# Human Material Research Quality Manual

**Reference:** HTA004

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<th>Author</th>
<th>Date of Approval</th>
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This Quality Manual has been compiled to meet the requirements of the Human Tissue Authority.

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Review Process Prior to Sign Off

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1. Introduction

1.1. Background

The Human Tissue Act (HT Act) (2004)\(^1\) applies to England, Wales and Northern Ireland. The HT Act (2004) established the Human Tissue Authority (HTA) to regulate all activities concerning the removal, storage, use and disposal of relevant human material. Relevant human material is defined a material, “other than gametes, which consists of or includes human cells” excluding embryos outside the human body, or hair and nails from the living, but including “surplus” tissue following clinical and diagnostic procedures\(^2\).

Under the HT Act (2004), the HTA has the power to define expected standards (or Directions) to establishments and has produced Codes of Practice (COP)\(^3\) that give guidance on the execution of procedures that lie within the remit of the HT Act (2004).

The HTA can also issue Directions to take into account changes in Policy and legislation or that are specific for a particular establishment. Directions 002/2009 were issued in September 2009 and updated in July 2014 to bring into force the HTA COPs and revoke 002/2006.

1.2. Licencing

The HTA regulates the removal, storage, and use of human bodies, body parts, organs and tissue for activities such as research, patient treatment, post-mortem examination, anatomical examination, and public display.

The HTA issues licences to establishments that carry out these activities in England, Wales and Northern Ireland, and inspect them to make sure regulatory requirements are met.

The University holds two Human Tissue Act licences, a Research Licence (HTA Research Licence) and a separate Licence for Anatomy. The Designated Individual (DI) for Research at University of Liverpool (University) and its associated sites is Dr Janet M. Risk. The Anatomy Licence has a separate DI, Professor J. Gallagher, and operates quality systems that are distinct from, but similar to, those outlined in this document for general research governance for human material.

1.3. Responsibilities for General Research Governance under the Human Tissue Act

The corporate licence holder is the University of Liverpool, whose representative is Professor Bob Burgoyne, Executive Pro-Vice-Chancellor.

The Designated Individual: Dr Janet M. Risk
North West Cancer Research Centre
200, London Road,
Liverpool
L3 9TA.

The HTA research licence number for the University is 12020.

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\(^3\) [https://www.hta.gov.uk/guidance-professionals/codes-practice](https://www.hta.gov.uk/guidance-professionals/codes-practice)
The Designated Individual (DI) has specific responsibilities set out in the HT Act (2004) which are summarised as:

- To supervise the licensed activity.
- To secure that the other persons to whom the licence applies are suitable persons to participate in the carrying out of the licensed activity.
- To secure that suitable practices are used by the persons under their supervision in the course of carrying out the licensed activity.
- To secure that the conditions of the licence are complied with.

Persons Designate (PD) work under the supervision of the DI to fulfill the same role as the DI in defined areas, for example, satellite sites. Satellite sites are geographically distinct areas of research activity operating to the same protocols and under the same governance system as the principal site. The DI at the University has delegated responsibility to the following Persons Designate:

- Professor R.J. Moots, Clinical Sciences Centre, University Hospital Aintree.
- Dr D. Hapangama, Liverpool Women’s Hospital.
- Dr B. Flanagan, Institute in the park at Alder Hey.
- Professor N. Williams, Leahurst Campus.
- Mrs J. Middleton, Institute of Translational Medicine.
- Dr J. Blaylock, Research Support Office.

Anyone acting under the direction of the DI or PD is a person to whom the licence applies. This includes Human Material Officers (HMOs), Chief/Principal Investigators (C/PI), and custodians of samples, who should all be fully conversant with the legislation and COPs. Researchers who use the samples (even if they have not been directly involved in the collection of the samples) must be aware that the samples:

- Must be obtained under ethical approval.
- Must be obtained following informed, relevant consent.
- Be processed and stored according to Standard Operating Procedures (SOPs).
- Must be associated with a log of their fate (i.e. tracked to disposal).

The DI has delegated the responsibility of Custodian to the respective managers of Research Tissue Banks that are held under the University Licence.

The University has a network of HMOs placed in each Research Institute in the Faculty of Health and Life Sciences and at the Faculty level in the two other Faculties at the University.

