



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

SOP HTA-A1027 UoL

Roles of Persons Designated for Research Licence 12384

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.

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](#).

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 Human Tissue Act (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.

2.0 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
HoS	Head of School
HT Act	Human Tissue Act
HTA	Human Tissue Authority
PD	Person Designated
SOP	Standard Operating Procedure
UoL	University of Leicester

3.0 Procedure

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

3.1 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. Advanced notification should be given to the HTA Monitor so that oversight of a replacement can be managed.

3.2 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.

3.3 PD Roles and Responsibilities


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.

4.0 Responsibilities

Responsibility	Undertaken by	Activity
Person Designated (PD)	Person Designated (PD)	Person designated to give a minimum of one calendar months' notice of stepping down as PD. Read and sign the PD roles and responsibilities.
Head of Department (HoD)	Head of Department (HoD)	Identify a replacement individual to act as PD for their Department
Research Governance Office (RGO)	HTA Monitor or equivalent role in RGO	Ensures oversight keeping the DI up to date with progress and ensuring SOP remain up to date.
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 Peter Bradding (Designated Individual) 	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	<ul style="list-style-type: none">• Administrative changes• Minor typographical changes• Slight amendment to appendix 1 relating to PD training.