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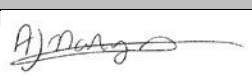
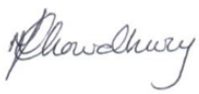
Approval History				
Version 1.0	Name	Role	Signature	Date
Written By:	Abbe Martyn	Hub PD		12.12.2019
Approved By:	Ferdousi Chowdhury	Head of RIGO		20.12.2019
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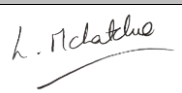
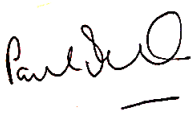
Revised by:	Linda McLatchie	Hub PD (acting)		03.06.2023
RIGO approval:	Gill Fairbairn	Interim Director R&I Services		26.06.2023
DI approval:	Paul Townsend	DI		19.06.2023

1. INTRODUCTION

The proper management of human material in research is an integral component of good research practice and ensures that samples are used and stored safely and securely with respect to the donor's wishes and in accordance with the relevant legislation and that the integrity of the samples are not compromised so that the data produced is reliable and accurate.
It is a requirement of the Human Tissue Act (HT Act), the Medicines for Human Use (Clinical Trials) Regulations, the UK Policy Framework for Health and Social Care Research and professional and ethical frameworks, for samples to be labelled, stored and tracked to an appropriate standard. The Human Tissue Authority's (HTA) Code of Practice for Research sets out the Governance and Quality Systems Standards and Traceability Standards that must be followed. This includes ensuring that there is full traceability from the point of sample collection to final disposal/disposition.
Any human samples being used under the auspices of the University of Surrey must therefore be labelled, stored and tracked in accordance with this standard operating procedure (SOP).
The procedures set out in this SOP are based on the HTA Codes of Practice and applies to all human tissue research taking place at the University.

2. SCOPE

This SOP applies to all projects (including those with Research Ethics committee (REC) approval) using any type of primary human material including material that is considered relevant by the HT Act, any non-relevant human material, human DNA, RNA, any human biological fluids and any cell lines being derived by the researcher from primary material.
All individuals, whether staff, student or visitor, conducting research with human material under the auspices of the University of Surrey must comply with 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* and that all researchers meet the HTA standards for sample labelling, storage and tracking to ensure full traceability.

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. They are responsible for supporting the training of individuals that collect, store or use any human material including training in the use of the electronic sample logging system, eLab Inventory. They are also responsible for allocating and monitoring human sample storage locations at the sites registered under the University's Human Tissue licence.

3.3 The Human Tissue Research Operations Group (HTROG) is the governing body overseeing all handling of human tissue under the HTA licence.

3.4 Research Integrity Governance Office (RIGO) are responsible for notifying both the PI and the hub PD when a study that has been registered with them has appropriate ethical approval for sample collection and/or transfer to begin. They are also responsible for maintaining a central log of storage areas.

3.5. The Principal Investigator (PI) is ultimately responsible for ensuring all samples in their study are labelled and tracked to the required standard and for ensuring full traceability.

3.6 All individuals working with human material must ensure that they adhere to this SOP with regards to labelling, storing and tracking their samples. It is the responsibility of all individuals to report any problems or concerns in relation to the labelling, storage and tracking of their samples to the Person Designated (PD). All individuals collecting, storing or using human tissue for research under the University's HTA research licence are accountable to the relevant PD(s) and the Designated Individual (DI).

4. PROCESS

4.1 Sample labelling

4.1.1 All samples must be labelled with an appropriate label type for the storage and downstream processing conditions, (e.g., cryo-labels for cold storage to reduce the risk of labels falling off over time, moisture resistant etc.) and appropriate ink (e.g., waterproof, IPA resistant etc.) with the following details:

- Unique identification number
- Full date of collection
- Sample type (full word or letter identifier, e.g., S=serum)
- Study reference number/protocol number

4.1.2. Unless samples are being sent to a hospital or local medical laboratory (e.g., safety samples) there should be no personal information of any kind (D.O.B, initials, names etc.) relating to the study participant anywhere on the sample itself, or the container the sample is stored in. Instead, the unique identification number should be linked-anonymously to the participant, with the code held securely within the University's premises e.g., on a secure access document on a University's SharePoint site or in a locked filing cabinet on site. This code should only be available to study staff on a need-to-know basis. This will allow samples to be removed and disposed if a donor wishes to withdraw their consent at any time but without risking de-identification within the lab.

4.1.3. The unique identification number must identify individual samples down to the aliquot level; therefore, all subdivisions of a sample should reference the master sample number. The format being used to generate the unique identification number must be clearly documented in a study specific working document and preferably in the study protocol.

An example of sample numbering could be:
ABC/001/01/U/01; where:

- ABC = Study ID or name
- 001 = Participant number
- 01 = Time point
- U = Sample type (U=Urine)
- 01 = Aliquot number

4.2. Sample Collection/Receipt

4.2.1 If samples are being collected directly by the research team, they should be labelled in accordance with section 4.1 at the time of collection.

