

# QUALITY MANUAL

## Acquisition, Storage, Use and Disposal of Human Tissue

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## Standard Operating Procedures – Research licence

AURIO001	Due Diligence Process for Approving Suppliers/Recipients of Human Tissue
AURIO002	Designated Individual Approval to Undertake Research with Human Tissue
AURIO003	Material Transfer Agreements for Human Tissue
AURIO004	Transport of Human Tissue
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AURIO006	Storage of Human Tissue
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## Standard Operating Procedures – Anatomy licence

AMS AURIO001	Human Specimens Due Diligence on Supplier
AMS AURIO002	Human Specimens Staff Training
AMS AURIO003	Material Transfer Agreement
AMS AURIO007	Decontamination, Cleaning and Maintenance
AMS AURIO008	Human Specimens Disposal
AMS AURIO015	Human Specimen Handling and Security
AMS AURIO016	Human Specimens Transport
AMS AURIO100	Human Specimens Storage
AMS AURIO103	Human Specimens File Management
AMS AURIO104	Human Specimens Adverse Event Reporting
AMS AURIO105	Human Specimens Audit
AMS AURIO106	Human Specimens Standard Operating Procedures

## Forms – Research

**(Available on request via [research\\_governance@aston.ac.uk](mailto:research_governance@aston.ac.uk))**

AURIO001	Application for Due Diligence on a Supplier/Recipient of Human Tissue
AURIO002A	Application for Designated Individual Approval for Research with Human Tissue (To be completed when HRA approval is required and Aston is the sponsor)
AURIO002B	Application for Designated Individual Approval for Research with Human Tissue (For all projects other than those requiring HRA approval and Aston are Sponsoring [then use AURIO002A])
AURIO003	Application for Designation of a Laboratory for the Storage and Use of Human Tissue
AURIO004	Application for Designation of a Freezer for the Storage of Human Tissue
AURIO006	Human Tissue Research Training Record
AURIO101	Adverse Event Report
AURIO102	Protocol Amendment

## Forms – Anatomy

**Available on request via [ams\\_mbchb@aston.ac.uk](mailto:ams_mbchb@aston.ac.uk)**

AMS AURIO002	HTA Training Checklist
AMS AURIO002	Staff and Visiting Honorary Staff Information and Regulations
AURIO002B	Student information and Regulations

## 1. Introduction

The purpose of this Quality Manual is to document the University's Quality Management System (QMS) for the governance of the acquisition, storage, use and disposal of human specimens/samples for research or anatomical examination and for education or training relating to human health to ensure that all staff and students understand the necessary requirements and procedures covered by the Human Tissue Act 2004 (HT Act), the Human Tissue Authority's (HTA) Codes of Good Practice and the University's HTA license for Research or Anatomical Examinations.

This Quality Manual forms part of the University's Quality Management System (QMS) for the governance of the acquisition, storage, use and disposal of human specimens for research or anatomical examination. Successful implementation of the QMS will ensure that all activities relating to research or anatomical examination are carried out in compliance with the licensing obligations of the Human Tissue Act and to the standards required by the HTA and Aston University. It is important that the academic community and the public have confidence that all human specimens for research or anatomical examination are acquired lawfully and with appropriate consent, and are stored, handled, used and disposed of respectfully, sensitively and responsibly.

## 2. Aston University Human Tissue Act (2004) Licenses

Aston University is licensed by the Human Tissue Authority:

License Number:	12381
License Holder:	Aston University
Licensed Premises:	Aston University
Licensed Activities:	Storage of Relevant Material

Designated Individual (DI):

Rebecca Case [r.case@aston.ac.uk](mailto:r.case@aston.ac.uk)

Persons Designated:

Jiteen Ahmed [j.ahmed4@aston.ac.uk](mailto:j.ahmed4@aston.ac.uk)

Professor Gavin Woodhall [g.l.woodhall@aston.ac.uk](mailto:g.l.woodhall@aston.ac.uk)

Dr David Nagel [d.nagel@aston.ac.uk](mailto:d.nagel@aston.ac.uk)

License Number:	12753
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License Holder:	Aston University
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Licensed Premises: Aston University

Licensed Activities: Anatomical Examination, Storage of an Anatomical Specimen

Designated Individual (DI):

