Human Samples in Research Standard Operating Procedure 8
Audit

Version:	2.1	Effective Date:	24/02/20243
Issue Date:	30/06/2023	Review Date:	14/07/2025
Author:	Professor Geraldine Hartshorne, Designated Individual (Research License)		
Review Lead:	Mathew Gane, Research Governance & QA Manager, Research & Impact Services (R&IS)		
Reviewers:	Professor Geraldine Hartshorne, Carole Harris, Mathew Gane, Dale Topley, Dr Natasha Kriznik		
Approved by:	Human Samples Steering Group (HSSG) / Professor Geraldine Hartshorne, Human Tissue Designated Individual (DI) – Research License		

Contents

Revision Chronology:	Effective date:	Reason for change:
HSR SOP 8_V1.02	13 December 2010	Clarification of University policy – QMS applies to all human samples. Creation of the role of Administrative Officer, Deputy DI and changes to the role of PD. Reorganisation of Biological Sciences to form the School of Life Sciences.
HSR SOP 8_V1.03	10 January 2012	Changes in staff, room numbers and external links.
HSR SOP 8_V1.04	25 February 2015	Changes to University governance structures relating to human samples.
HSR SOP 8_V2.0	14 July 2023	Various updates including changes made for clarity, accuracy and readability, removed sections duplicated in each SOP (to be included in Quality Manual), added reference to University's agreed three-tier 'risk-based' approach, links to HTA guidance updated as appropriate.
HSR SOP 8_V2.1	24 February 2024	Links updated

NOTE*:* SOPs will be reviewed on a 2-yearly schedule.

The definitive version of this SOP is available here: https://warwick.ac.uk/services/ris/research-compliance/human-tissue/hereatwarwick/sop/

Printed copies are outside the document control system. Ensure you are using the most up to date version.

Audit

1. Purpose and scope

The purpose of this Standard Operating Procedure (SOP) is to ensure that all staff and students understand the requirements and procedures for the audit and monitoring of processes and practices associated with the acquisition, storage, use and disposal of human samples for research, covered by the Human Tissue Act 2004 (HT Act), the Human Tissue Authority's (HTA) Codes of Practice, the University's HTA licence for research and the University's Quality Management System for the governance, storage, use and disposal of human samples for research.

2. Background

This SOP forms part of the University's Human Samples in Research Quality Management System (QMS). All research involving human samples at the University of Warwick must comply with this Quality Management System.

The University requires that all human samples defined as relevant material by the HTA and held at the University for Research shall meet the standards of quality management set out in its standard operating procedures. For the avoidance of doubt, this includes any cellular human material, regardless of whether it has current REC approval, unless it is a cell line that has been passaged at least three times. A risk-based approach will be applied.

It is important that the research community and the public have confidence that all human samples for research are acquired lawfully and with appropriate consent, and are stored, handled, used and disposed of respectfully, sensitively and responsibly. Audit is a means to check how well the University and its staff and students are complying with the requirements of the HTA and the Quality Management System, to deliver on their respective responsibilities.

This SOP has been produced in accordance with the HT Act which came into force on 1 September 2006, and should be read in conjunction with the HTA's *Codes of Practice*, available at: https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation/codes-practice

3. Responsibilities

The Registrar (as the Licence Holder's Representative) and the Designated Individual (DI) are responsible for ensuring that appropriate procedures are in place, and that staff and students involved in research using human samples are appropriately trained.

The Designated Individual is responsible for ensuring that audits are carried out and non-conformances addressed, to maintain the University's compliance with the HTAct through its Quality Management System.

The Principal Investigator or suitably trained person delegated by the PI, as custodian of the samples, is responsible for understanding and following the appropriate procedures and practices to comply with any requests for information or audit of materials held and processes under the University's Human Samples in Research Quality Management System.

Individual researchers are responsible for reading and following this SOP and complying with any requests for information or audit of materials held and processes under the University's Human Samples in Research Quality Management System.

Persons Designated (PDs) are responsible for assisting the DI in acquiring information, designing, carrying out and analysing audits, to ensure that samples are appropriately handled at all times and that staff and students are compliant with the requirements of the Quality Management System.

Heads of Department are responsible for ensuring that members of their department comply with the SOPs for working with human material.

The Human Samples Steering Group (HSSG) is responsible for reviewing and approving all human tissue SOPs.

Research and Impact Services staff are responsible for supporting the DI and PDs in administrative tasks associated with the Human Samples Quality Management System, including designing, scheduling, undertaking, writing up and disseminating audits.

4. Policies

The HT Act applies only to relevant material (defined at https://www.hta.gov.uk/guidance-professionals/hta-legislation/relevant-material-under-human-tissue-act-2004), however, the University of Warwick's Human Samples Quality Management System applies to a wider spectrum of human samples according to a 3-tier system. The University will undertake audits of any material or processes that fall within its human samples quality Management System.

Internal audits or reviews may be undertaken by persons authorised by the DI. Internal audits or reviews will be undertaken regularly according to a schedule that covers different aspects of the quality management system, staff and student compliance and the materials in storage. In addition, internal audits may be undertaken by the University's Internal Audit service.

