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Approval History				
Version 1.0	Name	Role	Signature	Date
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Approved By:	Ferdousi Chowdhury	Head of RIGO		13.03.2020
Version 2.0	Name	Role	Signature	Date
Revised by:	Linda McLatchie	Hub PD (acting)		03.06.2023
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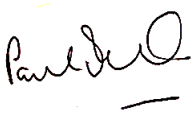
DI approval:	Paul Townsend	DI		19.06.2023

1. INTRODUCTION

The Human Tissue Act (HT Act) requires organisations collecting relevant human tissue from study participants to demonstrate effective management and suitable infrastructure as part of their quality and governance systems. These requirements encompass the facilities used, the training and competence of the personnel collecting tissue and the methods used for collection. The standards set out in the Human Tissue Authority (HTA) Codes of Practice ensure compliance with the HT Act.

The premises used must be safe and fit for the purpose of collecting human tissue. It is also a requirement to conduct staff training and maintain up-to-date staff training records, including attendance records, inductions for new staff and an assessment of competency. This standard operating procedure (SOP) is based on the HTA Codes of Practice and describes the University's requirements for collecting human tissue samples for research purposes.

2. SCOPE

This SOP applies to all projects, including those approved by a Research Ethics Committee, collecting any type of primary human tissue from participants on University Premises. This includes material that is considered relevant by the HT Act, any non-relevant human material, and any human biological fluids. 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.

Researchers collecting tissue at other sites should follow the practices of that location.

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 the conditions of the licence are complied with by all those who are collecting and storing human tissue.

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 working with lab managers to make sure that all those collecting and working with human tissue have attended training and have had a local lab induction to the areas in which they will be collecting and working with human tissue. Also, as part of the auditing process they support the DI under the direction of University's Human Tissue Research Operations Group (HTROG) in monitoring the sites used for human tissue collection registered under the University's Human Tissue licence.

3.3. The University's Biological Safety Officer is responsible for checking that appropriate H&S risk assessments are in place and followed where there is a health risk to either the person collecting the sample or the study participant such as if either party has a viral infection.

3.4. The Principal Investigator (PI) is responsible for ensuring that only appropriately trained individuals are allowed to collect and handle human samples for their studies. They must ensure that the collection method is documented in the study protocol and adheres to current best practices and that only those fully trained in phlebotomy (see section 7) are allowed to take blood samples and that this is only done in approved locations as detailed in 4.2 below. They should also keep a log of any recommended vaccinates for personnel collecting samples.

3.5. All individuals working with human tissue and material must ensure that they adhere to this SOP with regards to collection of human tissue from study participants. This includes ensuring samples are fully logged from collection through use to disposal. It is the responsibility of all individuals to report any problems or concerns in relation to collection of tissues to the Person Designated (PD) in the case of samples stored under the HTA licence and to the Research Integrity and Governance Office (RIGO) for all samples with research ethics committee approval.

4. PROCESS

4.1. **Safety requirements.** The PI should prepare a H&S risk assessment, to cover any risks to the researcher during the collection and use of human samples and have this approved with their local H&S advisor. They should also agree on the category of lab where the work can take place and any additional safety measures that are required before commencing any human tissue sample collection including any recommended vaccinations.

4.2. Location. All samples must be collected in clean rooms that have not been used for laboratory work with chemicals or biological agents, by personnel who have had appropriate training for the method being used. Rooms must be of adequate size to allow free access around the study participant during the procedure. Specific procedures for collection of samples must be documented before the study commences and must be reviewed to confirm the proposed collection area is appropriate.
Tissue biopsies and blood samples requiring phlebotomy (blood from a vein) including those requiring canulation may only be taken in areas designated for phlebotomy which meet the criteria below:

- Rooms should be private or have moveable screens or curtains to limit interruption.
- Flooring should be intact, washable non-slip surface with coved edges and no carpets.
- Furnishings and equipment should be kept to a minimum to facilitate effective cleaning and prevent dust build up. Work surfaces should be intact, seamless, and easily washable. Open shelving is not recommended.
- There must be ventilation to ensure the comfort of operator and patient. Air movement induced by any form of mechanical ventilation must flow from 'clean' to 'dirty' areas, i.e., air must not be drawn into a phlebotomy room from a laboratory.
- There must be hand wash basins with hot and cold running water in the room or close vicinity.
- Disposable hand towels must be available.
- Hand basins must comply with HBN00-10.
- Adequate storage for consumable supplies, preferably in closed cupboards.
- A telephone must be available to call for help in case of an emergency.
- An up-to-date list of local first aiders should be clearly displayed
- Close proximity to assistance in case of fainting or other medical problems.