Dr Claire Stocker [c.stocker@aston.ac.uk](mailto:c.stocker@aston.ac.uk)

Persons Designated:

Dr Sami Al-Ani [s.al-ani@aston.ac.uk](mailto:s.al-ani@aston.ac.uk)

Dr Noor Al-Antary [n.al-antary@aston.ac.uk](mailto:n.al-antary@aston.ac.uk)

Dr John Delieu [j.delieu@aston.ac.uk](mailto:j.delieu@aston.ac.uk)

Under the Act the Designated Individual (DI) is responsible for licensed activities and supervising compliance with the licensing arrangements.

## 3. Legislation and Regulation

### 3.1 Background

The Human Tissue Act (Act) came into full effect on 1<sup>st</sup> September 2004, replacing existing laws by setting an updated legislative framework for regulating body donation, and the removal, storage and use of human organs or tissues.

The Act is set out at: <https://www.legislation.gov.uk/ukpga/2004/30/contents>

The purpose of the Act is to provide a consistent legislative framework for issues relating to collection, storage, use and disposal of human tissue (including body parts, organs and whole bodies). It applies to England, Wales and Northern Ireland. There is separate legislation in Scotland (Human Tissue Act (Scotland) 2006). The Act allowed for the establishment of the Human Tissue Authority (HTA) in April 2005 as the regulatory and licensing authority and enabled licences to be issued to organisations storing tissue for human application (i.e., the use of human tissue to treat patients, for example, transplantation) from April 2006 and licences for all other activities (Scheduled Purposes) from September 2006.

The Act makes informed consent the fundamental principle underpinning the lawful removal, storage and use of human tissue from the living and from the deceased. It requires that all procedures involving human tissue be conducted with full respect for the dignity of the donor.

The HTA is an independent regulator, established by the HT Act to protect public confidence by ensuring human tissue is used safely and ethically, and with proper consent. The HTA licenses and inspects organisations that store and use human tissue for the following activities (Scheduled Purposes under the Act, for which consent from the donor is required):

- teaching about or studying the human body.
- carrying out post-mortem examination.
- using human tissue to treat patients.
- carrying out research on human tissue.
- displaying human bodies or tissue in public (e.g., in a museum).

The HTA aims to:

- make sure that these laws are followed by setting clear and reasonable standards.
- provide codes of practice and other advice, guidance and support (including the provision of workshops and e-learning packages).
- give the public confidence that their wishes when donating tissue will be respected, that their donated tissue will be put to the best possible use, and in turn increase the willingness of the public to donate
- give the professionals confidence that they are working within a clear and effective regulatory framework for the removal, retention, use and disposal of that donated tissue.

The HTA's Codes of Practice and Standards provides practical guidance to carrying out activities within the scope of the HTA's remit. Those relevant to Research or Anatomical Examination are:

- Code A (Guiding Principles and Fundamental Principles of Consent) is the overarching Code and contains information that is applicable to all establishments and professionals.
- Code C (Anatomical Examination) relates to the macroscopic examination by dissection for the purposes of teaching or studying, or researching into, the gross structure of the human body

- Code E (Research) relates to the acquisition, storage, and usage of relevant material for the purposes of teaching or studying, or researching into, the human body. It covers the consent and licensing requirements relevant to the research community and sets out the expectations for establishments licensed in the Research Sector.

Download the HTA's Codes of Practice here: [Codes of Practice | Human Tissue Authority \(hta.gov.uk\)](https://www.hta.gov.uk/codes-of-practice)

The HTA's Codes of Practice must be read in conjunction with the relevant University Standard Operating Procedures (SOPs) and the University's Quality Manual (this document).

### 3.2 Scope of the Act

The Act applies to any work on, or storage of, "relevant material". Relevant material is defined in the Act as: "*material, other than gametes, which consists of or includes human cells*" but does **not** include: "*embryos outside the human body, or hair and nail from the body of a living person*". The full definition of relevant material can be found [here](#). **The fundamental concept of relevant material is that if a sample is known to contain even a single cell that has come from a human body, then the sample should be classified as relevant material.**

**All research studies with human tissue for which living participants have given informed consent that have NHS Research Ethics Committee approval are outside the scope of the Act, but not outside of the scope of this Quality Manual.**

However, if tissue is to be stored for a future undefined research project as part of a Tissue Bank the Act applies to storage and use of the tissue even if NHS Research Ethics Committee Approval has been given.

