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Approval History				
Version 1.0	Name	Role	Signature	Date
Written By:	Ferdousi Chowdhury	Head of RIGO		26.03.2020
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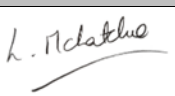
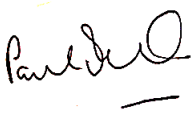
Revised by:	Linda McLatchie	Hub PD (acting)		03.06.2023
RIGO approval:	Gill Fairbairn	Interim Director, R&I Services		26.06.2023
DI approval:	Paul Townsend	DI		19.06.2023

1. INTRODUCTION

The regulations for working with human material are complex and there are several regulations and standards that govern the use of human material including the Human Tissue Act (HT Act), the Human Fertilisation and Embryology Act, the Data Protection Act, the UK Policy Framework for Health and Social Care in addition to other requirements such as the common law for consent, material transfer agreements, transportation prohibitions and health and safety standards.

The University has a Human Tissue Authority (HTA) Research Licence and in accordance with this has in place a governance framework to ensure the use of human material for research meets the necessary legislation and ethical and governance standards. This governance framework includes a quality manual (listed as UOS_HT_SOP_01) and a set of standard operating procedures (UOS_HT_SOP_02-14) that set out the procedures that must be followed when researchers intend to use human material for research purposes. The HTA Code E for Research requires a documented system of audit to be in place to cover all licensable activities. This SOP describes the University's system of audit for human tissue that is held under the authority of the HTA licence research to demonstrate human tissue research is conducted in accordance with the HTA standards and the University's governance framework.

2. SCOPE

Any human samples that are being held under the authority of the human tissue licence are subject to regular audit, as are the premises where they are held. Audits may be planned or conducted without warning. All individuals, whether staff, student, or visitor, conducting research with human samples must co-operate during audits. Non-cooperation may be considered research misconduct.

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 University is meeting the HTA licensing standard, GQ2c, that requires an audit to be conducted in an independent manner at least every two years across all licensable activities and ensuring that any non-compliance is identified and corrected.

3.2. The Persons Designated (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 should assist with the auditing process under the guidance of the DI and keep the DI informed of any problems or breaches identified.

3.3. The University's Human Tissue Research Operations Group (HTROG) is the governing body that is responsible for overseeing the auditing process.

3.4. The Principal Investigator (PI), or student supervisor, is responsible for ensuring the actions in response to audit findings are satisfactorily completed in the required timeframe. This may require delegation of the actions to others within the research team.

3.5. Research Integrity and Governance Office (RIGO) is responsible for keeping a central log of audit reports and a separate record of any problems or breaches identified during the audit process or at any other time. It also acts in an advisory capacity to assist with the auditing process and can conduct its own audit at any time if there are concerns.

3.6. All individuals working with human samples must co-operate during audits, including providing records and documentation when requested by the auditor. It is the responsibility of individuals to complete any actions delegated to them by the auditor within the timeframe set. They may seek the support of the PD and RIGO when completing actions in response to any audit findings.

4. PROCESS

4.1. Auditor: Auditors may be the DI or other persons acting on their behalf. They should be independent of the activities and documentation being audited. Where possible PDs and researchers should be involved in the auditing of each other's areas to promote independence and sharing of ideas and best practice. Where the auditor is not a PD, one of the PDs should accompany them to aide with documentation and follow-up as detailed in 4.4. No formal qualifications are required but anyone carrying out an audit should have read UOS_HT_SOP_01-14 and the HTA's code E for Research so that they are competent and understand what is required in the areas they are auditing.

4.2. Standards to be audited: The four areas covered by the HTA's licencing standards: Consent, Governance and Quality Systems, Traceability and Premises, Facilities and Equipment will all be audited. The table below gives a guide to the sorts of checks that will be made to ensure that each licencing standard is being followed. These should be made as a combination of horizontal audits looking at one of these areas across all projects or storage areas and vertical audits where an individual project is audited on all areas at once to permit the whole process from consent to sample collection, transport, import/export, logging, storage and disposal to be checked.

4.3. Schedule of audits: Internal audits will be conducted on a rolling basis such that all areas and projects of duration of at least two-years will be fully audited within a two-year period. This will be in addition to any external audit or inspections occurring during this period. Where projects are of shorter duration, than two years, they will be audited in at least one area but if adverse events occur or if the single area audit detects problems a more comprehensive audit will be scheduled. The dates of completed and up and coming audits will be recorded in the Schedule of audit document by the PDs.

4.4. Notification: The auditor will notify the PI or a member of their research team, at least 2 weeks prior to the scheduled audit date to ensure that they are available to provide access to the necessary records and documentation. If they are unavailable on that date, they must try and reschedule the date within a 2-week window or provide an appropriate alternative person to support the audit. Where an adverse event, incident or a report of poor practice is received, an unscheduled audit may be conducted. In these instances, no prior notification will be sent to the PI and they may only be informed on the day. Either the PI or a study representative for them should be present at the audit.

