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Human Samples in Research

Preparation, Issue, Approval and Review of HTA

Standard Operating Procedures

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Document History

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2.0	21.09.15	Amendment to front page, footer and review period. Appendix removed to create referenced standalone SOP template. Removal of reference to JSOPG	1.0	Lisa Wakeman
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4.0	18.04.18	Amendments to reflect revised HTA Codes of Practice and Standards	3.0	Lisa Wakeman

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to define the requirements and procedures for the production, review, approval and distribution of SOPs relating to the acquisition, storage, use and disposal of human bodies, tissues and cells covered by the Human Tissue Act 2004 (HT Act) and as set out in the Human Tissue Authority (HTA) Codes of Practice.

This joint HTA governance SOP may be used as a template for the development of local SOPs for specific use.

2. Background

This SOP is integral to the joint Swansea University/Abertawe Bro Morgannwg University Health Board (ABM UHB) Quality Management System (QMS) for the governance of the acquisition, storage, use and disposal of human samples for the Scheduled Purpose of research as defined in the HT Act.

Organizations which undertake research have a responsibility to ensure the confidence of researchers and the public with regard to the use of human tissue. Under the joint HTA QMS all human samples, regardless of whether they are from the living or deceased, cellular or acellular or classed as relevant or not under the HT Act should be treated in the same manner in accordance with the obligations and standards set out in the Joint HTA Quality Manual [*HTA-RES-Quality Manual*].

SOPs should be developed wherever there is a need for a standard written procedure. They should be prepared, reviewed, revised, approved and issued as described in this SOP. All core and local SOPs should be regularly reviewed, version controlled and available for inspection/audit.

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.

The HTA requires that the Designated Individual (DI) be responsible for ensuring that appropriate procedures and practices are in place for the storage of samples for research, and that these processes are adhered to. The DI is responsible for authorizing all SOPs related to the use of human tissue in research in compliance with the HTA requirements.

The Person(s) Designated (PDs) 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.

It is the responsibility of the Lead/Principal Investigator to understand and follow the joint HTA SOPs and attend update training as required and ensure a training log of activities is maintained.

The HTA Governance Officer is responsible for drafting, writing and periodic revision of core HTA SOPs and for ensuring they remain fit for purpose in relation to legislative and regulatory requirements and operational changes.

4. Procedure

Once the need for a standard procedure is identified, a SOP should be written by individuals with the required knowledge and skills to accurately represent the process in question. All local SOPs should be written in accordance with this SOP. A template is provided in *HTA-01-TEMPLATE-SOPs*, this can be tailored as required for local use in specific areas and projects.

4.1 SOP Content

All SOPs should contain the following information:

- SOP title
- Unique identifier
- Version number
- Effective date
- Chronology of review
- Author
- Signatories of approval
- Total number of pages

4.1.1 Unique Identifier

Each SOP should be identified by a unique code. Core HTA SOPs will be identified uniquely using the format HTA-number-SOP-title e.g. *HTA-01-SOP-SOPs*. The unique number will be displayed on the front page of each SOP.

4.1.2 Version Number

All SOPs will be issued with a version number to ensure that the current document is in use.

It is good practice to assign version number to each document using the format N.n where N represents a finalised document and n represents draft versions. When reviewing an SOP the following procedure for changing version numbers will be used:

- Assign each new, approved and finalised document a major version number e.g. 1.0.
- When taking a document for revision or as draft, assign a new minor version e.g. 1.1.
- During the review cycle assign each new revision of the draft the next minor version number e.g. 1.2, 1.3 etc.
- Upon approval of the document assign the next major version e.g. 2.0.
- Assign initial pre-approved drafts with version number 0.1 to allow revision and development of the first version to be tracked.

A chronological record of changes and version numbers will be maintained in a table on the front page of each SOP.

4.1.3 Author and Approval

The author of each SOP should be indicated on the title page of each document. The author will be primarily responsible for writing and updating the SOP.

University/Health Board SOPs written for the governance of human tissue in research shall be developed by the HTA Governance Officer and approved by the DI. SOPs will not be deemed effective until approval from the DI has been received. Approval will be considered received upon signature by the DI.

Local SOPs for specific research projects should be approved by the PI.

4.1.4 Effective date

All SOPs will be issued with the date of next review date of approval by the DI and effective date. This information will be displayed on the front page of each SOP.

Each SOP may also include the date that the documented process was implemented into practice following team training. This date may be different to the 'effective date'.

4.1.6 Purpose

A description of the intended purpose of the SOP, e.g. to ensure that all staff and students are aware of the procedure for preparing, reviewing and archiving SOPs for compliance with the quality management system and HTA requirements for the management of records in relation to the acquisition, storage, use and disposal of human tissue.

4.1.7 Background

The background section should provide an overview of the need for the SOP, the scope of the process being defined and the specific aims it is intended to satisfy.

4.1.8 Roles and Responsibilities

This section should identify the main roles and responsibilities of individuals involved in documenting, performing and supervising an activity detailed in the SOP.

