

ACQUISITION, STORAGE, USE

AND DISPOSAL OF HUMAN TISSUE

QUALITY MANUAL

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**Foreword**

At Manchester Metropolitan University, we undertake fundamental and translational research in order to improve the health and well-being of men, women and children. To this end we are involved in projects where we take tissue samples from humans. This aspect of our work is highly important and may enable us to identify interventions that will lead to improvements in biomarkers for good health. Subjects who volunteer to participate in our studies donate the samples of tissue, after informed consent. Human tissue samples are, therefore, a precious resource and their removal storage and subsequent use in research are regulated by the Human Tissue Authority.

The purpose of this Quality Manual is to ensure that the samples freely donated by volunteers on our studies are treated with the reverence and respect they deserve.

**Prof Bill Gilmore**

**Designated Individual**

1. **Introduction**

Manchester Metropolitan University operates a quality management procedure for the governance of the acquisition, storage, use and disposal of human tissue.

The procedures described in this Quality Manual ensure that all work involving human tissue is conducted in accordance with “good practice” and complies with the Human Tissue Act (2004).

**2. Manchester Metropolitan University Human Tissue Act (2004) License**

Manchester Metropolitan University is licensed by the Human Tissue Authority for:

***“Storage of relevant human material for a scheduled purpose”***

Under the Human Tissue Act (2004), subject to compliance with, its strictly regulated code of practice:

License Number: **12402**

License Holder: **Manchester Metropolitan University**

Licensed Premises: **Manchester Metropolitan University**

Designated Individual (DI): **Professor William Gilmore**

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**

3.1.1 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.

URL Link: <http://www.opsi.gov.uk/ACTS/acts2004/ukpga_20040030_en_1>

3.1.2 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.

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

3.1.4 Manchester Metropolitan University staff proposing to undertake any work with human tissue should consult the Act to ascertain if their work will be within or outside the jurisdiction of the Act.

3.1.5 If, after reading the Act and the reference information in this document staff are uncertain as to whether a proposed activity falls within the Act they should contact the Designated Individual.

**3.2 Scope of the Act**

3.2.1 The Act applies to any work on, or storage of, human tissue for which the consent of the individual or an appropriate representative is required *other than ethically (NHS Research Ethics Committee) approved studies for which living participants have given informed consent.*

3.2.2 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 is approved.

3.2.3 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.

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

3.2.5 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.

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

3.2.7 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. Further information is available at: <http://www.hta.gov.uk/licensingandinspections/sectorspecificinformation/research/faqs.cfm> [www.hta.gov.uk/guidance/licensing\_guidance/definition\_of\_relevant\_material.cfm](http://www.hta.gov.uk/guidance/licensing_guidance/definition_of_relevant_material.cfm)

**Types of Human Tissue covered by the Human Tissue Act (2006)**

|  |  |  |
| --- | --- | --- |
| Human  Material | Product | Relevance To HTA |
| **WHOLE**  **BLOOD** | Whole Blood | YES |
| DNA/RNA | NO |
| Serum | NO |
| Cells | YES |
| Plasma | NO |
| **CELL LINES** | After 3rd Passage | NO |
| **OTHER BODY FLUIDS** | Urine | YES |
| Cerebral Spinal Fluid | YES |
| Saliva | YES |
| Joint Fluid | YES |
| **BODY PARTS** | Small Biopsies | YES |
| Identifiable Body Parts | YES |

IF YOU ARE WORKING WITH ANY MATERIAL THAT IS NOT LISTED PLEASE REFER TO THE HTA WEBSITE OR DESIGNATED INDIVIDUAL

**4 Procedures for Working with Human Tissue**

4.1 Ethical approval to sample and store Human Tissue must be obtained from the University Ethics Committee or another recognised Ethics committee, for example, NHS, COREC before any work can commence.

4.2 Consent must be obtained from the subject(s) and a copy of this form sent to the relevant Research Administrative team. Consent should be generic and enduring if samples are to be kept beyond the project end date.

4.3 The University Ethics committee will inform the Research Administrative team when approval has been granted.

4.4 The Research Administrative team will maintain a file that should include the following:

Ethical approval documentation and correspondence

Consent forms

Audit reports

Records of adverse events

Evidence of disposal

4.5 Once ethical approval has been obtained, the Research Administrative team will advise the relevant Person Designated

4.6 The Person Designated will then set up a project account to record relevant information as required under the Human Tissue Act as shown below:

Operating Procedures

Risk assessments

Sample record(s) including storage location

Inspection reports

Disposal details

4.7 Good clinical and laboratory practice must be adhered to when sampling the material.

4.8 If the sample or a proportion of the sample is to be stored, Form MMUHTA 002 Adverse Events should be completed and returned to the Person Designated. The sample must be labelled with the following:

Time and date of sample

Unique reference number (supplied in advance by the Person Designated)

Principal Investigator or project title/code

Disposal date if applicable

4.9 The sample must only be stored in the place allocated by the Person Designated.

4.10 Any adverse events must be reported, in the first instance, to the Person Designated.

4.11 Laboratories will be inspected on a regular basis. Any samples of any nature, not complying with this protocol will be disposed of by the Person Designated.

