UNIVERSITY OF LEICESTER

Paper copies of this document might not be the most up to date version.

The definitive version of all University of Leicester (UoL) Human Tissue Authority (HTA) Standard Operating Procedures (SOPs) appear online, not in printed form, to ensure that the up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the Research Governance Ethics and Integrity (REGI) Website.

SOP: HTA-A1024-UoL

Version Number: 1.0

Effective Date: January 2021

Supersedes: HTA-1009-UoL

Last Review Date: Jul 2020 Next Review Date: Jan 2023

Development and Approval Record for this Document

Role	Name	Job title	Signature	Date
Author	Amanda Sutcliffe	HTA Monitoring Officer		08/02/2021
Reviewer	All members of the College of Life Sciences Human Tissue Governance Committee	College of Life Sciences Human Tissue Governance Committee	N/A	N/A
Authoriser	Professor Peter Bradding	Designated Individual		08/02/2021

Background

This document has been produced in accordance with the Human Tissue Act (HT Act). It should be read in conjunction with the University's 'Policy on Compliance with the Human Tissue Act in Research', HTA Standards and the HTA Codes of Practice. The HT Act must be followed by all researchers working under the UoL Research Licence and those transferring HTA relevant material as part of an ethically approved research project.

Purpose and Scope

This SOP describes the process of response to, and escalation of, any form of non-compliance to the HT Act 2004; including audit findings and whistleblowing.

This SOP applies to all individuals working under the UoL Research Licence, REGI Office staff and members of the Human Tissue Governance (HTGC) Committee.

Definitions:

CAPA	Corrective Action Preventative Action
DI	Designated Individual
HTA	Human Tissue Authority
HTGC	Human Tissue Governance Committee
LH	Licence Holder
PD	Persons Designated
PI	Principle Investigator
REGI	Research Governance Ethics and Integrity
SLT	Senior Leadership Team
SOP	Standard Operating Procedure
UoL	University of Leicester

Roles and Responsibilities

It is the responsibility of the Designated Individual (DI) to ensure that suitable practices take place within the licensed establishment that comply with the HTA Codes of Practice.

The HTA Monitoring Officer is responsible for ensuring this SOP remains fit for purpose taking into consideration any changes in legislation and any changes to the HTA Codes of Practice for research.

It's the responsibility of the Persons Designated (PD) to assist the DI in implementing and adhering to the governance processes.

All researchers / Principle Investigator (PIs) involved in using relevant material that have been officially transferred to the UoL HTA licence must comply with all the HTA SOPs. Where there has been an incident of non-compliance, it is their responsibility to report this to the PD to ensure the non-compliance can be addressed and resolved as accordingly.

Definitions

Forms of non-compliance are described as critical, major, minor or other in line with audit and inspection processes of regulatory authorities.

Critical non-compliance includes instances where:

A shortfall which poses a significant risk to human safety and/or dignity or is in breach of the HT Act 2004 or associated directions; or

A contribution of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

Major non-compliance includes instances of a non-critical shortfall that:

- Poses a risk to human safety and/or dignity; or
- Indicates a failure to carry out satisfactory procedures; or
- Indicates a breach of the relevant codes of practice, the HT Act, and other professional and statutory guidelines; or
- Has the potential to become a critical shortfall unless addressed; or
- A combination of a number of minor shortfalls, none of which is major in its own right, but which together could constitute a major shortfall and should be explained and reported as such.

Minor non-compliance includes instances of:

- A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards/good practice.

An "Other" finding can be identified as:

- Where a shortfall has not been identified, but areas for improvement have been identified, leading to the auditor providing advice to the auditee on improvements.

Procedure to follow

Non-compliance identified by whatever means, will be investigated using appropriate monitoring and audit processes by the REGI Office. The procedures described below are general, and each instance of non-compliance will be assessed and responded to on a case by case basis. Failure to respond to reported non-compliance will result in escalation from minor/other to major to critical.

Critical Non-Compliance

On identification of critical non-compliance as defined in the definitions, all relevant personnel will be alerted by the Designated Individual (DI) and/or REGI Office.

Depending on the nature of the non-compliance the use of samples may be suspended with immediate effect and will prompt an immediate audit in line with SOP *HTA-A1019*.

The relevant PDs, or Principal Investigator (PI), must respond within twenty (20) working days from the date of receipt of a detailed notification. It is expected that the Corrective Action/Preventative Action (CAPA) Template as detailed in SOP *HTA-A1019* will be used in all cases.

This will ensure that action taken is clearly documented. It is not necessary that all the action will have been taken within the twenty (20) working days, but it is expected that a plan of completion is outlined.

Non-response within this timeframe will cause the non-compliance to be escalated to the Licence Holder (LH) and appropriate higher University Management as detailed in the HTG Governance Organisation chart as demonstrated in figure 1.

