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

SOP HTA-A1018 UoL

PD Masterfiles

Version 2.0

Effective Date: December 2024

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

Please note the appendices associated with this SOP may be subject to interim changes. Please ensure that appendices are downloaded from the RGO webpages prior to use to ensure the latest version of the document is being used.

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 has been produced in accordance with The Human Tissue Act 2004 (HT Act). The HT Act and Human Tissue Authority (HTA) Codes of Practice mandate that there should be a systematic and planned approach to the management of records. This SOP should also be read in conjunction with all other UoL HTA SOPs.

2.0 Scope

The purpose of this SOP is to describe the procedure for creating a Person Designated (PD) Master File that will hold all records for stored HTA-relevant material for a particular area, thus ensuring it is inspection ready at all times.

Definitions:

CI	Chief Investigator
DI	Designated Individual
HRA	Health Research Authority
HT Act	Human Tissue Act
HTA	Human Tissue Authority
PD	Person Designated
PI	Principal Investigator
RGO	Research Governance Office
SOP	Standard Operating Procedure
UoL	University of Leicester

3.0 Procedure

The content of the PD Master File is shown in the PD Master File template file that can be located on SharePoint RGO webpages. The PDs should work with the Chief/Principal Investigators (CI/PI) in their area to ensure that the PD Master File is up to date at all times. PD Master Files will be subject to audit by the RGO bi-annually (every 2 years) and by internal departmental self-inspection. Please refer to the "Auditing HTA licenced areas" SOP HTA-A1020-UoL.

Any new areas that come under the HTA Research Licence must have a PD Master File in place within 3 months. This will be subject to audit by the RGO once set up and then bi-annually thereafter. It is recommended that PDs spot check the accuracy of the information within their PD Masterfile's on an annual basis to ensure they are accurate.
Masterfile documents can be either paper versions or electronic. Electronic versions are preferable. Where electronic versions are used, please ensure these are accessible to the HTA monitor for inspection purposes.

3.1 Non-Compliance

In the event of non-compliance refer to the Non-Compliance SOP HTA-A1024-UoL.

4.0 Responsibilities

Responsibility	Undertaken by	Activity
Chief Investigators (CI) / Principal Investigators (PI)	Chief Investigators (CI) / Principal Investigators (PI) / delegates	Ensuring PDs are kept in the loop about any applicable changes with their sample collections.
Research Governance Office (RGO)	HTA Monitor or equivalent role in RGO	Update Masterfile documents to incorporate any changes in HTA legislation.
Person Designated (PD)	Person Designated (PD)	Update contents of PD Masterfile's
Designated Individual (DI)	Designated Individual (DI)	Ensure suitable practices take place in the licenced establishment

5.0 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	HTA Monitor	UoL Human Tissue Governance Committee (HTGC)	Professor Pete Bradding 	28/11/2024

6.0 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	• Clarity to auditing of PD Masterfiles to bi-annually by the RGO • Formatting of the Masterfile to either be paper format or electronic and accessibility for auditing