and are not governed by HTA. However, NRS biorepositories are accredited by an independent expert panel using criteria comparable to and adopted from those for research tissue bank

licensing in England, Wales and Northern Ireland by the Human Tissue Authority. Therefore tissues sourced **from NRS biorepositories** can be treated the same as HTA licenced organisations from within England, Wales or Northern Ireland.

5. Risk Assessment

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

6. Definitions

A list of useful definitions of technical terms used within SU's HTA Core SOPs can be found in the HTA-Research Quality Manual.

7. Document History

Document History				
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1.0	N/A	New document	N/A	N/A
2.0	14/03/2024	Revised SOP to reflect the separation of the previous joint HTA licence between SU and SUHB and to establish new SU procedures moving forward.	1.0	Bethan R Thomas & DI

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