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-A1018-UoL

Version Number: 1.0

Effective Date: January 2021

Supersedes: HTA-1010-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 SOP has been produced in accordance with The Human Tissue Act 2004 (HT Act). The HT Act describes 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.

Purpose and Scope

The purpose of this SOP is to describe the procedure for creating a Persons Designated (PD) Master File that will hold all HT Act records 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	Persons Designated
PI	Principle Investigator
REGI	Research Governance Ethics and Integrity
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 or changes to the Codes of Practice for Research.

It's the responsibility of the PD to assist the DI in implementing and adhering to the governance processes and ensuing all research activities relating to HTA material are conducted appropriately within their area.

All researchers involved in using HTA relevant material have the responsibility to ensure all the HTA SOPs are adhered to at all times.

Procedure to follow

The content of the PD Master File is shown in *PD Master File* folder. 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.

Any existing PD Master Files will be subject to audit by the REGI Office annually and by internal departmental self-inspection. Please refer to the auditing HTA licenced areas SOP *HTA-A1020*.

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 REGI Office once set up and then annually thereafter.

All the template forms for the PD Master File are provided within the PD Master File Template.

Non-Compliance

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

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)

UNIVERSITY OF LEICESTER

SOP identifiers	SOP details
ID number	HTA-A1018-UoL
Title	PD Masterfiles
Version	1.0
Page Number	Page **4** of **4**

Distribution Record:

Date	Name	Department	Received Y/N