The Act covers use of material from a deceased person for clinical audit, education, training, testing medical devices, health monitoring, quality assurance, or using tissue to obtain genetic information that may be relevant to any other person.

The Act and this Quality Manual also applies to samples which are imported, purchased or obtained from a Tissue Bank. For a living person, consent is required to store tissue for information about that person that may be relevant to any other person (now or in the future), for public display or transplantation.

It is not permitted to have any human tissue for DNA analysis without the consent of the individual or an appropriate representative.

The Act does not apply to cultured cell lines or surplus or residual tissue from a diagnostic or surgical procedure used "anonymously" for ethically (NHS Research Ethics Committee) approved research. However, we require that colleagues let us know if they are working with this material so that we can make a full voluntary return to the HTA, and so that we are able to accurately monitor the storage space needed for human tissue research.

Storage of relevant material on site without DI approval could constitute either research misconduct, gross misconduct or a Fitness to Practice case, and will be investigated in line with the relevant policies.

### 3.3 Consent

Consent for the removal, storage and use of human tissue should be obtained in accordance with the Human Tissue Authority Code A: Guiding principles and the fundamental principle of consent: <https://content.hta.gov.uk/sites/default/files/2020-11/Code%20A.pdf>

For a deceased person, consent is required under the Act if consent has not already been given for an anatomical examination, post mortem, removal of organs/tissues during the foregoing, storage or public display, or research on specimens.

Procedures for obtaining consent for research purposes are outlined in:

SOP: *AURIO102 – Obtaining Consent from Research Participants.*

## 4. Personnel, Premises and Equipment

### 4.1 Responsibilities of Individuals using Human Tissue

#### 4.1.1 Licence Holder

The Licence is held by the University and the Licence Holder is a named individual in a senior managerial role who should be senior to the DI and be able to substitute for the DI where necessary. Although the role of the Licence Holder does not impose duties that are expected of the DI, the Licence Holder has the right to apply to the HTA to vary the licence, which may include recommending a new DI where, for example, the DI is unable to continue their role.

For further information on the role of the Licence Holder, see:

Designated Individuals and Licence Holders under the Human Tissue Act | Human Tissue Authority ([hta.gov.uk](https://www.hta.gov.uk))

#### 4.1.2 Designated Individual (DI)

Under the HT Act, it is the statutory responsibility of the relevant Designated Individual (DI) (Anatomy or Research) to ensure that appropriate procedures and practices are in place and followed, that those involved in research and anatomical examination using human specimens or samples are appropriately informed and trained, and that the conditions of the licence are complied with relating to the HT Act. The HTA expects compliance with all its standards and that the DI will be committed to improving quality, demonstrated by appropriate monitoring and an audit programme. The anatomical examination conducted in the University involving human specimens is under the supervision of the DI (Anatomy or Research) who is required to provide assurance to the senior management of the University that appropriate standards, legislative and regulatory requirements are met, and risks identified and managed effectively.

The DI (Anatomy or Research) must:

be in a position within the licensed organisation to ensure that the activities are conducted properly by individuals who are suitable (and appropriately trained) to carry out those activities and that all necessary legislative and regulatory requirements are complied with.

have knowledge and understanding of the HT Act and the relevant HTA's Codes of Practice.

have time to carry out the role of DI in addition to their substantive role.

ensure compliance with licence conditions.

demonstrate managerial capability, ensuring quality and supervisory responsibility to effect change.

have links to senior management/board level.

know when to seek specialist advice to perform their role.

In addition, the DI (Anatomy or Research) will:

act as a key point of contact for enquiries to the HTA.

be responsible for investigating and reporting adverse events (including to the HTA, as appropriate).

if required in addition to the above, meet with the Licence Holder to provide briefings and updates as part of the monitoring of the operation and compliance with the licence.

be informed of and authorise, as appropriate, all anatomical examination or research related activities in the University using human specimens/samples, in accordance with current University Standard Operating Procedures (SOPs).

