# **ROLE TITLE:**

Person Designated (PD)

**MAIN PURPOSE:**

Access to human tissue samples is essential for many aspects of translational medical research undertaken at Newcastle Hospitals and Newcastle University. The use of human tissue in research is regulated by the Human Tissue Authority, in accordance with the Human Tissue Act (2004).

Under the terms of Newcastle Hospitals and Newcastle University’s Human Tissue Act research licence, it is the responsibility of the Designated Individual (DI) to oversee governance with the licence requirements.

To support the DI in discharging this responsibility, it is a licencing requirement that the DI names key individuals on the licence who undertake the role of the ‘Person Designated’ (PD). The role of the PD is to work with the DI to ensure compliance with the Act across the storage locations.

The main purpose of the PD is therefore to operate at a local level to help coordinate and maintain the governance support for research using human tissue within their local environment. This role does not impose any legal responsibility but plays a vital function in assisting the DI to meet HTA regulatory requirements.

**RESPONSIBILITIES**

The responsibilities of the PD include:

* Proactively support the DI to ensure compliance with the Human Tissue Act (2004) and any subsequent amendments, within their local environment by acting as local ambassadors for the Act.
* Attend regular meetings and training sessions as required by the DI to ensure a comprehensive understanding of the Human Tissue Act and associated responsibilities.
* Provide support and advice to personnel in their specified premises in the delivery of activities using human tissues for Scheduled Purposes, as defined in the Human Tissue Act
* Communicate all Human Tissue Act related information to all personnel involved in working with human tissue in their specified premises to ensure that they are suitably informed and aware on their responsibilities under the Act.
* Work with local researchers to establish and facilitate any HTA related training requirements (informing the DI where required) to ensure all personnel are suitably trained and have access to required resources.
* Ensure the specified premises, facilities, equipment and all local documentation are in place and maintained in accordance with the standards set out in the Human Tissue Act Codes of Practice and Quality Manual.
* Ensure systems are in place for regular review/update of quality policies to maintain compliance with the licensing requirements.
* Through active engagement and feedback, work with local personnel to continually improve the Quality Management System and ensure high levels of quality compliance with the Act.
* Where an adverse event or near miss is identified, ensure the event is immediately reported to facilitate prompt corrective action to be implemented, where required.
* Facilitate quality audits by providing access to suitable systems, documentation or facilities as required by the DI, local Quality Assurance Manager, or external auditors (e.g. Human Tissue Authority).
* The PD should make provision for another person to act on their behalf in their absence

**ORGANISATIONAL CHART**

A PD under the Human Tissue Act is accountable to the DI, on behalf of the Licence Holder, for ensuring that the requirements for licensing relevant activities under the Human Tissue Act are met. A PD may also choose to appoint one or more Human Tissue Act Coordinators to help support them within their local environment. These persons may be chosen at the discretion of the PD (e.g. a member of technical staff) however their names must be disclosed to the DI to ensure that these individuals are included in all HTA related communication.



# **Acceptance of the role of Person Designated on the HTA Research Licence**

I agree to act as a Person Designated for the Human Tissue Act Research Sector Licence outlined below, in accordance with the role description set out above. I understand that my name will be provided to the Human Tissue Authority for inclusion on the Licence.

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| **HTA Research licence to which the PD role applies:** | Please select (tick) as appropriate |
| Newcastle Hospitals (Ref. 12193) |  |
| Newcastle University (Ref. 12534) |  |

|  |  |
| --- | --- |
| **Name (print)** |  |
| **Department** |  |
| **Date** |  |
| **Signature** |  |