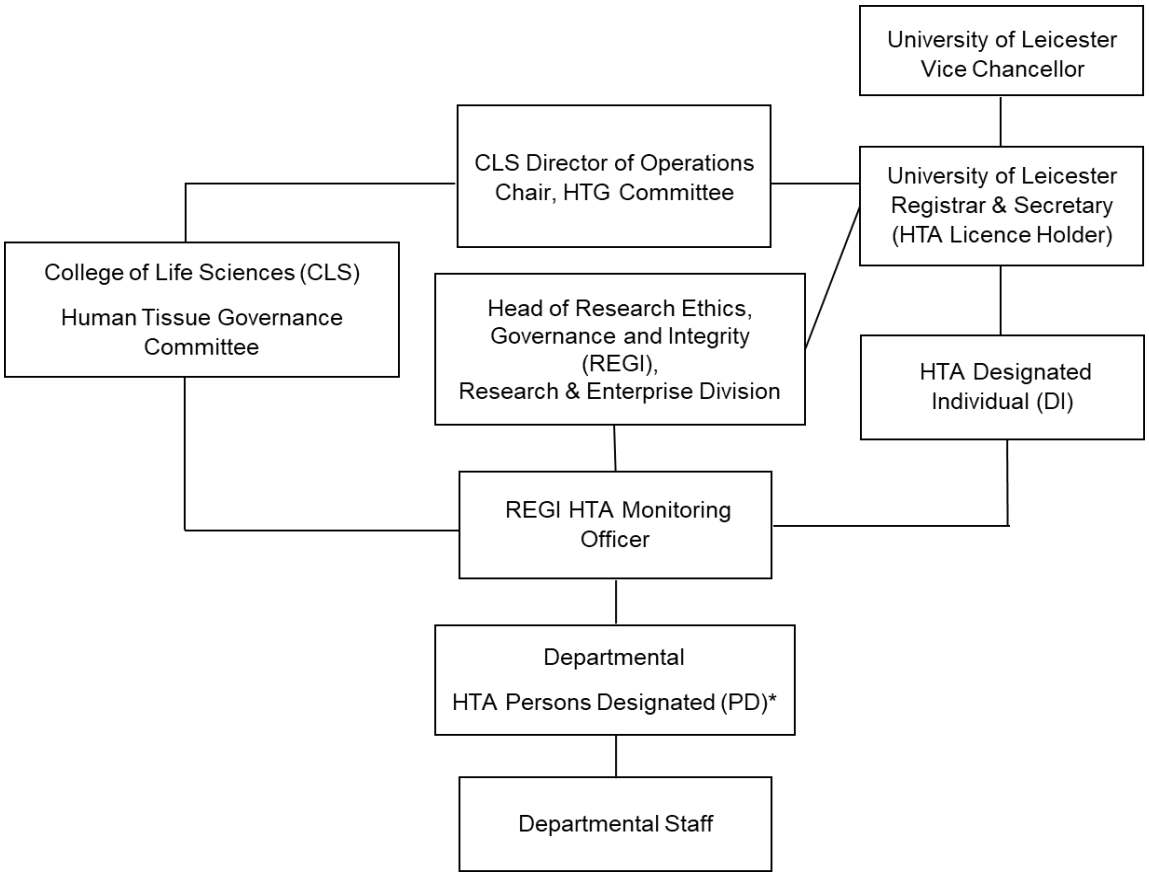

Figure 1. Details the HTG Organisational chart reporting lines. Departmental staff report to departmental PDs, then to the HTA Monitoring Officer. Issues will be discussed in the HTG committee, which includes the DI and the CLS Director of Operations. The HTA Monitoring Officer reports both to the DI and the REGI Manager. The DI and the REGI manager report to the Senior Leadership Team (SLT).

Non-response within this timeframe will lead to the suspension of the use and quarantine of samples in all cases, and possible suspension of associated trials in consultation with the REGI office.

Major Non-Compliance

On identification of major non-compliance as defined in section 4, all relevant personnel will be alerted by the DI and/or REGI Office.

Dependent on the nature of the non-compliance the use of samples may be suspended with immediate effect and may prompt an immediate audit in line with SOP *HTA-A1019*.

The relevant PD or PI must respond within twenty (20) working days from the date of receipt of a detailed notification. It is expected that the Corrective Action Preventative Action Template as detailed in SOP *HTA-A1019* will be used in all cases. This will ensure that action taken is clearly documented. It is not necessary that all the action will have been taken within the twenty (20) working days, but it is expected that a plan of completion is outlined.

Failure to respond within twenty (20) working days will prompt a reminder to respond within a further ten (10) working days.

Non-response within this timeframe will cause the non-compliance to be escalated to a critical non-compliance and the LH and appropriate higher SLT would be notified as appropriate.

Non-response within this timeframe will lead to the suspension of use and quarantine of samples in all cases, and possible suspension of associated trials in consultation with the REGI Office. (*SOP HTA-A1019*).

Failure to respond to notification of non-compliance will constitute escalation to a critical non-compliance as per the critical non-compliance workflow.

Minor or other Non-Compliance

On identification of minor/ other non-compliance, that is neither major nor critical as defined in section 4, all relevant personnel will be alerted by the DI and/or REGI Office.

The relevant PD or PI must respond within twenty (20) working days from the date of receipt of a detailed notification. It is expected that the CAPA template as detailed in *SOP HTA-A1019* will be used in all cases. This will ensure that action taken is clearly documented. It is not necessary that all the action will have been taken within the twenty (20) working days, but it is expected that a plan of completion is outlined.

Failure to respond to notification of non-compliance will constitute escalation to a major non-compliance as per the major non-compliance workflow.

Closure of Non-Compliance Issue

On completion of all CAPA, and approval by the DI, the non-compliance will be considered complete and closed.

This table is used to track the development and approval of the document and any changes made on revised / reviewed versions

Review Record

Date	Issue Number	Reviewed By	Description Of Changes (If Any)

Distribution Record:

Date	Name	Department	Received Y/N