The main roles of HMOs are to advise and support researchers in recording the information required for project development and research monitoring, to assist in annual training events organised by the DI and PDs, and to assist in audit and monitoring of storage of relevant material in their areas.

The DI meets with the human material oversight committee every 3 months to review University human material policies and other relevant documentation relating to human material governance. In addition the DI, PDs and HMOs meet 2-3 times per year to review training, annual activity monitoring and adverse events. Reporting to the University Senior Management Team is through the Research Governance Committee. Line management is facilitated through Faculty and Research Institute Regulatory Affairs Committees.

The lines of lines of responsibilities (solid arrows) and communication (broken arrows):

Chart 1
1.4. Relevant Premises

The licence covers the whole of the main University campus, located in the city centre and its named satellite sites.

Satellite Sites:

- The Clinical Sciences Centre at Aintree University Hospital
- The University Departments based at the Liverpool Women’s Hospital
- The University Departments based and the Institute In the Park at Alder Hey
- The University Leahurst Campus


The University HMR Quality Manual summarises the Human Material Research Quality Management System (HMR QMS).

The University HMR Quality Manual is available to all staff via the University Human Tissue Internet Page. The HMR Quality Manual will be managed via Ideagen Workbench in accordance with SOP001 and will be subject to a full review every two years. Ad-hoc updates will be completed when required. The version available via the University Human Tissue Internet Page will be the current and definitive version.

The DI is responsible for the HMR Quality System through discussion with the Human Material Group and HM oversight committee. The HMR QMS will ensure that the legislation of the HT Act (2004) and the standards set by the Human Tissue Authority (HTA) directions, including the HTA codes of Practice, are successfully implemented in the University practices, guidance and policies.

The licencing requirements of the HT Act (2004) are limited to the storage of relevant human material (from living patients) for unspecified future research however, the University recognises that all human material (for current and future research) should meet the same standards of quality management.

Research using human material in the University should be carried out to the highest standards and in accordance with University Policies, current legislation and national ethical and clinical guidance.

- University of Liverpool Policy on the Use and Storage of Human Material for Research (HTA001)\(^5\).
- University of Liverpool Policy on the Disposal of Human Material for Research Purposes (HTA002)\(^6\).
- University of Liverpool Human Material Code of Practice (HTA003)\(^5\).
- Human Tissue Act (2004)\(^7\).
- HTA Codes of Practice\(^6\).

\(^5\) [https://www.liverpool.ac.uk/intranet/human-material-research-governance/](https://www.liverpool.ac.uk/intranet/human-material-research-governance/)
\(^6\) [https://www.liverpool.ac.uk/intranet/research-support-office/crg/sops/](https://www.liverpool.ac.uk/intranet/research-support-office/crg/sops/)
3. The HMR QMS

The HMR QMS outlines the legislative requirements of the HT Act (2004) and subsequent amendments (July 2014). It describes the standards required for storage of human material for research use at the University. Furthermore it provides guidance and examples of best practice for procedures including, but not limited to the collection, processing, storage, analysis and disposal of human material donated following informed consent to the human material repositories distributed throughout the University and distinguish between human material that requires a licence from that which does not.

The University Human Material Governance Team (DI, PDs and HMOs) and HM oversight committee, shall conduct periodical review of documented policies and procedures of the HMR QMS to ensure that the storage of human material for research continues to meet the standards defined by the HTA. An annual report will be provided to the Research Governance Committee describing the current status of stores of human material and recommending CAPAs or improvements for storage.

As with the HMR QM, HMR QMS documents will be managed via Ideagen Workbench in accordance with SOP001 and will be subject to a full review every two years. Ad-hoc updates will be completed when required.

Related activities carried out by NHS employees in NHS Trusts that are research partners of the University are likely to be subject to HTA licences held by the Trusts. The University will aim to ensure that, wherever possible, there are no significant differences between its own procedures and protocols and those of partner Trusts.

4. Structure of the HMR QMS

An illustration of the University HMR QMS is included in Appendix 9.1.

