



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-A1027-UoL



Version Number: 1.0

Effective Date: August 2022

Supersedes: N/A

Last Review Date: N/A Next Review Date: Aug 2024

Development and Approval Record for this Document

Role	Name	Job title	Signature	Date
Author	Amanda Sutcliffe	HTA Monitoring Officer		10/08/2022
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		10/08/2022

SOP identifiers	SOP details
ID number	HTA-A1027-UoL
Title	Persons Designated for Research Licence 12384
Version	1.0
Page Number	Page 2 of 4

Background

A Person Designated (PD) is an individual designated by the Designated Individual (DI) to whom the Research licences applies and to whom the legal authority conferred by the licence extends. PDs do not have the same legal duties of the DI as set out in the HT Act (Section18), but the role of the PD carries the responsibilities to “direct” others in relation to the HTA Act.

This SOP is to clarify the process that is required for replacing PDs as there are circumstances that may arise where a PD might need replacing, examples of this include; due to long term sickness, due to leaving the University, being seconded to a new university post, this list is not exhaustive as there may be other circumstances where a PD might require substituting either on a temporary basis or on a longer term basis.

Purpose and Scope

This SOP describes the process for where a PD might need replacing / substituting to ensure there is HTA oversight within the departments at all times.

Definitions:

DI	Designated Individual
HOD	Head of Department
HT Act	Human Tissue Act
HTA	Human Tissue Authority
PD	Persons Designated
REGI	Research Governance Ethics and Integrity
SOP	Standard Operating Procedure
UHL	University Hospitals of Leicester
UoL	University of Leicester

SOP identifiers	SOP details
ID number	HTA-A1027-UoL
Title	Persons Designated for Research Licence 12384
Version	1.0
Page Number	Page 3 of 4

Roles and Responsibilities

It is the responsibility of the DI to ensure that suitable practices take place within the licensed establishment that comply with the HTA Codes of Practice. The DI must act as a gatekeeper for any material that is to be reported on the UoL HTA research licence.

It is the responsibility of the HTA Monitoring Officer to ensure this SOP is kept up to date and to assist the DI in ensuring that PDs have the support they need to achieve their roles and responsibilities. The HTA Monitoring Officer will also assist PDs in queries that they might receive and offer expert advice where sought.

It's the responsibility of the Persons Designate (PD) to assist the DI in implementing and adhering to the governance processes and to ensure researchers are aware of process that require to be undertaken for all sample sets that require reporting against the licence.

Procedure to follow

This is the procedure to be followed in circumstances where a PD for the area requires substituting or changing on a more formal basis.

Person Designated notice period

Where a PD is knowingly going to be leaving the University or moving to a different post within the University meaning they would be unlikely to be able to fulfil their role as a PD, where possible one months' notice should be given to enable a replacement to be found including some informal hand over to take place.

Identification of replacement PDs

Where appropriate, if committee members can not suggest an alternative PD for the area, the departmental Head of Department (HOD) should be approached to give them the opportunity to put someone forward who they feel would be suitable for the role of PD.

SOP identifiers	SOP details
ID number	HTA-A1027-UoL
Title	Persons Designated for Research Licence 12384
Version	1.0
Page Number	Page 4 of 4

PD Roles and Responsibilities

The main responsibilities of the PDs have been documented in the PD roles and responsibilities. These can be found within HTA_A1027_Appendix 1.

Formal Recruitment as a PD

Once a replacement or substitute has been identified and an informal hand over taken place the new PD will be required read and sign the PD roles and responsibilities document (HTA_A1027_Appendix 1), which will be countersigned by the DI of the Research HTA licence. Upon a fully executed roles and responsibilities document the PD will then begin to fulfil the duties of a PD.

The new PD will be supported by the other more experienced PDs and the HTA Monitoring Officer for the complex issues that may arise.

Review Record			
Date	Issue Number	Reviewed By	Description Of Changes (If Any)
Distribution Record:			
Date	Name	Dept	Received