For further information on the role of the DI, see:

Designated Individuals and Licence Holders under the Human Tissue Act | Human Tissue Authority ([hta.gov.uk](https://www.hta.gov.uk))

#### 4.1.3 Deputy Designated Individual (In extremis)

An individual can be nominated by the DI (Anatomy or Research) to act as Deputy DI (in extremis). The Deputy DI (in extremis) will be a member of academic staff and have knowledge and understanding of the HT Act, the relevant HTA's Codes of Practice and compliance with the relevant licence conditions. The role of Deputy DI (in extremis) ensures there is continuity of support for those involved in anatomical examination if the DI is unavailable for an extended period of absence. The Deputy DI (in extremis) will not automatically replace the DI should the DI no longer be able to continue the role, as a formal application to undertake the role of DI must be made by the Licence Holder to the HTA for HTA Approval.

#### 4.1.4 Persons Designated (PDs)

Individuals can be nominated as Persons Designated (PD) by the DI to work under the direction of the licence in support of the DI. PDs do not have the legal duties of the DI as set out in the HT Act (Section 18) but the role of the PD carries with it the ability to “direct” others in relation to the HT Act - e.g., to assist in developing and implementing the SOPs and offering advice and guidance to those working with human specimens. This means other individuals working under the direction of the PD are advised about how and why they need to follow procedures and systems agreed by the DI to comply with the HT Act and the University’s Human Specimens Quality Manual. The PDs will be academic members of staff who are appropriately qualified and experienced in the use of human specimens in research or anatomical education and/or anatomical examination.

PDs will assist the DI through the support and guidance they give staff and students and also in audits and monitoring activities and practices. PDs will also have regular dialogue with all researchers using relevant material and educators specialising in human anatomy, for example, to ensure they are confident in their work, SOPs are workable and support the highest quality output in research or anatomical examination.

PDs and the DI together play an important role in the monitoring of activity and the effectiveness of the SOPs in the working environment, to give the University and external agencies, including the HTA, assurance of compliance with the licensing obligations under the HT Act and HTA standards. Ongoing dialogue, active engagement with and feedback from the staff and students involved in research or anatomical examination is vital to underpin the development and successful implementation of the QMS.

#### 4.1.5 Individual Educators and Researchers

All educators and researchers (Research or Anatomical Examination) using human specimens must:

register as an individual working with human specimens.

undertake the appropriate training.

receive and maintain awareness of training support materials.

have access to advice and guidance.

understand and adhere to the University’s Quality Management System.

comply with the requirements of the related university policies and Standard Operating Procedures (SOPs).

maintain a Personal Training Portfolio to record relevant training and development activities.

The University maintains a register of all staff working with human specimens in research or anatomical examination. Registration requires the staff member to undertake training appropriate to their immediate needs and to maintain a training programme that demonstrates they are competent to perform duties appropriate to their role. The

responsibility for ensuring the accuracy and completeness of ongoing personal development rests with the individual staff member.

#### 4.1.6 Head of Department

Each Head of Department is accountable for human tissue operational compliance within their department (including ensuring appropriate storage units, appliances and accommodation exist) and are embedding into performance management processes. They are responsible for monitoring research or anatomical examination involving human specimens activity within their department and for ensuring, on the advice of the DI (Anatomy or Research), that those involved in anatomical examination activities are complying with the relevant quality manual and SOPs.

#### 4.1.7 Chief Investigators (CIs) and Principal Investigators (PIs)

The PI is the individual who is responsible and accountable for conducting work using human tissue at Aston University in accordance with the Quality Manual.

It is the responsibility of PIs to ensure that any proposed research studies or teaching activities involving human tissue have: an appropriate ethical committee favourable opinion; DI approval; and that the acquisition, storage, use and disposal of the tissue is undertaken in accordance with the procedures within this Quality Manual.

Additionally it is the responsibility of PIs to ensure that all staff and students engaged in such activities have undertaken appropriate training to allow them to comply with the requirements of this Quality Manual.

**4.1.8 Co-investigators; Teaching and Technical Staff; and Students** – it is the responsibility of co-investigators; teaching and technical staff; and students to ensure that all work that they undertake using human tissue is carried out in accordance with the procedures within this Quality Manual.