4.1. Level 1 – Main Policy and Procedure Documents

- University of Liverpool: Policy on the Use and Storage of Human Material for Research Purposes- HTA001
- University of Liverpool: Human Material Code of Practice- HTA003
- University of Liverpool: Human Material Research Quality Manual – HTA004
- University of Liverpool: Summary Record of Documented Procedures Necessary to Ensure Compliance with the HT Act 2004- HTA005
- University of Liverpool: HTA Licence Risk Assessment- HTA006
- University of Liverpool: Procedure for Internal Audit of Relevant Human Material - HTA007
- End of Study Human Material Holdings Declaration- FORMHTA001
- Human Material Disposal Form- FORMHTA002

4.2. Level 2 – Supporting Document Suite

- Human Material Supporting Document- Consenting for Research - SDS001
- Human Material Supporting Document- Use and Storage of Human material - SDS003
4.3. Level 3 – Template Standard Operating Procedure (SOP) Suite

- HTASOP001-Reporting Adverse Events
- HTASOP002- Adverse Events Report
- HTASOP003- Informed Consent
- HTASOP004- Withdrawal of Consent
- HTASOP005-Laboratory Contingency Plan
- HTASOP006- Data Contingency Plan
- HTASOP007- Human Material Research Record Management
- HTASOP008- Equipment use and Maintenance
- HTASOP009- Transporting Samples
- HTASOP010- Human Material Transfer Log
- HTASOP011- Sample Records Labels and Tracking
- HTASOP012- Sample Tracking Log
- HTASOP013- Sample Use Log
- HTASOP014- Induction and Training
- HTASOP015- Training Log
- HTASOP016- Production and Control of SOP’s
- HTASOP017- Security and Storage
- HTASOP018- Human Material Disposal

4.4. Level 4 – University Principal Investigator (PI)/ Group SOPs

Defined by the needs of the individual Group/Study/Project. The Summary Record of Documented Procedures Necessary to Ensure Compliance with the HT Act 2004 document should be used along with the level 3 templates to ensure there is an SOP in place to cover each of the procedures required.

4.5 Human Material Database

Human material database will collect Information that falls into two groups:

- Data on samples of human material stored and used in research that will be collected through an annual email/web based monitoring exercise from individual researchers.

- Data on compliance with governance processes that will need to be collected separately, usually at Research Institute/Departmental/research group level, through a self-assessment questionnaire and regular audits.

In more detail, the information will include:

i. Data collected by current annual survey of all academic staff/known PIs.

ii. Data from HRA, JRO Sponsorship and University Ethics Committees identifying new projects collecting, storing and using relevant material collected by means of bi-monthly reports from the respective research Integrity teams.

iii. Data collected in relation to HTA licensing:
   a. range of material collected
   b. origin of material (living, dead)
c. conditions of storage  
d. number of samples stored and distributed  
e. adverse events  
f. documentation of disposal

iv. Evidence or assurance that appropriate consent is obtained and that records are held securely.

v. Evidence of compliance with University policies and procedures relating to:
   a. storage of tissues  
   b. risk management  
   c. regular governance meetings  
   d. complaints  
   e. training

5. Responsibilities for Governance and Quality Systems

5.1 Responsibilities and reporting lines

The work of staff undertaking research on University premises are subject to a system of governance. All staff working under the HTA licence should be aware of the governance arrangements in place, and they should be represented at governance meetings by their local HMO.

Reporting lines pass through local HMOs to Research Institute and then Faculty Research Advisory Committees to the Senior Management Team and through the DI to the University Research Governance Committee and Senate. Accountability (particularly with regard to the individual researchers and the DI) is through personnel line managers, including Departmental and Research Institute Heads, to the head of HR. Documented roles and responsibilities and training and development are in place.

The HT Act (2004) states that there must be documented policies and procedures in place which cover all actions and processes relating to the storage of relevant human material for research (Human Material Research Quality Management System (HMR QMS) section below). Further details of the documented procedures required by those utilising human material are described within the University Summary Record of Documented Procedures Necessary to Ensure Compliance with the HT Act 2004.

For Research, the focus for the HTA is on non-compliance with the HT Act (2004), HTA COPE or tissue integrity issues. All staff should understand what is meant by an adverse event and there should be a system in place to report these and, where appropriate, undertake root cause analysis.

