

Human Tissue Research at UWE

1. The Quality Management System

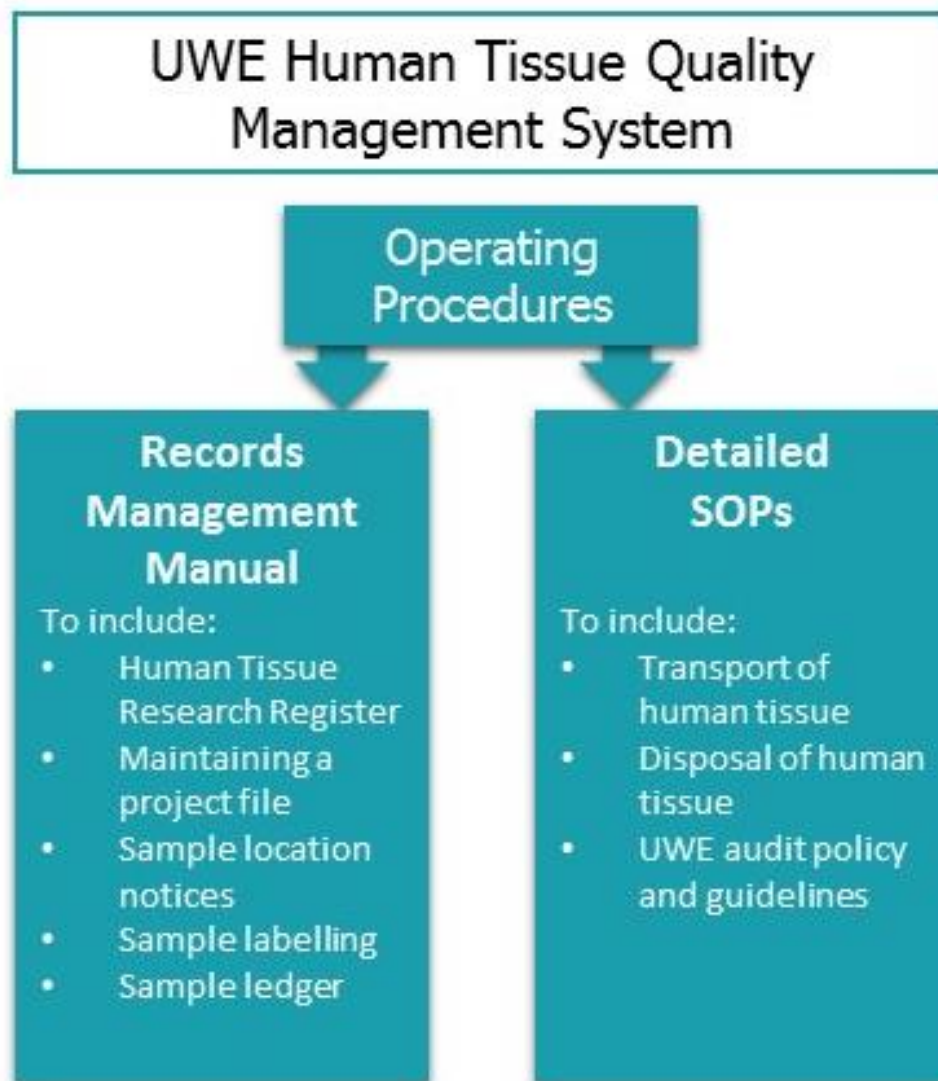
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1. Introduction to the Quality Management System

In line with Medical Research Council guidelines (www.mrc.ac.uk/news-events/publications/human-tissue-and-biological-samples-for-use-in-research/), UWE is developing a Quality Management System (QMS) for the management of human tissue research at UWE.

The UWE Human Tissue Quality Management System is laid out in the documentation within the following three areas: The UWE *Human Tissue Operating Procedures and Guidance for Staff and Students*, The UWE *Human Tissue Records Management Manual* and the UWE *Human Tissue Standard Operating Procedures*. The relationship between these three areas is illustrated in the diagram below:



The QMS will define appropriate quality systems in the collection, processing, storage and disposal of human tissue at UWE. The QMS will use a combination of procedures and records to ensure that:

- **Researchers** know what is expected of them if they wish to undertake human tissue research at UWE
- **Researchers** understand how human tissue research projects at UWE should be managed
- **Researchers** understand how any human tissue samples being stored on UWE premises should be managed.

The QMS will allow **Research Managers** to:

- quickly and easily identify what human tissue research is taking place at UWE
- quickly and easily identify any human tissue samples that are being stored on UWE premises
- demonstrate good practice in the management of Human Tissue research is taking place at UWE.

Whilst we recognise that the NHS REC does not require this level of records management for human tissue research, we are moving towards the standards required to be a Human Tissue Authority licensable establishment, therefore once this Quality Management System is approved, this represents UWE's view of best practice, and must be in place for all new and ongoing projects.

2. The UWE Human Tissue Operating Procedures and Guidance for Staff and Students

The UWE *Human Tissue Operating Procedures and Guidance for Staff and Students* set out the University's requirements in relation to the ethical review, oversight and management of Human Tissue Research. They can be found at:

<http://www1.uwe.ac.uk/research/researchgovernance/resourcesforresearchers/humantissueresearch.aspx>

Background information about the Human Tissue Act (2004) and its *Codes of Practice* are also laid out in these procedures, along with further information about what is considered a 'relevant material' under the Act, and Human Tissue Authority (HTA) licencing requirements and exemptions.

UWE does not currently hold an HTA licence for storage of human tissue for research purposes (as defined by the Human Tissue Act). This means the licensable storage of relevant material for research at UWE must be covered by a valid, in date, NHS Research Ethics Committee favourable opinion for a specific research project, or covered by the NHS REC approval of a Research Tissue Bank, prior to human tissue being brought on to UWE premises.

3. The UWE Human Tissue Records Management Manual

The UWE *Human Tissue Research Records Management Manual* sets out expectations of the records that need to be kept by UWE Project Managers, by Laboratory Managers and by central Research Governance and Ethics teams, and by individual researchers working on Human Tissue projects in support of the Quality Management System.

The Manual can be found at:

<http://www1.uwe.ac.uk/research/researchgovernance/resourcesforresearchers/humantissueresearch.aspx> and includes:

- Procedures for recording Human Tissue research at UWE – The UWE *Human Tissue Research Register*
- Requirements for maintaining project level information by the UWE Project Manager – The Project File
- Procedures for managing and recording the locations where human tissue samples are stored at UWE – Individual Sample Labelling, Sample Location Notices, Sample Ledgers.

4. The UWE Human Tissue Standard Operating Procedures

The UWE *Human Tissue Standard Operating Procedures* set out detailed procedures for how certain standard processes related to human tissue research should be managed at UWE.

The Standard Operating Procedures can be found at:

<http://www1.uwe.ac.uk/research/researchgovernance/resourcesforresearchers/humantissueresearch.aspx> and cover:

- The Transport of Human Tissue onto UWE Premises
- Disposing of Human Tissue Samples at UWE
- The UWE Human Tissue Subcommittee Audit Policy and Guidelines

5. Contact for further details

For further information and guidance on conducting research using human tissue at UWE, please contact the Officer of the Human Tissue Subcommittee:
researchgovernance@uwe.ac.uk.

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