External audits may be expected from the Human Tissue Authority. In addition, the Registrar, at their discretion, may authorise external audits by other organisations.

All those engaged in research involving human samples must ensure that they maintain and make available all appropriate and required records and documentation for audit.

5 Procedures

5.1 Routine Monitoring

The DI, supported by members of the technical team, Persons Designated and/or PIs, will periodically tour the premises, and informally inspect the equipment and facilities at the hub and satellite sites. Monitoring tours provide important opportunities for informal discussions and dialogue with staff and students in the working environment, to obtain detailed feedback e.g. on deficiencies in any SOPs, changes in related local procedures and practices needed, additional training and resource requirements, and ensure that the QMS and the SOPs remain workable and supportive of the research effort. From observation of the working environment, the DI will give assurance that all remains fit for purpose or will highlight issues for adjustment or improvement in support of research involving human samples.

5.2 Regular reviews

The DI, assisted by RIS and PDs, will schedule and implement a rolling programme of regular reviews covering both the hub and satellite sites to evidence compliance with the licensing obligations of the HT Act and to the required standards set by the HTA. The objectives of each review will be to test and verify, for example:

- adherence to the Standard Operating Procedures (SOPs);
- accuracy of sample records;
- completeness of data and documentation (including training records).

Records scrutinised during a review may include:

- GMBSC project assessments;
- applications for ethical approval and confirmation of approval;
- consent forms and/or patient information sheets;
- Materials Transfer Agreements;
- Import records
- Sample Register;
- Disposal records;
- Export records.

Samples held on the premises may also be audited, to check for example:

- traceability,
- location,
- confidentiality
- consent

Sample-to-record and record-to-sample tests will be undertaken to investigate their traceability. Samples will be selected from a range of different Lead Investigators and research projects. Over a period of time, reviews will cover the full range of human samples held and used by the University. A range of sample types and samples stored under different storage conditions will also be tested.

The effectiveness of the implementation of a SOP and of the procedures themselves will be prioritised for review following a significant amendment/revision to an existing SOP or a new SOP being introduced. A review may also be triggered as a result of an adverse event or incident, or in an area where poor practice may be suspected.

The reviews will be conducted with the support of the PD at each site and include other academic and technical staff as appropriate and agreed by the DI. Reviews will be conducted at pre-arranged times of which staff will be notified.

A review report will be completed, highlighting good practice and including a plan of any corrective action required, and will be presented to the HSSG and made available to staff impacted/affected, as appropriate. A report on completion of the corrective action will be brought back to the HSSG within an agreed timescale.

A composite report of findings and actions arising from the review programme will be collated by the DI to provide a statement of compliance (i.e. a self-assessment) with the HTA standards and licensing obligations under the HT Act, and reported to GMBSC, as appropriate.

5.3 University Internal Audit

The University's Internal Audit Service may undertake audits of research project activity where projects selected may include the use of human samples, and will also undertake audits of research governance procedures and management processes which may also include the QMS and SOPs for research using human samples.

5.4 External Audit and HTA Inspection

Occasionally, audits will be conducted by external agencies including site inspections by the HTA. Any internal reviews conducted by the DI will aim to mirror (at least, in part) the requirements of such external monitoring, with preparations for external inspections co-ordinated by the DI and through Research and Impact Services. Historically HTA has requested reports on tissues held at approximately 2 yearly intervals. Inspections undertaken by HTA, may be announced or unannounced. These usually occur every few years.

Reports from any such inspections and any actions arising will be considered by the HSSG with recommendations agreed by the DI for any significant changes in the QMS or SOPs, for example, made to GMBSC. Where there may be issues of significant risk, reports and recommendations may be made to the University Health and Safety Executive Committee (UHSEC).

5.5 Reports

The DI is integral to a number of SOPs and processes that monitor activities in research involving human samples, for example:

- training and registration of researchers;
- authorisation of sample import, export and disposal;
- storage of human samples;
- logging and investigating adverse events and incidents.

Regular reports on these activities will be prepared by the DI for consideration at the HSSG, GMBSC and by the Licence Holder's Representative. The DI is also responsible for the preparation of reports and investigations relating to serious incidents or adverse events, as appropriate, in accordance with HSR SOP 5 Adverse Events.

The DI is responsible for co-ordinating the response to the annual review to the HTA on behalf of the Licence Holder's Representative. The HTA report requests information on the nature and number of human tissue samples held by the University and can include questions related to other aspects of the licence (for example, consent and/or ethical approval). These reports appear to have been temporarily halted during the covid pandemic. It is unknown whether and when they may restart and guidance is awaited from the HTA.

6. Training

All those involved in research involving human samples are required to read this SOP and to understand how its requirements in terms of monitoring and audit relate to their research. This should be recorded in the Personal Training Portfolio, in accordance with HSR SOP 7 Training.

7. Advice and guidance

Further advice on audit procedures and requirements may be sought from the DI. The DI may seek advice from the HTA directly when appropriate.

List of Abbreviations

HTA	Human Tissue Authority
HT Act	Human Tissue Act 2004
DI	Designated Individual
HSSG	Human Samples Steering Group
PD	Persons Designated
PI	Principal Investigator
R&IS	Research & Impact Services
SOP	Standard Operating Procedure