University of Leicester Research Governance Office Standard Operating Procedures relating to the Human Tissue Act 2004

SOP HTA A-1024 UoL

Procedure in the event of non-compliance

Version 2.0

Effective Date: 01 December 2024

This SOP will be implemented in line with this document's effective date for all UoL HTA SOPs.

1.0 Introduction

This document has been produced in accordance with *The Human Tissue Act 2004* (HT Act). It should be read in conjunction with the University's 'Policy on compliance with the Human Tissue Act in Research', and the Human Tissue Authority's *(HTA) Codes of Practice*.

This SOP should be followed where there are there is an incident of non-compliance has been identified. The HTA reporting lines are also documented here.

2.0 Scope

This SOP describes the process for responding to an escalating 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 HTA Research Licence, Research Governance Office (RGO) and members of the Human Tissue Governance (HTGC) Committee.

Definitions:

CAPA	Corrective Action Preventative Action
CI	Chief Investigator
DI	Designated Individual
HTA	Human Tissue Authority
HT Act	Human Tissue Act
HTGC	Human Tissue Governance Committee
LH	Licence Holder
PD	Persons Designated
PI	Principal Investigator
RGO	Research Governance Office
SLT	Senior Leadership Team
SOP	Standard Operating Procedure
UoL	University of Leicester

3.0 Definition

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

Critical non-compliance:

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

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:

Shortfalls that:

- Pose a risk to human safety and/or dignity; or

- Indicate a failure to carry out satisfactory procedures; or
- Indicate a breach of the relevant HTA Codes of Practice, the HT Act, or other professional and statutory guidelines; or
- Have the potential to become a critical shortfall unless addressed; or
- Comprise 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:

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

An "Other" finding is defined 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.

4.0 Procedure

Non-compliance identified by any means will be investigated using appropriate monitoring and audit processes by the RGO. 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 through to critical.

4.1 Critical Non-Compliance

On identification of critical non-compliance as defined above, all relevant personnel (DI, HTA monitor, chair of the HTGC will be alerted by the PD and/or RGO.

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

The individuals involved in investigating the non-compliance 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-UoL 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 result in escalation to the Licence Holder (LH) and appropriate higher senior leadership members as detailed in the HTG Governance Organisation chart as demonstrated in figure 1.

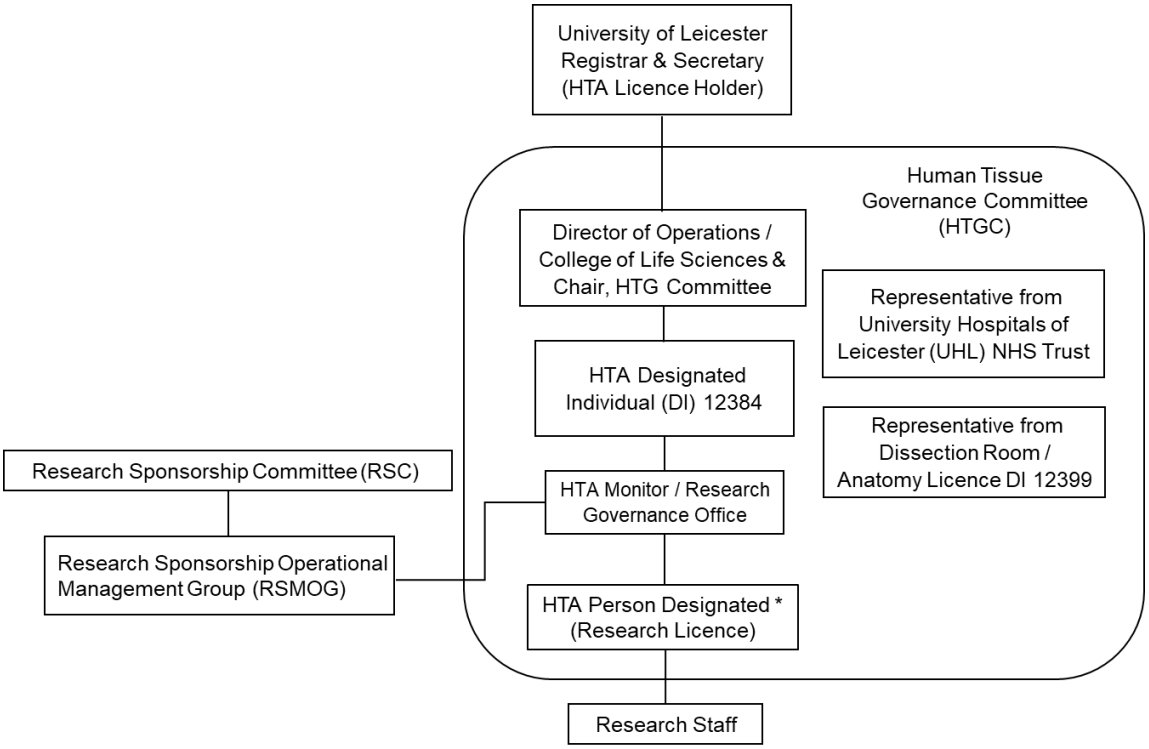

Figure 1. Details the HTG Organisational chart reporting lines. Departmental staff report to departmental PDs, then to the HTA Monitor. Issues will be discussed in the HTG committee, which includes the DI and the CLS Director of Operations and a representative from the University Hospitals of Leicester (UHL) NHS Trust, representatives from the dissection room of the Anatomy licence 12399. The CLS operations manager reports into the University of Leicester Registrar & Secretary (HTA Licence Holder). The HTA Monitor reports both to the DI and the RGO Manager. The HTA Monitor provides a report to the RSMOG committee. Any issues are then escalated by the Head of Research Governance to the Research Sponsorship Committee (RSC).

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 RGO.

4.2 Major Non-Compliance

On identification of major non-compliance as defined in section 4, all relevant personnel (DI, HTA Monitor, Chair of the HTGC) will be alerted by the PD and/or RGO.

Depending 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-UoL.

The relevant PD or CI/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-UoL 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 result in escalation 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 RGO. (SOP HTA-A1019-UoL).

5.0 Responsibilities

Responsibility	Undertaken by	Activity
Chief Investigator (CI) / Principal Investigator (PI)	Chief Investigator / Principal Investigator or their delegate	The Chief Investigator / Principal Investigator is responsible for responding to notifications of non-compliance in line with this SOP.
Person Designated (PD)	Person Designated (PD)	The Person Designated for the area is to help support the Chief Investigator / Principal Investigator in investigating the non-compliance.
Research Governance Office (RGO)	HTA Monitor or equivalent role in RGO	Undertake to audit sample-based studies, according to risk assessment which will be influenced by findings of non-compliance. Will advise in respect of non-compliance. Will escalate action if response is insufficient.
Designated Individual (DI)	Designated Individual (DI)	Ensure appropriate practices takes place in the licenced establishment.

6.0 Development and approval record for this document

This table is used to track the development and approval of the document.

Author	Job title	Reviewed by	Approved by	Date approved
Amanda Sutcliffe	Human Tissue Act Monitor	UoL Human Tissue Governance Committee (HTGC)	Professor Peter Bradding (Designated Individual) 	28/11/2024

7.0 Review Record

This table is used to track the changes made on revised/reviewed versions.

Date	Issue number	Reviewed by	Description of changes (If any)
November 2024	v2.0	A Sutcliffe	• Administrative changes • Slight change to Introduction and scope • Minor typographical changes • Update to Organogram