## 4.2 Premises

The following areas within Aston University have been designated for research with human tissue and as appropriate for research which falls within the Human Tissue Act 2004:

Main Building Laboratories: MB326/324, MB327, MB334, MB351, MB356, MB358, MB360, MB362, MB363, MB531, MB537, MB633, MB634c, MB635.

Freezer Room: MBLG59

Liquid Nitrogen Facility

Aston Day Hospital: all theatres, associated rooms and laboratories

Vision Sciences VSG56 and VSG26 : collection of tear and saliva samples and packaging for transport **ONLY**

Biomedical Facility

Aston Medical School MB G72 (Storage only); G75, G77, G79, G80 and G81 (Education and Teaching activity only).

Access to Laboratories, Freezer Rooms, Liquid Nitrogen Facility and the Biomedical Facility is restricted to authorised University personnel only in line with University policy. Access for research staff and students will only be granted to those named on a DI approval form.

The laboratories are Class II compliant and operate according to Good Laboratory Practice.

Advice relating to Class II compliance and Good Laboratory Practice and associated training can be obtained from The College of Health and Life Sciences (HLS) Head of Technical Services Mr Jiteen Ahmed, e-mail, [j.ahmed4@aston.ac.uk](mailto:j.ahmed4@aston.ac.uk)

Each laboratory/research group should have in place risk assessments and Standard Operating procedures for the use of human tissue.

Requests for designation of additional laboratories for the storage and use of human tissue for research should be made to the DI using **Form AURIO003 – Application for Designation of a Laboratory for the Storage and Use of Human Tissue**.

### 4.3 Equipment

#### Freezers for the Storage of Human Tissue

Freezers designated for storage of human tissue are:

Location	Make	Serial Number
MBLG59 Freezer Room	Innova U535-86	F535KR031679
	Eppendorf F570n	F571LH801424
	Thermo Fisher	1125214801220218

Freezers containing human tissue must remain locked or be in a locked room to which access is controlled and monitored as part of the University external monitoring contract with Tutela Monitoring Systems. **They must not be used for storing animal tissue.**

#### Storage of samples/specimens at room temperature

Cupboards containing human tissue must remain locked or be in a locked room to which access is controlled; this room should be named on the above premises list. **They must not be used for storing animal tissue.**

#### Laboratory Equipment

All laboratory equipment used for research with human tissue must be maintained according to manufacturer's requirements and records should be maintained of: decontamination; servicing; and calibration maintained. These records must be made available for audit and HTA inspections.

Procedures for the use of equipment should be documented in Standard Operating Procedures (SOPs) which also must be made available for audit and HTA inspections.

## 5. Approvals Required for use of Human Tissue

All research projects and teaching activities involving human tissue require a “*favourable opinion*” from an NHS Research Ethics Committee (or approval from your College REC) **and** Designated Individual approval. Please contact [research\\_governance@aston.ac.uk](mailto:research_governance@aston.ac.uk) if you are unsure of the appropriate approval route for your project.

For projects where Aston University is the Sponsor formal Sponsor’s approval for the project is also required.

### 5.1 Research Ethics Committee

#### College REC

For research projects that do not involve the NHS, College Research Ethics Committee (CREC) approval is required if human tissue samples are being collected/purchased/used.

If Aston is responsible for collection of the human tissue to be used in the study an application should be made to the appropriate CREC. Questions about the ethics application process can be sent to the appropriate CREC: <https://www.aston.ac.uk/research/integrity-ethics/ethics>

For studies where anonymised human tissue collected by a third party is to be used **Form AURIO002B: Application for Designated Individual Approval for Research with Human Tissue**, and the associated supporting documents should be submitted to [research\\_governance@aston.ac.uk](mailto:research_governance@aston.ac.uk) and advice will be provided regarding any ethics approvals required.

#### NHS REC

Guidance on making an application to a NHS REC can be found on the Health Research Authority website:

<http://www.hra.nhs.uk/research-community/applying-for-approvals/>

Please contact [research\\_governance@aston.ac.uk](mailto:research_governance@aston.ac.uk) if you intend to submit an application to a NHS REC for your research.

