Swansea University
Prifysgol Abertawe

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

GIG CYMRU NHS WALES
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Human Samples in Research

Training

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Document History

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2.0	21.09.15	Amendments to front page and footer	1.0	Lisa Wakeman
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4.0	18.04.18	Amendments to reflect revised HTA Codes of Practice and Standards. Removal / update of redundant links	3.0	Lisa Wakeman

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to ensure that all staff involved in current and historical human tissue activities are fully aware of the required training to ensure compliance with Human Tissue Act 2004 (HT Act) legislation and Human Tissue Authority (HTA) Codes of Practice.

2. Background

The HTA Research Sector licensing standards require that staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills. Staff appraisal and personal development plans must be in place and must include access to health and safety, fire, risk management and infection control. Staff working with human tissue should be trained in compliance with the HTA legislation and codes of practice. Training in the requirements of the HT Act is required for all individuals working under the HTA licence.

3. Roles and Responsibilities

The Designated Individual (DI) is responsible for ensuring that systems are in place to evidence that staff working with human tissue under a HTA licence are appropriately trained and are working with knowledge of, and in compliance with the HT Act and HTA Codes of Practice.

Principal Investigators (PIs) and Persons Designate (PDs) have a role in identifying personal development needs and training opportunities for staff and students for whom they are responsible.

All staff working with human tissue have personal responsibility to access and undertake role-related training to evidence of skill development and human tissue-related legislation and regulation.

All staff and line managers working under a HTA licence are responsible for engaging in Swansea University and/or ABM University Health Board (ABM UHB) personal development frameworks and induction arrangements.

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

4. Procedure

Individual staff members and students working with human tissue should maintain documented evidence of all role-related and HTA specific training and development covered in this section. Such evidence should be available on request for internal and external audit.

4.1 Staff Induction

All University and Health Board staff should engage with their organizational induction programmes and adhere to induction policies.

4.2 Personal Development

Swansea University and ABM UHB are committed to supporting the training and development needs of staff. Both organizations operate development review procedures. All staff and students (where appropriate) should engage fully in the process to maximize opportunities for personal development. Reflective learning is encouraged to support and evidence the development process.

4.3 General Training

Staff and students undertaking human tissue related research should demonstrate an appropriate level of skill, knowledge and understanding to evidence suitability to perform their role. The following areas of training are recommended as a minimum.

- Consent training
- Health and Safety training
- Research Governance procedures
- Adverse Event Reporting
- Record Management and Archiving
- Risk assessment and management
- Data Protection and Confidentiality
- Research Ethics
- Good Clinical Practice (GCP) training
- Fire training
- Infection Control training

Additional training is available within both the University and Health Board.

4.4 HTA Specific Training

All staff and students (undergraduate and postgraduate) within Swansea University and ABM UHB who work with human tissue should undertake training in human tissue legislation and regulatory requirements. All staff and students involved in human tissue activities should undertake training on the HTA legislation including training on informed consent. This is to ensure that all staff have the necessary knowledge and skills to carry out their roles and responsibilities in compliance with the HT Act and HTA Codes of Practice. As a minimum, it is recommended that staff familiarise themselves with the following:

- HT Act
- HTA Codes of Practice (codes A and E)
- All joint Swansea University/ABM UHB HTA Governance SOPs
- Local SOPs

Individuals who obtain consent or are responsible for sample collections that are held under the licence must undertake consent and GCP training.

4.4.1 Self-Taught

Individuals may self-teach using the Medical Research Council (MRC) e-learning package available at: http://byglearning.co.uk/mrcrsc-lms/course/category.php?id=1

4.4.2 Group/Individual Sessions

In-house training sessions can be provided to research groups/individuals, please contact abm.HTA@wales.nhs.uk

4.5 Designated Individual Training

All DIs are required to complete HTA accredited training (online or otherwise). This must be completed to the HTA's satisfaction within a time period of 12 months from the date of the licence or such other period as may be specified by the HTA. Online training has previously been available on the HTA website, however more recently this has been removed. Clarification of the future format of DI training is required to inform ongoing DI training provision (e.g. group, online).

4.6 Training Records

All staff should maintain an individual record of training activities in a personal development portfolio and copies held by the relevant PD. All certificates issued following successful completion of on-line courses should be kept as evidence of training and should be accessible in the event of internal audit by the University/Health Board and external audit by the HTA. Template training and reflective learning logs are available in appendices A and B respectively. Locally modified logs should be version controlled and reviewed as defined in local record management procedures

Further information on other research record keeping requirements can be found in the joint Swansea University/ ABM UHB HTA Standard Operating Procedure on Management of Records.

5. References

ABM University Health Board Training
http://howis.wales.nhs.uk/sites3/page.cfm?orgid=743&pid=31821

HTA Code of Practice A: Guiding Principles and the Fundamental Principle of Consent
https://www.hta.gov.uk/sites/default/files/files/HTA%20Code%20A.pdf

HTA Code of Practice E: Research; Code of Practice and Standards
https://www.hta.gov.uk/sites/default/files/Code%20E.pdf

Medical Research Council Online HTA Training Modules 'Research and Human Tissue Legislation'
http://byglearning.co.uk/mrcrsc-lms/course/category.php?id=1

6. Risk Assessment

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

7. Definitions

Chief Investigator – 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 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.

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.

Personal Development Portfolio - A record of documentation regarding the training received and training support materials relating to the acquisition, storage, use and

disposal of human samples in research, which is required to be constantly maintained and updated.

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.

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.

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, disposal).

Training Log (HTA) - A record of documentation regarding the training received and training support materials relating to the acquisition, storage, use and disposal of human samples in research, which is required to be constantly maintained and updated.

8. Appendix A – Training Log

NAME: ……..

Date	Description of Activity	Training Provider	Signed

Appendix B – Reflective Learning Log

Date & description of the Learning Activity
What did you learn?
Did you have any difficulties?
How have you used this learning in the workplace?
How has the learning changed how I work?
Any further action needed?