4.2.2 If samples are being received by the research team following collection by someone else, the researcher must check the samples are as detailed in the accompanying log and labelled appropriately **as soon as they receive them** and confirm to the sender that the samples have been received and checked. If there are any inaccuracies, the sender should be notified **immediately,** and details of any inaccuracies discussed to clarify the cause, e.g., samples missing because it wasn't sent or samples lost in transfer etc., incorrect volume, incorrect ID, sent at incorrect temperature etc. These discrepancies should then be added to the notes section on eLab Inventory or excel log sheet and the sample inventory sent with the samples. In the event of any sample loss or compromise of sample integrity this should also be reported to the PD via an adverse event and incident form (UOS_HT_SOP_11).

4.2.3 The details of all samples received must be entered on to the electronic tracking system, eLab Inventory, (or agreed alternative) as soon as possible after receipt. This should be within five working days wherever possible and always before the samples are used. If the quantity of samples or other factors means that researchers expect a delay in adding the samples to the system of more than a month, they should seek help with this process by emailing HTAlabfacilities@surrey.ac.uk.

4.2.4. Any inaccuracies in labelling at the time of receipt and the cause of inaccuracies must be logged. If samples need to be disposed of (e.g. due to incorrect transportation) the samples should still be entered onto eLab Inventory system but the disposal section completed with additional notes to explain the issues. They can then be deleted from the storage area section of eLab Inventory and will move to the archive section to maintain full traceability.

4.2.5 If samples need processing and/or aliquoting before storage, this should be detailed in the study protocol or working document and all steps should be fully logged to the aliquot level. It is the PI's responsibility to ensure that these records are kept, and any deviations reported, and that once the samples are ready to be stored, they are entered onto the electronic tracking system (or equivalent) as detailed above in 4.2.3.

4.3. Sample Storage

4.3.1 Suitably maintained and monitored storage, as detailed in UOS_HT_SOP_12, to hold human tissue samples is available in designated storage areas, offering -196°C (LN_2), -80°C, -20°C, 4°C and room temperature storage.

4.3.2 Allocation of these storage spaces is made by the local Laboratory Manager under the direction of the PD. Different storage locations will be allocated for samples being held under the HTA licence and for NHS REC approved studies.

4.3.3 All samples should be stored in appropriate containers, such as cryovials for cold storage and containers should not be over-filled.

4.3.4. Samples should be stored in appropriately sized boxes or bags within the racking or drawer units provided and clearly labelled in a way that will not rub off with time and which will withstand the storage conditions. This labelling should include:

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- Individual box number (unique to that location, no duplicates)
- Study code/protocol number
- Ethics number and expiration date
- Principal Investigator (PI) name (or initials)
- Sample Types

4.3.5 The amount of storage space in each designated area will be monitored by the site PD and discussed with the Hub PD. If there is considered to be insufficient storage space in any area and the local lab manager is unable to provide additional suitably maintained and monitored storage space this will be raised with the DI and HTROG.

4.4. Sample Tracking

4.4.1 The electronic sample logging system eLab Inventory will be used to track all samples held under the authority of the HTA licence except in cases, such as Surrey CRB, where this system does not have the required functionality to handle the quantity and/or turnover of samples and excel spreadsheets will be logged on a SharePoint site instead. Access to eLab Inventory and training can be arranged by emailing: HTAlabfacilities@surrey.ac.uk.

4.4.2 The details of all samples should be entered onto the eLab Inventory system (or alternative) as soon as possible after receipt as detailed in 4.2.3 above. The PI or person in the research team designated sample ownership by the PI should then ensure that the system is updated immediately following any sample use/disposal/transfer including addition of waste Tag and destruction certificate numbers where appropriate. This will ensure that the system is a full and up- to-date sample record and there is full traceability for every sample.

4.4.3. Upon creation or major update of a sample log there should be confirmation of accurate transposition of information by a secondary member of staff.

4.4.4. Any additional aliquots made from initial samples should be entered as new samples on the system but given unique identifiers that allow them to be connected to the original sample as detailed in 4.1.3.

4.4.5. When entering samples onto the eLab Inventory system the following essential information is be required:

- Sample type
- Precise Storage location
- Name = Unique sample identifier
- Study ID
- University ethics number
- Ethics expiration date
- Principle investigator
- Date of sample collection
- Location of consent forms
- Details of sample receipt (date, who took receipt etc.)
- Whether the samples have been disposed of

The system also allows additional information about sample quantity, study staff, sample details and any notes to be added, which should be included whenever possible. Details of transportation and delivery can be added to the notes section but any documents relating to this should be kept in the study folder as detailed in UOS_HT_SOP_09, Human Tissues records management.

5. ASSOCIATED DOCUMENTS

UOS_HT_SOP_03 Training requirements for using human tissue.
UOS_HT_SOP_09 Human tissue records management
UOS_HT_SOP_12 Maintenance and monitoring of storage areas

6. REFERENCES

Human Tissue Authority (HTA) Codes of Practice

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 (formally: UOS_HTA_SOP_012)	Abbe Martyn	12.12.2019
2.0	Major revision including new numbering UOS_HT_SOP_10	Linda McLatchie	03.06.2023