### 5.2 Designated Individual

SOP: **AURIO002 – Designated Individual Approval to Undertake Research with Human Tissue**

All research studies using any human tissue samples must have DI approval. To apply for Designated Individual approval you should complete **Form AURIO002A/B – Application for Designated Individual for Research with Human Tissue**, available on request from the Aston University Research Integrity Office (AURIO) ([research\\_governance@aston.ac.uk](mailto:research_governance@aston.ac.uk)).

Acquisitions of any new specimens under our Anatomy licence requires DI approval – please consult the SOPs detailed in the list on page 5 and contact the DI to discuss. REC approval is not required for specimens being purchased or donated from another institution.

### 5.3 Aston Sponsorship

To apply for University Sponsorship of a project investigators should contact AURIO ([research\\_governance@aston.ac.uk](mailto:research_governance@aston.ac.uk)) having first consulted University guidance available here: <https://www.aston.ac.uk/research/integrity-ethics/sponsorship-guidance>

## 6. Transfer of Human Tissue

### 6.1 Material Transfer Agreements

Transfer of human tissue to and from the University should only be undertaken with HTA licensed establishments or organisations for which the DI has undertaken due diligence and approved as a supplier/recipient.

The Due Diligence process for research is outlined in:

SOP: **AURIO001 – Due Diligence Process for Approving Suppliers/Recipients of Human Tissue**

The Due Diligence process for the Anatomy licence is outlined in:

SOP: **AMS AURIO001 - Human Specimens Due Diligence on Supplier**

A Material Transfer Agreement must govern **all** tissue transfers to and from the University.

Procedures for the development and approval of Material Transfer Agreements (MTAs) are outlined in:

Research

SOP: **AURIO003 – Material Transfer Agreements for Human Tissue**

Anatomy

SOP: **AMS AURIO003 - Material Transfer Agreement**

### 6.2 Transport of Human Tissue

Procedures for the transport of tissue to and from the University are outlined in:

Research

SOP: **AURIO004 – Transport of Human Tissue**

Anatomy

SOP: **AMS AURIO016 - Human Specimens Transport**

The scope of SOP: AURIO004 is limited to the physical transfer of tissue. Additional procedures associated with documentation of the process can be found in SOP: **AURIO005 – Human Tissue Records**.

## 7. Documentation of Research with Human Tissue

### 7.1 Site Files

When Designated Individual approval is received, it is the responsibility of the Principal Investigator to ensure an investigator site file is produced and maintained at each research site. These site files must contain copies of all documentation outlined in the **Standard Operating Procedure “AURIO103 – Site File Management”**. For research projects involving the use of human tissue for which Aston University has no Sponsorship responsibilities, it is the responsibility of the Aston Principal Investigator to produce the site file.

Information on Site File Management for research projects can be found in SOP: **AURIO103 – Site File Management**

### 7.2 Human Tissue Records

All records relating to the receipt, storage, use, transfer and disposal of human tissue should be stored electronically on a University network drive.

The location of the records should be recorded in the Site File.

Research

SOP: **AURIO005 – Human Tissue Records** describes the procedures to be followed to ensure Quality Manual compliance in the management of Human Tissue Records.

Anatomy

SOP: **AMS AURIO103 – Human Specimens File Management** describes the procedures to be followed to ensure Quality Manual compliance in the management of Human Specimen Records

## 8. Storage of Human Tissue

Research

SOP: **AURIO006 – Storage of Human Tissue** describes the procedures to be followed to ensure Quality Manual compliance in the storage of human tissue.

Anatomy:

SOP: **AMS AURIO100 – Human Specimens Storage** describes the procedures to be followed to ensure Quality Manual compliance in the storage of human specimens.

## 9. Cleaning and Decontamination

Research

SOP: **AURIO007 – Cleaning and Decontamination Procedures for Laboratories working with Human Tissue** describes the procedures to be followed to ensure Quality Manual compliance in the cleaning and decontamination of laboratories working with human tissue.

Anatomy

SOP: **AMS AURIO007 – Decontamination, Cleaning and Maintenance** describes the procedures to be followed to ensure Quality Manual compliance in the cleaning and decontamination of spaces where human specimens are stored and used.

## 10. Disposal of Human Tissue

Research

SOP: **AURIO008 – Disposal of Human Tissue** describes the procedures to be followed to ensure Quality Manual compliance in the disposal of human tissue.