5.2. HMR QMS - Quality Management

Overall responsibility for HMR QMS, Human Material Audit and Quality Assurance will rest with the DI. The Human Material Governance and Quality Officer (HMGQ Governance Officer) is responsible for creating and managing the documents of the HMRQMS under the oversight of the DI.

The HMGQ Officer is directed by the Designated Individual and acts as a central PD. The HMGQ Officer/central PD will collaborate with the DI, Satellite site PDs and Institutional and faculty HMOs to ensure that the HMR QMS functions effectively.

The HMGQ Officer is based in the University Research Support Office with formal line management to the Head of that office.
Adherence to the University standards of Human Material Governance will be facilitated through a process of:

- Ensuring ongoing maintenance and development of the Human Material Returns database.
- Ensure that data collected from researchers is held confidentially, used only for monitoring research activity and is not shared with other organisations without the agreement of the researchers.
- Ensuring that the requirements of the HMR QMS are brought to the attention of current and new academic staff in the relevant Faculties of the University (induction courses, training).
- Undertake internal audits of the HMR QMS and revise and update documents as required.
- Set quality objectives to implement and maintain the documents of the HMR QMS.
- Ensuring effective communication with the Joint Research Office Sponsorship Committee and the University of Liverpool Research Ethics Committees for research governance.
- Ensuring through audit and monitoring that Human Material users have adequate SOPs in place for processes requiring documentation thereby accruing evidence to present to the HTA.
- Facilitating inspections by the HTA of the University when required under the conditions of the licence.

6. Responsible Research

6.1 General

The University recommends all staff who undertake research utilising human material strictly follow the guidance policies and procedures described within the University of Liverpool Research Integrity Policies and Guidelines HMR QMS document suite relating to the storage, use and disposal of all human material for research.

6.2 Misconduct

Staff and students are reminded that failure to observe the HT Act (2004) or the University of Liverpool Policy on the use and storage of Human Material for Research Purposes may mount to misconduct and could result in disciplinary action being taken. Failure to comply with the HT Act can lead to criminal penalties and fines for the individuals concerned, the DI and the University.

All those to whom this HMR Quality Manual applies should report any known or suspected relevant misconduct. Members of staff and students are encouraged to raise concerns about suspected relevant misconduct either through their PD/HMO or in confidence under the Policy on Public Interest Disclosure. The University has a responsibility to investigate allegations of misconduct. It also has a responsibility to protect staff and students from malicious, mischievous or frivolous allegations.

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8 https://www.liverpool.ac.uk/research-integrity/integrity-issues/
9 https://www.liverpool.ac.uk/intranet/hr/my-hr/information/policies/working/whistleblowing/
7. Abbreviations

CI/PI  Chief/University Principal Investigator
COP  Code of Practice
DI  Designated Individual
HTA Research Licence  Human Tissue Authority Research Licence
HMO/HMOs  Human Material Officer/Officers
HM Code  University of Liverpool Human Material Code of Practice
HMGQ Officer  Human Material Governance and Quality Officer
HM Oversight Committee  Human Material Oversight Committee
HMR QMS  Human Material Research Quality Management System
HRA  Human Research Authority
HTA  Human Tissue Authority
MC Act 2005  Mental Capacity Act 2005
PD  Persons Designate
NHS  National Health Service
SOP  Standard Operating Procedure
University  University of Liverpool

8. Associated Documents and References

- Human Tissue Act 2004¹.
- HTA List of Materials considered to be Relevant Material under the HT Act (2004)².
- Human Tissue Authority Codes of Practice³.
- University of Liverpool: Policy on the Use and Storage of Human Material for Research (HTA001)⁴.
- University of Liverpool: Human Material Code of Practice (HTA003)⁶.
- University of Liverpool: Summary Record of Documented Procedures Necessary to Ensure Compliance with the HT Act 2004 (HTA005)⁷.
- University of Liverpool: Human Tissue Authority Licence Risk Assessment (HTA006)⁸.
- University of Liverpool: Procedure for Internal Audit of Relevant Human Material (HTA007)⁹.
- University of Liverpool: Human Material Supporting Documents (SDS001-SDS003)¹⁰.
- University of Liverpool: Research support office Standard Operating Procedures¹².
- University of Liverpool, Research Integrity Policies and Guidelines¹⁴.
- University of Liverpool, Human Resources policy on whistleblowing¹⁵.
9. Appendices

