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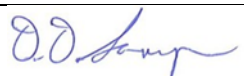
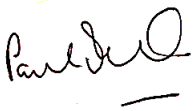
Approval History				
Version 1.0	Name	Role	Signature	Date
Written By:	Ferdousi Chowdhury	Head of RIGO		20.01.2020
Approved By:	David Sampson	DI		10.02.2020
Version 2.0	Name	Role	Signature	Date
Revised by:	Linda McLatchie	Hub PD (acting)		03.06.2023
RIGO approval:	Gill Fairbairn	Interim Director R&I Services		26/06/2023
DI approval:	Paul Townsend	DI		19.06.2023

1. INTRODUCTION

There are several regulations and standards that govern the use of human material in research including the Human Tissue Act (HT Act), the Human Fertilisation and Embryology Act, the Data Protection Act and the UK Policy Framework for Health and Social Care. It is therefore important for researchers to maintain records that demonstrate samples have been managed in accordance with relevant regulations and standards and used for the purpose for which they are intended.

As an establishment holding a Human Tissue Authority (HTA) Research Licence, the collection, use, and storage of human tissue for research must be in accordance with the Human Tissue Authority (HTA) Code of Practice for Research: Code E: Research and the associated Research Standards and Guidance. These codes set out the standards which must be met and include the requirement for a systematic and planned approach to the management of records. These standards have been used as the basis of the standard operating procedure (SOP) detailed here and should be referred to for further guidance on best practice for record management.

This SOP describes the essential elements that should be followed to ensure appropriate record management for human samples being used for research purposes.

2. SCOPE

This SOP applies to projects intending to use any type of human sample, including material that is considered relevant under the HT Act; non-relevant human material; human DNA and RNA; human biological fluid; and human-derived cell lines.

All individuals, whether staff, student or visitor, conducting research with human samples under the auspices of the University of Surrey on or off site must follow the requirements set out in this SOP.

3. RESPONSIBILITIES

3.1. The Designated individual (DI) has *a legal duty to ensure that statutory and regulatory requirements are met. They are responsible for supervising licensed activities and ensuring suitable practices are taking place*. They are responsible for ensuring that all researchers meet the HTA standards for record management.

3.2. The Persons designate (PD) *assist the DI in ensuring compliance with HTA standards.* There is a PD for each of the areas; Stag Hill (Hub PD and FEPS PD), Leggett, VSM, VSP and Surrey CRB. The PDs are responsible for assisting researchers in following the guidance in this SOP and for notifying the DI of any problems or breeches regarding record management.

3.3. The Human Tissue Research Operations Group (HTROG) is the governing body overseeing the storage and documentation of human tissue held under the HTA licence.

3.4. The Research Integrity and Governance Office (RIGO) is responsible for maintaining a central log of research projects and training records. This does not however, replace the need for researchers to keep a full record of their own study documents as detailed in this SOP.

3.4. The principal (or lead) investigator (PI) is responsible for ensuring that they keep all the required documentation for their study as detailed in this SOP. Before commencing the study, the PI (or student supervisor) must ensure that all staff and/or students supporting the study understand the study protocol and the processes that they must follow with regards to the records that must be maintained. Where documents have been updated, they must also ensure that all study staff have seen and are using the latest versions of all documents.

3.5. All individuals, whether staff, student or visitor, conducting/supporting research activities with human material under the auspices of the University of Surrey must ensure that they adhere to this SOP with regards to record management. It is the responsibility of all individuals to report any problems or concerns in relation to the record management of samples to the PI, who should then discuss any problems with the PD or report them on an adverse event and incident form as detailed in UOS_HT_SOP_11, adverse event, and incident reporting.

4. PROCESS

4.1. Record management: records should be managed using the systematic and planned approach detailed in the record and data management processes submitted as part of the application to use human tissue for research as detailed in UOS_HT_SOP_02 applying to use human tissue in research.

4.2 Study folder: PIs should have a central study file containing the following documents in an organised manner that can be easily accessed.

- List of individuals involved in the research project (e.g., delegation log)
- Training records for individuals involved in the research project
- Study Protocol and any amendments
- Evidence of that favourable ethical opinion has been received from an appropriate ethics committee, e.g., the University Ethics Committee or the NHS Research Ethics Committee and date of expiration.
- Participant Information Sheet (where applicable for prospective studies)
- Copy of a blank Consent Form
- Destruction certificates
- Details of collaborators/collaboration agreements
- Material transfer agreements or equivalent document for samples being sent to or received from other organisations.