Anatomy

SOP: **AMS AURIO008 – Human Specimens Disposal** describes the procedures to be followed to ensure Quality Manual compliance in the disposal of human specimens.

## 11. Training

All staff and students (including those holding honorary or visiting contracts) proposing to undertake work with human tissue or specimens at Aston University must complete appropriate competency-based training prior to commencement of the work. This will include familiarisation with relevant documentation (codes of practice, standard operating procedures, and risk assessments) and undertaking training courses where required.

Research

Completion of the Aston University Human Tissue Act Training Programme is a mandatory requirement for all members of the research team, which includes both online and internally delivered training. This, and Good Clinical Practice training, must be taken at least once every three years.

Training requirements are determined according to the role of the individual within the proposed programme of work. Training requirements for PIs are advised by the DI and those of the Research Team by the PI.

Training records relating to the use of human tissue (**Form AURIO006 Human Tissue Research Training Record**) form part of an individual's overall training record. Copies of records for all staff and students working on a project should be filed in the Site File for the project.

SOP: **AURIO009 – Training Records for Research with Human Tissue** describes the procedures to be followed to ensure Quality Manual compliance.

Anatomy

Individuals wishing to be involved in anatomical examination using human specimens must attend the following:

- Training session 1 – The HTA – Knowing your Responsibilities (provided by Research Integrity and Governance Lead for all new staff and provided on a regular basis).
- Training session 2 - Anatomical Examination (provided as required by the DI and PDs AMS).

A record of this training will be provided in certificate form for each course: these should be filed in the Personal Training Portfolio. The only exception to this will be for Visiting Honorary academics working under the supervision of a trained and registered member of staff. Such individuals are only required to undertake Training Session 2.

All individuals working with human specimens in anatomical examination are also required to undertake the Medical Research Council (MRC) e-learning module: Research and human tissue legislation. This should be undertaken after completion of training session 1.

SOP: **AMS AURIO002 – Human Specimens Staff Training** describes the procedures to be followed to ensure Quality Manual Compliance.

## 12. Adverse Event Reporting

### 12.1 Adverse Event Definition

For the purpose of this Quality Manual an Adverse Event is defined as:

***“Any event that affects or has the potential to affect the integrity of human tissue or the programme of work in which it is being used”***

And/or

***“Any event which has resulted in a deviation from an Aston University Quality Manual SOP or its associated policies and procedures”***

Examples include:

- Damage to the integrity of the tissue/specimen during transport, storage or use
- Unauthorised access to tissue/specimens
- Loss of data
- Freezer failure or any other damage in storage location
- Failure to maintain and calibrate equipment in accordance with manufactures requirements or local laboratory SOPs
- Loss of power supply to laboratories (freezers) – even if the freezer maintains its temperature during the loss of power – or other event affecting laboratories or storage facilities (fire, flood)
- Any injury to staff or students whilst working with human tissue
- Withdrawal of ethical approval

All adverse events should be reported to the relevant DI no later than 48 hours after the research/teaching team are aware that they have occurred in accordance with the procedures for the reporting of adverse events outlined in:

Research:

SOP: **AURIO104 – Adverse Event Reporting**

Anatomy:

SOP: **AMS AURIO104 – Human Specimens Adverse Event Reporting**

If researchers are unsure how they should appropriately deal with the Adverse Event they should contact the relevant DI for advice.

In addition, any Adverse Event that falls within the requirements of the Aston University Adverse Event Reporting Policy should be reported through appropriate processes.

## **13. Monitoring, Auditing and Inspection**

### **13.1 Monitoring**

All research projects will normally be monitored annually to ensure Quality Manual (and as appropriate, GCP) compliance following collection/receipt of the first sample.

### **13.2 Internal Audit**

All research projects involving the use of human tissue (relevant material) will be subject to internal audit at random intervals following receipt of DI approval and at three months following completion of the project.

Audits will comprise a review of documentation and data, and a laboratory visit.

Internal audit procedures for research are outlined in SOP: **AURIO105 – Internal Audit**. Internal audit procedures under the Anatomy licence are outlined in SOP: **AMS AURIO105 - Human Specimens Audit**

Additionally projects where human tissue is being collected in a NHS organisation may be audited by the appropriate NHS organisation.