Appendix 9.1- The University Human Material Research Quality Management document structure.
Appendix 9.2- Summary of HTA Governance and quality system standards

GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process

a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities

Guidance
At a minimum, it is expected that most establishments will have standard operating procedures (SOPs) covering the following activities:

- consent
- collection
- receipt
- labelling
- specimen preparation/preservation
- storage
- relevant transport arrangements
- cleaning and decontamination
- disposal

More complex establishments, especially those releasing material, may need to cover more areas in their suite of documents.

A standard operating procedure (SOP) should be a clear and accurate representation of an existing procedure or process, preferably set out in the format of a stepwise guide. SOPs should be understandable to enable new staff to follow a procedure from beginning to end. They should be detailed enough to ensure uniformity between staff in the performance of a specific function and should be followed to the letter by all staff who have been appropriately trained.

People undertaking the processes should be involved in developing the SOPs to ensure that the written procedures reflect actual practices. Regular review of SOPs will help to prevent incremental departure from written processes with passing time and allow establishments to identify improvements. Establishments should introduce a system to record that staff have read and understood SOPs.

If human tissue is to be transferred between establishments, consideration must be given to minimise the likelihood of theft, damage or loss during transport. Some form of formal transfer arrangement, for example, as part of a Material Transfer Agreement (MTA) should define how the human tissue is preserved, any potential contamination risks associated with it; and who is responsible for disposal, if applicable. We do not specify or endorse any particular format for MTAs; a number of template agreements are publically available and can be adapted to suit individual circumstances. Transportation procedures should also give sufficient detail to ensure the integrity of the tissue.

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10 https://www.hta.gov.uk/policies/research-sector-hta-standards
b) There is a document control system.

Guidance

*Governance documents should include:*
- Revision history and version number
- ‘Effective from’ date
- Review date (at least every three years)
- Pagination
- Author and reviewer names

c) There are change control mechanisms for the implementation of new operational procedures.

Guidance

Change control mechanisms should take into account the risks of any planned changes, any validation required, any training required and how implemented changes will be reviewed.

d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff.

Guidance

All staff working under the HTA licence should be aware of the governance arrangements in place, and they should be represented at governance meetings. Overall governance processes should be supported by regular meetings with staff at the establishment who are engaged in licensed activities. Formal meetings should be minuted and the actions should be noted and followed up. Documented minutes of meetings should be distributed to all relevant staff to help to ensure that they are aware of all important information relating to licensed activities at the establishment. National and local information relevant to activities should also be disseminated.

e) There is a system for managing complaints.

General guidance

A formal quality management framework helps to establish minimum expectations for governance and quality systems, and facilitates continuous improvement. The work of the staff at the establishment must be subject to a system of governance. This means that there should be clear reporting lines and accountability (particularly with regard to individual staff and the DI), documented roles and responsibilities.

Establishments are encouraged to have an over-arching quality document which provides an overview of the establishment’s main purpose, organisation and structure and approach to governance and quality. This document should be accessible to all staff involved in licensed activities.

The HTA recommends that establishments adopt a harmonised approach to sample management as there are risks of varying practices where samples being stored for REC-approved projects are managed differently to samples subject to HTA’s licensing standards.

GQ2 There is a documented system of audit

a) There is a documented schedule of audits covering licensable activities
b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these

General guidance
Audits will demonstrate compliance with our standards and demonstrate whether establishments are meeting the requirements of their own systems.

A documented schedule of audits should be in place at each establishment. Vertical audits of records and specimens will allow the establishment to assure itself that specimens and records are fully traceable from consent to disposal. Records, including records of consent, should be audited regularly to ensure completeness, accuracy and legibility.

Audits should ideally include horizontal audits by staff involved in the processes, to ensure that SOPs accurately reflect actual practices and to identify areas for improvement. All audit findings and related corrective and preventative actions should be recorded to allow the establishment to demonstrate compliance with HTA standards and follow-up outstanding actions.

