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| **Human Tissue in Research**  **HTA-Template-SOP** |

## **Instructions**

* Tailor the text in the Header and Footer that has been highlighted in yellow.
* Add the appropriate information about the process you are standardising under each numbered heading.
* Remove all the grey text which has been added for guidance.
* Delete this cover page.

1. **Purpose**

A description of the intended purpose of the SOP.

e.g., The purpose of this SOP is to ensure all staff and students are aware of the procedure for handling, documenting, labelling and storage of relevant material collected and stored for the [insert title] study.

1. **Scope**

An overview of the standard process being defined within the document, establishing the specific aims it is intended to satisfy, how the SOP meets HT Act requirements and any exclusions and constraints.

1. **Roles and Responsibilities**

This section should identify the main roles and responsibilities of individuals involved in documenting, performing, and supervising an activity detailed in the SOP.

1. **Procedure**

This section details the specific steps to be performed when the task or process the SOP intends to describe is undertaken. For technical SOPs, the instructions in this section should be written as clearly and comprehensively as possible. All abbreviations should be defined on first use to aid understanding.

1. **Risk Assessment**

All procedures involving the acquisition, storage, use and disposal of human tissue must be risk assessed to comply with HTA requirements. SOPs describing manual, technical and scientific procedures involving human tissue must be accompanied by a risk assessment to ensure that any individual undertaking the process is aware of the possible hazards and understands the steps to be taken to minimise them.

To comply with HTA standards the risk assessment must include consideration of the risks to the integrity of the tissue, the respect for the donor and the safety of the handler.

The carrying out of health and safety risk assessment must be performed with consideration to Swansea University Health and Safety Policy Arrangements.

The SOP must reference all related Risk Assessment documents and their titles.

1. **Reference**

Provide links or signpost references used in the development of the SOP.

1. **Definitions**

This section should be included where an explanation of definitions aids the reader to carry out the procedure or increases the safety of the procedure described. The definitions listed in each SOP should be concise and applicable to the specific SOP.

1. **Review and Amendments**

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| **Document History** | | | | | | | |
| **Version** | **Review Date** | | **Comment** | | **Replaces** | | **Reviewed by** |
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| **Approver** | | **Name and role** | |  | | | |
| **Signature and date** | |  | | | |
| **Effective Date:** | |  | | **Next Review Date:** | |  | |

1. **Appendices**

Include all information referenced in the SOP text as necessary.