Human Samples in Research

Risk Management and Contingency Planning

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Document History

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2.0	21.09.15	Updated front page and footers. Updated links. Removal of template risk assessment and contingency plan to standalone documents	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	3.0	Lisa Wakeman

1. Purpose

Risk management is a process of systematically identifying potential risks and the subsequent implementation of measures to minimize risk and plan suitable contingency arrangements. The Human Tissue Authority (HTA) requires that all critical processes from consent through to receipt, storage and then transfer or disposal of the tissue are identified and subject to risk assessment to minimize risks to the integrity of tissues and to the health and safety of handlers. The purpose of this Standard Operating Procedure (SOP) is to set out the processes and procedures for risk assessment and contingency planning where relevant material is collected, stored, used or disposed of for the purpose of research in connection with disorders, or the functioning, of the human body. The terms 'relevant material' and 'human tissue' are used interchangeably in this SOP.

Risk management, as detailed in this SOP, refers to risk to relevant material and associated risks to handlers and, where appropriate, should be used alongside the ABM University Health Board (ABM UHB) and Swansea University risk management protocols that manage risks outside the remit of human tissue governance. This SOP applies to, and aims to provide guidance and simple tools for all staff and students of Swansea University and ABM UHB to assess the risks to donated relevant material and to develop contingency plans to protect tissue in the event of system failures.

2. Background

The HTA standards for the Research Sector require that appropriate risk management systems are in place as part of the overall governance process. Health and safety, fire, risk management and infection control should form part of a documented training program for staff and students (refer to *HTA-08-SOP-Training*). Premises, facilities and equipment should be subject to risk assessment to ensure they are fit for purpose and systems should be in place to ensure the safety of staff, students and visitors. The HTA also prescribe that potential risks to donated human tissue should be managed and subject to risk assessment; such risks include accidental disposal, loss, damage and contamination. All elements of the organizational risk management systems should be subject to regular review.

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 risk 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 Human Tissue Act 2004 (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 PI of each research project to ensure that risks related to their research and tissue use are assessed and reviewed and to understand and follow the appropriate procedures.

It is the responsibility of PIs, individual researchers and research groups to hold copies of all local risk assessments and contingency plans related to human tissue and ensure that they are regularly reviewed and available for internal audit and HTA inspections.

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

4. Procedure

4.1 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. A template for local use (*HTA-05-TEMPLATE-Risk Assessment*) is available. Guidance for completing the risk assessment is in appendix A.

SOPs involving the use of chemicals should include a separate assessment of risk and detail steps for risk reduction based on existing organizational risk management protocols. Risk assessment guidance for the wider management of risks is available in the Swansea University Risk Assessment Manual and the ABM UHB Risk Management Strategy & Policy.

4.2 Contingency Planning

The HT Act specifies that contingency plans must be in place for equipment and facilities used to handle and store tissues for research. This section should be read in conjunction with *HTA-03-SOP-Storage*. SOPs detailing contingency plans can be developed using the HTA SOP template in *HTA-01-SOP-SOPs* for ease.

Contingency plans should identify as a minimum:

- The tissue at risk and the specific study involved
- The storage units at risk
- Critical equipment which, if should fail, would compromise tissue integrity
- Current preventative measures for storage units and critical equipment (e.g. maintenance contract, routine maintenance procedures)
- Conditions under which the tissue would be considered at risk based on a risk assessment
- Emergency contact details for the individuals to be contacted in the event of critical failure of a storage unit. Preferably a hierarchy of contacts should be defined
- Details of location of contingency storage units and equipment (as labeled in accordance with HTA-03-SOP-Storage) which are to be used in the event of failure

5. References

ABMU HB Risk Management Strategy and Policy 2016-2019

http://howis.wales.nhs.uk/sites3/Documents/743/57.%20RM%20Strategy.pdf

Swansea University Health and Safety Policy

http://www.swansea.ac.uk/media/Health%20and%20Safety%20Policy.pdf

Swansea University Safety, Health and Environment Handbook

Health and Safety The Grove, The Institute Of Life Science and Margam building User's Handbook

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

Human samples, tissue and material - All material derived from a human (cellular and acellular) that may be acquired, stored and used in research.

Human Tissue Act 2004 (HT Act) - 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 (HTA) - 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.

Quality Management System (QMS) - 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.

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

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 (SOP) - 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).

Appendix A

Guidance notes for tissue risk assessment

1. Risk assessments should be read by all members of the research team. Evidence that each member has seen the assessment should be documented and be available for inspection.

2. The focus of this risk assessment process should be on the possible risks to tissue integrity. Human tissue is donated to research altruistically and as such researchers have a responsibility to take all reasonable steps to avoid damage or loss.

3. Risks to tissue at all stages of the research process should be considered in the assessment, from procurement to disposal.

4. Consideration of risks during the assessment process should include damage or loss to tissue including that caused by but not limited to:

    a. Storage unit failure
    b. Lack of contingency arrangements
    c. Accidental disposal
    d. Transfer/transport
    e. Lack of training
    f. Failure to consider future use of tissue during the consent process leading to unnecessary disposal of tissue at study end
    g. Inadequate equipment maintenance
    h. Lack of standardised protocols
    i. Poor sample tracking systems

j. Inadequate sample labeling systems
k. Contamination
l. Incorrect storage conditions
m. Identification and procurement from appropriate study subjects

5. Where possible the risk assessment should be based on a SOP or group of SOPs relating to a specific activity or study.

6. Risk assessment and adverse event reporting are linked. Where investigations into adverse events highlight previously unconsidered issues of risk, these should be incorporated into a revised risk assessment to be read and acknowledged by all relevant personnel.

7. Contingency plans detailing actions to be taken in the event of storage unit failure should be in place for all human tissue stored for research in Swansea University and ABMU HB. Such plans should be robust and cover failure outside of core hours unless documented risk assessment details why this is not required.