Aston University

QUALITY MANUAL

Acquisition, Storage, Use and Disposal of Human Tissue

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Authorisation Rebecca Case Designated Individual	Date: 25th October 2021

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Forms

(<u>Available on request</u> via 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
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1. Introduction

Aston University operates a quality management system for the governance of the acquisition, storage, use and disposal of human tissue.

This system ensures that all work involving human tissue is conducted in accordance with "good practice" and complies with the Human Tissue Act (2004).

Quality manual procedures are applicable to **all** research involving human tissue at Aston University.

This manual sets out the operating procedures for the system.

2. Aston University Human Tissue Act (2004) License

Aston University is licensed by the Human Tissue Authority for:

"storage of relevant human material for a scheduled purpose"

License Number: 12381

License Holder: Aston University

Licensed Premises: Aston University

Designated Individual (DI):

Rebecca Case r.case@aston.ac.uk

Persons Designate:

Jiteen Ahmed j.ahmed4@aston.ac.uk

Professor Gavin Woodhall g.l.woodhall@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 (HTA) came into full effect on 1st September 2006, 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: http://www.opsi.gov.uk/ACTS/acts2004/ukpga_20040030_en_1

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.

It sets up an overarching Authority (the Human Tissue Authority) to regulate activities through licensing and to introduce supplementary directions and guidance.

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.

All 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.

However, if tissue is to be stored for a future undefined 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.

Special allowance is made to preserve organs pending consent for transplantation.

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 do ask 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.

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 are outlined in:

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

4. Personnel, Premises and Equipment

4.1 Responsibilities of Individuals using Human Tissue

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.

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: MB334, MB356, MB358, MB360, MB363, MB633, MB634c, MB351, MB326/324, MB531, MB537.

Freezer Room: MBLG59

Liquid Nitrogen Facility

Aston Day Hospital: all theatres, associated rooms and laboratories

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

Biomedical Facility

Aston Medical School MB G72 (Storage only); G75, G77, G79, G,80 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.

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) Technical Services Manager Mr Jiteen Ahmed, e-mail, 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 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
MB633	NBS U725	1016-0279-0410
	Sanyo MDF-U3386S	08060005
MB634C	NBS U535	F535JN131535
MB326	Sanyo MDF-U5411	20708164
	Sanyo MDF-U74V	10020180
	Sanyo MDF-U73V	70208789
	Sanyo MDF-U74V	11020256
MB334	NBS U535	F535EI330289
MB356A	Revco 8925	830046-80
MB358	Forma 905	40975374
	NBS U360	1005-9408-0413
MB360	New Brunswick U535 Innova	F535EK730327
MB363	New Brunswick U725-G Innova	F725FJ233189
Day Hospital	NBS U360	F360CQ830026

MBLG59 Freezer Room	NBS U725 (Freezer F023)	F725EL531849
	NBS U725 (Freezer F024)	F725GN534657
	Thermo Scientific UXF30086V (Freezer F026)	1118026301170807
	New Brunswick U535 Innova (Freezer F028)	F535GH530596

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 contact with Tutela Monitoring Systems. They must not be used for storing animal tissue.

Requests for designation of additional freezers for the storage of human tissue should be made to the DI using ***Form AURIO004 – Application for Designation of a Freezer for the Storage and Use of Human Tissue.***

Storage of Paraffin Embedded Tissue Blocks and Slides

Cupboards containing human tissue must remain locked, or be in a locked room to which access is controlled. 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 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 SOPs which also must be made available for audit and HTA inspections.

5. Approvals Required for Research using Human Tissue

All research projects and teaching activities involving human tissue require a *"favourable opinion"* from an appropriate Research Ethics Committee (College/University or NHS REC) **and** Designated Individual approval.

In addition for projects where Aston University is the Sponsor formal Sponsor's approval for the project is also required.

5.1 Research Ethics Committee

University REC

For projects that do not involve the NHS a College Research Ethics Committee (CREC) favourable opinion is required.

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 ethics@aston.ac.uk.

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 form the application and are submitted to Aston University Research Integrity Office (AURIO) i.e. there is no requirement to complete a separate ethics application.

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 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***

To apply for Designated Individual approval you should complete ***Form AURIO002 – Application for Designated Individual for Research with Human Tissue*** and submit it to the Aston University Research Integrity Office (AURIO) (research_governance@aston.ac.uk, 0121 204 5069).

5.3 Aston Sponsorship

To apply for University Sponsorship of a project investigators should contact AURIO (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 on which the DI has undertaken due diligence and approved as a supplier/recipient.

The Due Diligence process is outlined in:

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

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:

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

6.2 Transport of Human Tissue

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

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

AURIO011 – Transfer of samples using a Statebourne Biotrek 3 Vessel

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 Chief 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 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 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.

Normally this should be undertaken using Pro-curo (www.pro-curo.com/) software but where a project involves a limited amount of data (e.g. a single test or set of tests on all of the samples) a spreadsheet can be used subject to DI approval.

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

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

8. Storage of Human Tissue

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

9. Cleaning and Decontamination

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.

10. Disposal of Human Tissue

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

11. Training

All staff and students proposing to undertake work with human tissue 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.

Completion of the Aston University Human Tissue Act Training Programme is a mandatory requirement.

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.

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 during transport, storage or use
- Loss of data
- Freezer failure
- 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
- Any injury to staff or students whilst working with human tissue
- Withdrawal of ethical approval

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

SOP: ***AURIO104 – Adverse Event Reporting***

If researchers are unsure how they should appropriately deal with the Adverse Event they should contact the 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 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 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 are outlined in SOP: ***AURIO105 – Internal Audit.***

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

13.3 Inspection

All research projects 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 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 University Executive who will deal with it through the formal University complaints process.

15. Archiving

On completion of 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 Individual in the development of University wide policies, procedures and processes to support compliance.

Membership

Designated Individual (Chair)

HTA Licence Holder

Persons Designate

Head of Office of the General Counsel

College of Health & Life Sciences Chief Technician

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

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 a Communications Framework is 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 recommend to the Executive Operation Group for new facilities; equipment; resources; and staffing to ensure Human Tissue Act 2004 compliance.

Frequency of Meetings

Once a term, and additionally as required to ensure the terms of reference are met.

17. Amendments to the Quality Manual

Any proposed amendments to the Quality Manual and the associated SOPs should be drafted by the DI. 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. 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.

- All staff and students who have completed the Aston University Human Tissue Act Training Programme will be informed of the changes by the DI via the weekly "all staff e-

mail" that is sent out by the central marketing department.

- Notification of changes will be put onto the staff intranet site in a position where it is seen prior to accessing the Quality Manual and SOPs and also prior to making a College Ethics Committee application via other relevant communication channels within the University for example, the School of Life and Health Sciences All School e-mail.