4.1.9 Procedure

This section details the specific steps to be performed when the task or process that the SOP is intended to describe is undertaken. For technical SOPs, the instructions in this section should be written as clearly and comprehensively as possible. All abbreviations should be defined on first usage to aid understanding.

4.1.10 References

All references related to the development of the SOP and to principles on which the SOP is based should be documented in this section.

4.1.11 Risk Assessment

All procedures involving the acquisition, storage, use and disposal of human tissue must be risk assessed to comply with HTA requirements. SOPs describing manual, technical and scientific procedures involving human tissue must contain an evaluation of the risks involved to ensure that any individual undertaking the process is aware of the possible hazards and understands the steps to be taken to minimize them.

To comply with HTA standards the risk assessment should include; consideration of the risks to the integrity of the tissue, the respect for the donor and the safety of the handler. This section may be omitted or marked 'not applicable' where appropriate. A risk assessment template and guidance for local use is provided in *HTA-05-*

TEMPLATE-Risk Assessment. SOPs involving the use of chemicals should also include a general health and safety assessment of risk and detail steps for risk reduction. This section can be omitted or marked 'not applicable' where appropriate.

The carrying out of health and safety risk assessment within each organization must be performed with consideration of the respective Swansea University Health and Safety Policy Arrangements and the ABM UHB Risk Management Strategy & Policy.

4.1.12 Definitions

This section should be included where an explanation of definitions aids the reader to carry out the procedure or increases the safety of the procedure being described. The definitions listed in each SOP should be concise and applicable to the specific SOP.

4.1.13 Appendices

Include all information referenced in the SOP text as necessary.

4.2 Review and Amendments

SOPs are working documents and are subject to regular review. HTA SOPs will be amended in the light of changes to legislation, HTA regulatory requirements and Codes of Practice and other advisory information.

University/Health Board core HTA SOPs will be reviewed every two years as a minimum. Individuals involved in tissue use for research may request revision of HTA SOPs at anytime if a deficiency or potential improvement is noted. Requests should be made in writing via the HTA Governance Officer or the DI.

Local SOPs should be reviewed and approved within the research team, the minimum period between review should be defined when the document is created. Relevant amendments should be made whenever necessary.

4.3 Distribution

Approved current versions of core SOPs will be available for download on the Swansea University website and ABM UHB Research and Development intranet webpage.

Individuals are responsible for ensuring that they are working with the current version of each SOP. Once a revised version of any SOP is available, each individual working under the licence should record in their training log that they have read and understood the document. Where printed copies of previous versions have been in use, these should be retained and marked as superseded.

4.4 SOP Training

As a minimum training requirement, all individuals working with human tissue are required to read each core HTA SOP and record as self-directed training in their personal research training log to evidence that the document has been read and understood. Training logs for all staff working with human tissue evidencing training to the core HTA SOPs should be available during internal audit and external HTA inspection.

When a new SOP is authorised or when an existing SOP is revised, self directed training must be carried out by all staff to whom the SOP is relevant and this training documented in a training record as above. If required, SOP training can be provided by the HTA Governance Officer to facilitate clear understanding of the documented processes related to HTA compliance. Researchers should visit the relevant website regularly to ensure that they are aware of and working to the latest SOPs and guidance documents relevant to their research. Please contact the HTA Governance Officer for further assistance and advice.

4.5 Suspending a SOP

In the event that it is deemed necessary to suspend a core HTA SOP, the HTA Governance Officer will provide email notification to all relevant individuals with the following information as a minimum:

- SOP name, identifier and version number
- Effective date of suspension
- Brief details of the reason for suspension

4.6 SOP archival

Obsolete core HTA SOPs will be archived by the HTA Governance Officer as required.

All local SOPs should be retained for the duration of each research project and for the period of storage of the human tissue. Superseded SOPs should be marked as such and archived but not destroyed. Superseded SOPs should be available for inspection during internal audit and inspection by the HTA from the date of commencement of a Human Tissue Licence. Further guidance is available in *HTA-07-SOP-Management of Records*.

4.7 Audit

The effectiveness of implementation of this SOP will be monitored as part of a schedule of internal audit.

HTA SOPs and local SOPs will be subject to internal audit to assess compliance with the HTA requirements. All core and local HTA SOPs will be subject to inspection by the HTA.

5. References

HTA Code of Practice E: Research; Code of Practice and Standards

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

6. Risk Assessment

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

7. Definitions

Acquisition - The collection and receipt of human samples. Consent from the donor must be in place unless exemptions to the consent provisions under the HT Act apply.

Audit - The evaluation of a system, process or procedure in order to ascertain its effectiveness and the validity and reliability of the information.

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

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.

Person Designated: Individual appointed by the DI to assist them in supervising the licensable activities carried out within their organisation.

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 comprising 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.

Relevant Material - Human samples that consist of or contain human cells. It excludes gametes and embryos, hair and nail from a living person; cell lines which have divided outside the human body and extracted DNA and RNA.

Research - A study which 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.

Risk Assessment - a careful examination of what could cause harm to people or resources. Workers and others have a right to be protected from harm caused by a failure to take reasonable control measures.

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).

Training Log - A record of documentation of self-directed learning or training received.