Category	For each study it will be checked that:
Consent	• The version of the consent form in use matches that on the most recent FEO letter • The location of consent forms matches that on the logs • Consent forms for 5 random samples can be produced, are correctly stored and completed with no ambiguities • There is documentary evidence that any consent withdrawal requests have been actioned • The type and number of samples held are in agreement with the approved protocol • For samples from third parties, that the consent form allows these samples to be stored and this consent has been given for all samples received • All staff taking consent have up to date mandatory consent training (UOS_HT_SOP_03)
Governance and quality systems	• Two study documents requested from the required list in UOS_HT_SOP_09, section 4.2. can be produced as evidence that study documents are being held in an organised way • The versions of these documents should match those on the most recent FEO letter. • Ethical approvals are in date • If samples were received/sent to third parties, there is legal document such as a MTA or study contract/collaborator's agreement that fully covers the samples received/sent • All study staff have up to date mandatory training (UOS_HT_SOP_03). • All relevant SOPs have been read and acknowledged on Q-Pulse (or other document record system) by all study staff • If adverse events/incidents have been reported that the corrective follow-up actions have been completed and are being fully implemented.
Traceability	• That a sample tracking log is available • That sample boxes/bags are appropriately labelled as detailed in UOS_HT_SOP_10 • That 5 or more samples chosen at random from the tracking log can be found in the correct location in the storage facility • That 5 or more samples chosen at random in the storage facility are correctly entered on the tracking log. • That 2 or more samples listed as disposed/used on the log are no longer present in the storage facility and that destruction certificates can be produced • That all samples checked are appropriately labelled as detailed in UOS_HT_SOP_10. • That any samples where consent for storage/use has been withdrawn are no longer present. • That where samples have been received or sent to a third-party full transport documentation can be supplied, including documentation that samples have been received and checked for damage and accuracy on arrival.
	For each storage facility it will be checked that:
Premises, facilities and equipment	• Storage units are in good working order • Servicing and maintenance records indicate that storage units are being correctly maintained • Locks and monitoring systems are in place and regularly tested • Internal organisation is sufficient to allow easy access to samples • External signage is present to indicate that samples are held under the HTA licence • External signage clearly indicates the location of these samples within the unit • Storage areas are clean and tidy and there is documentation of regular cleaning • Risk assessments are in place and include contingency plans in case of failure of storage units and what to do in the case of emergencies

	• Local lab managers/persons responsible for storage facilities have read, understood and acknowledged on Q-Pulse, UOS_HT_SOP_12, and have attended human tissue training • Equipment needed for human tissue processing has been serviced and is properly maintained.

4.5. **Documentation and follow-up**: The PD either undertaking the audit or accompanying the auditor will update the appropriate audit spreadsheet within the schedule of audits document with the outcome of any audit undertaken. All non-compliance will be logged and where appropriate an adverse event and incident (AE/I) form also completed as detailed in UOS_HT_SOP_11. Follow-up corrective and preventative actions will be added to the audit action tracker and the person responsible for their completion informed by the PD. Where the auditor or PD cannot decide on the corrective or preventative action that should be taken, they will ask the DI or HTROG for advice. Where necessary follow-up visits will be scheduled by the PD to check that actions have been completed or to aid with completion if necessary. The PI must ensure that all corrective actions assigned to them are completed satisfactorily within the timescales agreed. Where actions are not completed, this should be reported to the hub PD who will then report it to HTROG and where necessary, research will be suspended until the audit action has been completed.

4.6. Reporting: The hub PD will submit audit update reports to each HTROG meeting and an annual summary report at the last meeting of each calendar year. Any non-compliance deemed serious enough to be reported on an AE/I form will also have been directly reported to the DI and RIGO as detailed in UOS_HT_SOP_11, human tissue adverse event and incident reporting.

5. ASSOCIATED DOCUMENTS

UOS_HT_SOP_02 Applying to work with human tissue
UOS_HT_SOP_03 Training requirement for using human tissue
UOS_HT_SOP_10 Human tissue sample labelling, storage and tracking
UOS_HT_SOP_11 Human tissue adverse event and incident reporting
UOS_HT_SOP_12_ Maintenance and Monitoring of Storage Areas
Code E for Research (https://content.hta.gov.uk/sites/default/files/2020-11/Code%20E.pdf)

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/htacodes-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.

In addition, any persons conducting internal audits must have read and understood all of the SOPs, i.e., UOS_HT_SOP_ 01-14 and the HTA document Code E for Research.

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	Ferdousi Chowdhury	03.04.2020
2.0	Major revision	Linda McLatchie	03.06.2023