4.3. Equipment. The following equipment must be available in rooms to be used for tissue biopsies and phlebotomy and must not have been stored or used in a laboratory handling chemicals or biological materials:

- Soap/alcohol rub.
- Single use non-sterile gloves (EN374 micro-organism resistance level 2) in appropriate sizes.
- Sharps bin of appropriate size
- Clinical waste bin, to be emptied as often as required.
- Appropriate single use in-date hypodermic needles or cannulas and collection devices (preferably conforming to Sharp Instruments in Healthcare Regulations 2013, https://www.hse.gov.uk/pubns/hsis7.pdf) for phlebotomy.
- Appropriate plasters, dressings, and sterilisation wipes.
- Paper towels.
- Disinfectant wipes or spray bottle of suitable disinfectant
- Pen to label collection and sample tubes.
- Trays for organising phlebotomy or tissue collection equipment.
- Sample box for transportation of samples, must be compliant with UN PI650.
- Chair or couch with wipe-clean surface and armrest or pillow to support the study participant's arm if phlebotomy is being performed. If pillows are required these must be wipe-clean vinyl covered and impermeable to fluids. A separate chair for the phlebotomist (person taking blood) also with a wipe-clean surface should be available.

4.4. Records and Labelling. Before collecting tissue, 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 in accordance with UOS_HT_SOP_09 Human Tissue Records Management.

4.5. Collection procedures. The study protocol should include details of the sample collection procedure and this should be read and followed by all those collecting samples.

4.5.1 **Blood**. When performing cannulation and phlebotomy to collect blood samples of more than 220mls the participant should be lying on a couch. For smaller samples and finger pricks the participant may be sitting but there should be sufficient space to lie them down should they feel faint.

4.5.2 **Tissue biopsies** should only be taken with the participant lying on a couch.

4.5.3 **Saliva** samples should be collected with the participant sitting. In the case of larger volumes, it may be most suitable to have the participant leaning over a collection vessel placed on a table.

4.5.4 **Urine and faeces** should be collected by providing participants with appropriate disposable sample collection equipment to collect their own urine or faeces wherever possible. Single-use non-sterile gloves (EN374 micro-organism resistance level 2) must be worn when handling faecal collection equipment.

4.6. Emergency procedures. If a sharps injury or exposure to bodily fluids or faeces occurs:

- Encourage bleeding but do not scrub the wound as this may increase tissue damage.
- Wash any wound or contaminated skin with soap and clean water and cover with a sterile dressing.
- If blood, bodily fluid or faeces is splashed into the eye or mouth, immediately wash out tap water or saline.
- If on University premises and first aid treatment is required contact the local first aider. **If emergency medical treatment is needed dial 3333 from a campus phone.**
- If the blood or bodily fluid is suspected or known to contain Hazard Group 3 pathogens (e.g. HIV, Hepatitis B or C), follow the emergency procedures relevant to the pathogen and proceed to the nearest Hospital Accident & Emergency Department. At A&E, inform the receptionist that you have had a body fluid exposure from either a known or suspected infected tissue or blood sample.
- The person responsible for taking the samples should make sure that the incident is reported via the H&S incident reporting system to Occupational Health as soon as reasonably practical.
- They should also report the incident as detailed in UOS_HT_SOP_11, human tissue adverse event and incident reporting.

5. ASSOCIATED DOCUMENTS

UOS_HT_SOP_03 Training requirements for using human tissue
UOS_HT_SOP_05 Consent and withdrawal for using human tissue
UOS_HT_SOP_09 Human Tissue Records Management
UOS_HT_SOP_11 Human tissue adverse event and incident reporting
UOS_HT_SOP_13 Disposal of Human Tissue Samples
FHMS-SOP-97 Safe handling and disposal of sharps

6. REFERENCES

Health Building Note HBN 00-10 Part C : Sanitary Assemblies, Department of Health
Essential Practice for Infection Prevention and Control, Royal College of Nursing, 2017
WHO guidelines on drawing blood: Best practices in phlebotomy

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. Also, anyone using or handling sharps is also advised to read FHMS-SOP-97, safe handling and disposal of sharps.

All those conducting phlebotomy must be trained in accordance with the NHS best practices and attend training given by either a NHS Trust or certified training provider. Guidance on specific training content is given by the National Association of Phlebotomists (http://www.phlebotomy.org). A record of training and competence must be obtained such as an NHS Certificate of Competence (Competence: observation). A copy of the certificate should be sent to RIGO so that they can keep a record of those with up-to-date Phlebotomy training. Competence must be maintained by either refresher training (for infrequent phlebotomy activities) or regular practice and evaluation of phlebotomy skills.

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 Transport Agreement
REC- Research Ethics Committee
UEC – University Ethics Committee

9. REVISION HISTORY

Version number	Revision details	Author	Date
1	New document	Chris Bradley	13.03.2020
2	Major Revision	Linda McLatchie	03.06.2023