- Import/export details if samples have come/been sent to countries outside of England, Wales and NI.

These documents should be version controlled with effective dates and include evidence for ethical approval for amendments. The PI should also ensure that all study staff are using the most recent versions of all documents. If paper versions of documents are stored this should be in a secure location on University premises, e.g., a locked cabinet in the PI's office in a dedicated study file.

4.3. **Consent forms:**

4.3.1. Signed participant consent forms should be held in a secure, controlled-access location that is separate to the other study documents.

4.3.2. All study staff should know the location of these but not all should have access. This location should be declared on the application to use human tissue for research and also entered on the sample log or on the electronic tracking system, eLab Inventory as part of the information for each sample.

4.3.3. Any requests from participants for withdrawing from the study should be held with the original consent forms.

4.3.4. A process for linking coded samples to the consent form is required. The link to codes should be kept securely, with controlled access, so that those working in the lab cannot personally identify samples whilst conducting the research, but the code should enable samples to be removed and destroyed if a donor wishes to withdraw their consent. Where a researcher is involved in recruitment as well as sample analysis a 'middle person' should be used to take or code the samples such that the researcher cannot link actual samples to the participants.

4.4. Sample logging: All samples held should also be logged on the electronic sample tracking system, eLab Inventory (UOS_HT_SOP_10), unless the use of an alternative system has been agreed with the PD or DI. PIs should contact HTAlabfacilities@surrey.ac.uk to gain access to this system and arrange training for themselves and all members of their group handling human samples before commencing sample collection or arranging for samples to arrive at the University if coming from a third party.

4.5. Electronic records:

4.5.1. Electronic study documents should be maintained within a university secure storage area, e.g., a University SharePoint site in a dedicated study file. This will ensure the records are held securely and are backed up by the University IT systems.

4.5.2. Personal data should be managed in accordance with the University's Data Protection Policy. Advice can be sought from the University's Information Compliance Unit.

4.5.3. Removal storage devices (external hard drives, USB sticks etc.) should only be used if essential. If removable storage devices must be used, ensure the device is encrypted, and that any documents created or accessed on it are password protected. Any records related to human samples must be downloaded from the removable storage device to a University secure storage area as soon as practicable to ensure the information is backed up and can be recovered in the event of the device being lost.

4.6. On completion of research, where appropriate, research data needed to reproduce the results of the study should be deposited for open access purposes. The library can advise further on open access. All study records and data should be held in accordance with the University's Open Research Policy, which states that outputs and research data will be retained in an appropriate format for a period of at least 10 years or as required by funders, professional or regulatory bodies (whichever is longer).

5. ASSOCIATED DOCUMENTS

UOS_HT_SOP_02: Applying to use human tissue in research
UOS_HT_SOP_03: Training requirements for using human tissue.
UOS_HT_SOP_10 Human tissue sample labelling, storage and tracking

6. REFERENCES

Human Tissue Authority main website: https://www.hta.gov.uk/
Human Tissue Authority Codes of Practice and Standards:
https://www.hta.gov.uk/htahttps://www.hta.gov.uk/hta-codes-practice-and-standards-0codes-practice-and-standards-0

7. TRAINING

Before commencing any work with human tissue samples anyone wishing to do so must have completed all the training detailed in UOS_HT_SOP_03, Training requirements for using human tissue.

8. USEFUL ABREVIATIONS

HTA – Human tissue authority
HRA – Human Research Authority
HT Act – Human Tissue Act
LH - Licence holder
DI- Designated individual
RIGO – Research Integrity and Governance Office
HTROG – Human Tissue Research Operations Group
PD- Person Designate
SOP-Standard Operating procedure
AE/I - Adverse event or incident
GCP – Good Clinical practice
MTA – Material Transfer Agreement
REC – Research Ethics Committee
UEC- University Ethics Committee

9. REVISION HISTORY

Version number	Revision details	Author	Date
1.0	New document (UOS_HTA_SOP_011)	Ferdousi Chowdhury	20.01.2020
2.0	Major revision including new numbering (UOS_HT_SOP_09)	Linda McLatchie	03.06.2023