Persons Designated (PD) on the HTA Research Licence Role Description

Role: Person Designated (PD)

College: College of Life Sciences (CLS)

Matrix relationships:

- Designated Individual (DI)
- Human Tissue Act (HTA) Monitor
- University Hospitals of Leicester (UHL)

Summary:

The HT Act (Human Tissue Act 2004) sets out a legal framework for the storage and use of tissue from the living and for the removal, storage and use of tissues and organs from the dead. The HT Act applies to all 'relevant material', defined as 'material other than gametes, which consists of or includes human cells, but excluding

a) embryos outside the human body, or

b) hair and nail from the body of a living person.'

This includes 'residual' tissue following clinical and diagnostic procedures and covers blood, blocks, and slides. DNA (deoxyribonucleic acid) is not bodily material; however, qualifying consent must be in place. The HT Act repeals and replaces previous legislation in this area and establishes the Human Tissue Authority (HTA) as the regulatory body. The HTA framework provides for various models of governance around three key roles, as outlined in the Human Tissue Act. These three roles are:

• Designated Individual (DI)

• Licence Holder (if different to DI); and

• Person Designated as a person to whom the licence applied.

Quality framework communication –

The Executive Lead on operational HTA matters is the Registrar and Secretary of the University under the protection of the CLS HTG Committee. The Designated Individual (DI) has statutory responsibility under Section 18 of the Human Tissue Act 2004. The DI for research is accountable to the HTA for relevant material handled under the authority of the University HTA Research Licence and is responsible for making relevant University staff and students aware of this Act.

The HTA Monitor is accountable to the DI and will act on his/her behalf to oversee adherence to the University Research Licence, HT Act 2004, HTA Codes of Practice and HTA standards. The Research Governance Office (RGO) will maintain a list of PDs.

PDs are accountable to the DI and responsible for ensuring that staff and students working in the licensed areas are aware of the HTA Codes of Practice in respect of HTA-relevant material and that these Codes of Practice are adhered to. This includes making sure that all relevant staff and students who collect, store, or use such tissue are aware of the University policies and Standard Operating Procedures (SOPs). PDs can 'direct' others in relation to the Act on behalf of the DI.

PDs do not have a legal duty comparable with those set out for the DI under Section 18 of the HT Act 2004.

The DI and the HTA Monitor will provide training and guidance for PDs. All PDs must demonstrate appropriate training before undertaking the role.

All University of Leicester staff, students and individuals employed by external organisations collecting, storing, or using human tissue for research under the University Research Licence are accountable to the DI for undertaking work in compliance with the HT Act. In compliance with the Research Licence issued by the HTA, the University expects all persons operating on University sites to comply with the HT Act and its subsequent amendments, and to comply with all Codes of Practice issued by the HTA and relevant University wide and/or local SOPs.

The HTA has taken the view that PDs need to have a knowledge and understanding of the HT Act 2004 and the relevant Codes of Practice. She/he should demonstrate managerial capability, as well as assisting the DI and RGO with the development and implementation of quality management systems. Importantly, she/he should be given time (estimated at 10% of a WTE post) within their substantive role to carry out the responsibilities of the PD and should provide local guidance concerning HTA compliance.

It is a condition of a licence that PDs complete specified HTA training.

PDs are listed on the HTA Licence in a notice to the HTA. They are then regarded as a person to whom the licence applies, and to whom the authority conferred by the licence extends.

Section 17 of the HT Act states that the authority conferred by a licence extends to any person who is designated as a person to whom the licence applies by a Notice given to the HTA by the DI, and to any person acting under the direction of such a PD. Other people can work under the direction of PDs as a person to whom the licence applies.

Principal Accountabilities (Responsibilities) of the Persons Designated:

- Make staff and students who collect, store, and use human samples, and relevant material as defined under the University of Leicester HTA Research Licence, aware of the HT Act, the HTA Codes of Practice, relevant University of Leicester SOPs as well as local SOPs and Work Instructions.
- Work in collaboration with the RGO and the wider RGO team to monitor compliance, identify breaches and implement corrective actions.
- PDs do not have a legal duty comparable with those set out for the DI under Section 18 of the HT Act (i.e., to ensure that suitable practices are used and that there is compliance with licence conditions). The position of PD carries with it the ability to "direct" others in relation to the HT Act.

- To maintain a register of studies using human samples that are currently under ethical approval, and of HTA-relevant material which is stored under the University of Leicester's HTA Research Licence.
- To maintain an up-to-date register of staff and students using ethically approved human material or HTA-relevant material within their areas with in-date training records and certificates.
- To ensure that a record of the freezers and other areas storing ethically approved human material or HTA-relevant material is accurate and up-to-date, ensuring any changes in use of freezers or storage areas are documented, and ensuring that staff in their areas keep the appropriate freezer maps and labels accurate and up-to-date.
- Ensure that all local research processes using HTA-relevant material follow the University of Leicester HTA SOPs for the collection, use, storage and disposal of these samples, unless superseded by local SOPs, UHL SOP or SOPs provided by a third party.
- Develop and maintain a detailed knowledge of the HT Act and the relevant consent and research Codes of Practice of the HTA.
- Maintain professional development activities in this area and attend any mandatory training as required.
- Attend regular meetings and training sessions as required by the DI and HTA Monitor and the CLS HTG Committee.
- Work according to the University HTA Policy and Procedures.
- Provide guidance on maintaining local documentation, record sets, error logs and risk assessments as listed in the procedures specified by the University of Leicester HTA SOPs.
- To assist with inter-departmental sample audits to ensure sample logs are accurate.
- Where a significant risk or incident is identified, immediately notify (within 24 hours) the DI and HTA Monitor, such that a decision can be made in relation to cessation of relevant activity or corrective actions, in consultation with relevant Clinical Directors.
- Lead projects within their departments to support the DI and RGO.

Internal and External Relationships:

- HTA Monitor
- University of Leicester CLS HTG Committee.
- Research Governance Team at the University of Leicester
- Clinical and academic research staff, at all levels, within the University of
- Leicester and UHL.

- Research and Innovation team at UHL NHS Trust if necessary.
- Human Tissue Authority.
- Licence Holder.
- External Sponsors of research studies
- Research and Enterprise (RED) contracts team

Planning and Organising:

- The PD role provides support to their local department, and ensures on behalf of the DI, that material collected, stored and used under the University of Leicester HTA Research licence meets the requirements of the Human Tissue Act 2004 in a coordinated and standard manner. Processes will be run according to University of Leicester HTA SOPs (unless superseded by local, UHL or third-party SOPs) which will be reviewed biannually as part of research governance standards.
- The PD will support, and escort where appropriate, the HTA Monitor, DI, and external organisations when conducting departmental audits, servicing and during Human Tissue Authority Regulatory Inspections.

Person Designated

Name	
Licensed area name or Department	
Signature	
Date	

Designated Individual

Name	
Signature	
Date	