Audit processes can benefit from being undertaken by a person who is not normally involved in the activity at the establishment: a ‘fresh eyes’ view. Internal auditors should not be involved in auditing their own work.

Some establishments may be able to make use of existing in-house expertise or services.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

a) Qualifications of staff and all training are recorded, records showing attendance at training.
b) There are documented induction training programmes for new staff.
c) Training provisions include those for visiting staff.
d) Staff have appraisals and personal development plans.

General guidance
Training and induction packages help to ensure that staff are fully trained on all policies and procedures relevant to their work. Establishments should ensure that training and development plans are in place and that these are reviewed periodically.

Staff should be encouraged to attend professional meetings and training events to ensure that they keep abreast of good practices in their areas of expertise.

GQ4 There is a systematic and planned approach to the management of records

a) There are suitable systems for the creation, review, amendment, retention and destruction of records.

Guidance
Documented records are used by establishments to evidence traceability and ensure a robust audit trail. In this context, traceability refers to the completeness of auditable information about every step in the pathway for the use of relevant material, from consent through to disposal, or the material has been used up entirely.
Documented procedures for the creation, review, amendment, retention and destruction of records are required to help to ensure that records are maintained appropriately. SOPs should detail the frequency of document review required to ensure that documents are regularly reviewed and updated as necessary.

b) There are provisions for back-up / recovery in the event of loss of records.

Guidance
Records may be in various formats, including paper based, electronic, or stored on recordable media.

A centralised system for the storage of records can help to ensure that records are regularly backed-up.

c) Systems ensure data protection, confidentiality and public disclosure (whistleblowing).

Guidance
Consideration must be given to other relevant legislation, including compliance with the Data Protection Act 1998 where tissue has been taken from the living, and compliance with professional guidelines where applicable.

GQ5 There are systems to ensure that all adverse events are investigated promptly

a) Staff are instructed in how to use incident reporting systems

b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made.

General guidance
All establishments licensed by the HTA are required to have an internal system for reporting adverse events and, where necessary, instigating an investigation or root cause analysis.

Clearly assigning responsibilities for incident management is important. As the DI is responsible for licensed activities at the establishment, there should be a process in place to allow them to be made aware of adverse events so that proper investigation and reporting can take place. There should be an adverse incident SOP detailing how adverse incidents are logged, reported, addressed and monitored.

Although there is currently no requirement for establishments in the research sector to report adverse incidents to the HTA, if a DI has concerns about an adverse event, they are encouraged to contact us for further advice.

Relevant examples of adverse events include:

- specimen loss;
- missing or incorrect documentation;
- security breach;
- abnormalities in storage temperature readings;
- inappropriate disposal.
GQ6 Risk assessments of the establishment’s practices and processes are completed regularly, recorded and monitored

a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA’s Codes of Practice.

Guidance
All establishments should identify the risks inherent in the key activities, and procedures should be developed in consideration of and to mitigate these potential risks where appropriate. Establishments may tend to focus risk assessments on health and safety issues which, in themselves, are not sufficient to meet our standards. Dls should also assess the risks associated with licensed activities. Documented risk assessments should include an evaluation of the level of the risk and, where appropriate, the mitigating actions identified and the level of residual risk remaining.

Risk assessments should include the risks relating to the premises, practices and procedures connected with licensed activities, including:

- receiving and/or storing specimens without appropriate consent documentation
- storing or using human tissue after consent withdrawal
- storage failure or other damage affecting human tissue quality for useful research
- loss of human tissue
- sample mix-up or loss of traceability
- transport of specimens to and from the establishment
- security arrangements
- incorrect disposal

b) Risk assessments are reviewed regularly.

Guidance
Risk assessments should be reviewed periodically (typically, every 1-3 years) and the actions to mitigate risks updated as necessary. Risk assessments should also be reviewed following an incident.

c) Staff can access risk assessments and are made aware of risks during training.

Guidance
By documenting risk assessments, staff are made aware of identified risks, which helps to prevent risks materialising and informs the development of procedures and relevant documentation.
### 10. Confirmation Sheet

**Document:** The University of Liverpool Human Material Research Quality Manual

**Reference:** HTA004

**Declaration:**

I confirm that I have read, understood and agree to follow the policy and procedures described.

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