The University's central quality control and audit systems may undertake audits of any activities using human tissue or specimens under our licences, and may also undertake audits of the related governance procedures and management processes (which may also include the Quality Manual and SOPs related to use of human tissue or specimens). All those engaged in use of human tissue or specimens must ensure that they maintain and make available all appropriate and required records and documentation for such audits.

### **13.3 Inspection**

All activity involving the use of human tissue may be subject to Inspection by the Human Tissue Authority.

## 14. Complaints

Any complaints in relation to the storage and use of human tissue at Aston University should be made in writing to the appropriate DI. The complaint will then be investigated by the DI and, if appropriate, action taken to resolve the issue raised by the complainant.

The DI will provide a written response to complaints within one month of receiving the complaint.

In the event of the DI being unable to resolve the complaint it will be escalated to the Pro-Vice Chancellor Research Integrity.

Complaints against a decision made by the DI should be made in writing to the appropriate Corporate Licence Holder Contact:

Research – Professor Jo Lumsden

Anatomy – John Alcolado

Appeals against a decision made by a Corporate Licence Holder Contact should be made in writing to the Pro-Vice Chancellor Research (Research licence) or to the Executive Dean of the College of Health and Life Sciences (Anatomy licence).

## 15. Archiving

On completion of research studies using human tissue all documentation and data relating to the project should be transferred to AURIO for archiving.

Archiving procedures are outlined in SOP: **AURIO106 – Archiving**

## 16. Human Tissue Act Compliance Oversight Group

Governance of the acquisition, storage, use and disposal of human tissue at Aston University is overseen by the Human Tissue Act Compliance Oversight Group:

**The purpose of the group is to:**

1. Provide oversight of activities to ensure compliance with the Human Tissue Act (2004).
2. Support the Designated Individuals in the development of University wide policies, procedures and processes to support compliance.

The HTA Oversight Group meets at least quarterly and may be convened at short notice for extraordinary meetings if the need arises. It is the Committee that oversees all HTA related activity in the University, both anatomy teaching and research.

### Membership

Designated Individual - Research (Chair)

Designated Individual – Anatomy (Deputy Chair)

HTA Licence Holder contact – Research

HTA Licence Holder contact – Anatomy

Persons Designated – Research

Head of Legal Services

College of Health & Life Sciences Head of Technical Services

College of Engineering & Physical Sciences Technical Manager

Health and Safety representative

Head of the Biomedical Unit

Chair of College of Health & Life Sciences Ethics Committee

Chair of College of Engineering & Physical Sciences Ethics Committee

**Co-opted members – as required to support specific projects/initiatives**

Persons Designated – Anatomy

**Terms of Reference**

1. To ensure that the “Aston University Quality Manual: Acquisition, Storage, Use and Disposal of Human Tissue” and associated policies, procedures and processes support compliance by the University with the Human Tissue Act 2004.
2. To monitor the effectiveness of operational structures that support compliance with the Human Tissue Act 2004.
3. To ensure appropriate communications are in place to enable all staff and students and any visiting research staff to be aware of and operate in accordance with the “Aston University Quality Manual: Acquisition, Storage, Use and Disposal of Human Tissue”.
4. To keep under review national and international directives on human tissue.
5. To review any adverse events in relation to the use of human tissue.
6. To review internal and external monitoring visit and audit reports relating to projects using human tissue.
7. To receive reports on the monitoring of equipment and facilities for the storage of human tissue.
8. To make recommendation to the Executive Operation Group for new facilities; equipment; resources; and staffing to ensure Human Tissue Act 2004 compliance.

## 17. Amendments to the Quality Manual

Any proposed amendments to the Quality Manual and the associated SOPs should be drafted by the DI (appropriate to the changes being requested). The amendment must then be formally approved by the HTA Compliance Oversight Group before a new version of the document is issued.

Additionally, the Quality Manual and Standard Operating Procedures will be reviewed annually.

Changes to the Quality Manual and Standard Operating Procedures will be communicated in the following ways:

- All Principal Investigators who are undertaking work with human tissue will be informed of changes by the DI (Research). They will be asked to confirm that they have communicated the changes to all staff and students involved in the project and implemented the required changes.