STANDARD OPERATING PROCEDURE – INTERNAL AUDIT

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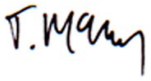
Superseded Version Number & date	**MMU-HTA 009 (V1 2012)**
Authorisation	**Designated Individual** **Professor Tristan McKay** Signature 

Background

The University has introduced a quality management system for the governance of the acquisition, storage and use of human tissue. This system will ensure that all work is carried out to the highest standard and that the University complies with the licensing obligations of the Human Tissue Act (2004).

This SOP forms part of a suite of SOPs (MMU HTA 001 – MMU HTA011) that support implementation of the quality management system and should be used as directed in the Quality Manual:

Purpose

The purpose of this SOP is to describe the process of internal audit of projects using human tissue.

Definitions

Human Tissue
Any, and all, constituent part/s of the human body formed by cells.

Internal Audit
An examination of records, policies, and procedures that is conducted by the DI and/or deputies to ensure best practice and compliance with the Quality Manual SOPs.

Scope (of this SOP)

All work carried out within Manchester Metropolitan University involving human tissues.

Related SOPs

SOPs MMU HTA001 – MMU HTA011 relating to the acquisition, storage, use and disposal of human tissue.

Responsible Personnel

Designated Individual (DI)

Persons designated (PDs)
Principal Investigators (PIs)

Procedure

All research projects involving the use of human tissue will be subject to internal audit on an annual basis and at six months following the completion of the project.

The Research Ethics and Governance team will undertake audits with the assistance of the DI. The audits will comprise of a documentation review and laboratory visit.

PIs will be asked to make available all the documentation associated with the project for the audit including; consent forms, sample information, samples disposed information, samples used information, risk assessments, standard operating polices and training records.

Compliance with the ***Standard operating procedures contained within in the Quality Manual*** will be assessed and documented via the forms laid out in Appendix 1-7.

Any corrective action required as a result of the audits must be undertaken as soon as is reasonably practicable.

When any corrective actions have been identified on the audit forms. The actions must be confirmed in writing to a member of the audit team identified.

The written confirmation should be filed as part of the project record when all identified corrective actions are complete. The designated individual is responsible for closing the audit as complete.