**5. Adverse Event Reporting**

5.1 All adverse events associated with the use of human tissue, and any deviations from the procedures within this Quality Manual should be reported in the first instance to the Designate Individual or one of the Persons Designated

5.2 Procedures for the reporting of adverse events are outlined in MMUHTA002 Standard Operating Procedure Adverse Event Reporting. Reports should be submitted within 24 hours.

5.3 For further advice on how to appropriately deal with an adverse event, staff should contact the Designated Individual or one of the Persons Designated.

5.4 In addition to reporting the adverse event to the Designated Individual via the Persons Designated, if appropriate and if/or human health is put at risk the incident should also be reported to the University Health & Safety Unit for the appropriate action to be taken.

**Process for Reporting Adverse Events**

Adverse Event Identified

**↓**

Appropriate corrective action identified and agreed with PI

**↓**

Corrective action taken

**↓**

Adverse Event Form completed

**↓**

Copy of Form sent to the Person Designated

**↓**

DI reviews form and approves corrective action

**6 Consent**

6.1 The Human Tissue Act does not specify the format in which consent should be given or recorded for research. However, it is considered best practice for written informed consent to be obtained. An appropriate record of all other forms of consent must be held by the Research Administrative Team.

6.2 Informed consent is a process rather than a “one off event” and should be sought in advance of the intervention supported by a Participant Information Sheet (MMUHTA001C) and the provision of any further information that is requested

6.3 For research, it is generally expected that consent will be confirmed by the signatures of the participant and the investigator. Consent must be given on the appropriate form (MMUHTA001A or MMUHTA001B) and at least 24 hours after the provision of the Participant Information Sheet.

6.4 For consent to be valid it must be given voluntarily; by an appropriately informed person, who has the capacity to give consent.

6.5 The individual seeking consent should be suitably trained and qualified and have sufficient knowledge of the proposed investigation or treatment.

6.6 For research where several areas of specialist knowledge are involved participants should be offered access to specialists if they require additional information.

**Provision of Participant Information**

6.7 It is expected that a written Participant Information Sheet (PIS) MMUHTA001C will be used to support the process of gaining informed consent.

6.8 It is expected that consent will be confirmed in writing via a consent form being signed and dated by the participant and the person seeking consent.

6.9 A copy of the consent form should be given to the participant and a copy should be placed in the participant’s research record.

6.10 For research involving participants who are recruited in the NHS the consent should also be documented in the participants’ notes and consent form MMUHTA001B should be used.

**Vulnerable Groups**

6.11 There are specific requirements for obtaining consent from vulnerable groups, which include:

 Children under 18 years of age

 Unconscious patients

 Adults without capacity to give consent

 Prisoners and Young Offenders

 Disability: Physical/Mental

 A participant who is a dependant of the Investigator

6.12 For research involving these groups, listed in 6.11, it is important that all relevant legislation and requirements be considered when developing the consent process and associated documentation.

6.13 Additionally, it is important to develop an appropriate process for gaining informed consent from patients whose first language is not English.

**Procedure for obtaining informed consent**

Prepare Participant Information Sheet(s) and Consent Form(s)

Seek required ethics committee approvals for the PIS(s) and consent form(s) as part of the study approval process

**↓**

Explain the study to potential Participant; answer any questions that they have; give them a PIS; make it clear that they do not have to participate and do not have to give a reason why they do not wish to participate

Allow the potential Participant time to decide if they wish to participate in the study

Answer any further questions that the potential participant has

If the potential participant is willing to give consent confirm the consent by signing and dating two copies the consent Form MMUHTA001A)

(For NHS research MMUHTA001B consent form is also required)

Give one copy of the consent form to the participant and file one copy of the consent form in the participant’s Research Record

**PROCEDURE FOR OBTAINING CONSENT FOR STORAGE AND WORK ON HUMAN TISSUE FROM THE LIVING**

Consent is not required

Was the tissue retained for research prior to 1 September 2006?

**YES**

**NO**

Qualified consent is required (see HTA)

Is the tissue to be used for DNA analysis?

**YES**

**NO**

Appropriate consent is required

**YES**

Is the tissue from the deceased?

**NO**

Will the tissue be identifiable to the researcher?

Is the tissue from an adult lacking capacity?

**YES**

**NO**

**YES**

**NO**

Has ethical approval for research without consent been given?

**[[1]](#endnote-1)**

See

Clinical Trials Regulations 2004

Mental Capacity Act 2005

Human Tissue Act 2006

Appropriate consent is required

**YES**

**NO**

Seek ethical approval for use without consent

Consent is not required

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 Standard Operating Procedure MMUHTA001

**7. Retaining Samples after an Ethically approved Study**

7.1 Tissue samples can be retained at the end of an ethical approved study provided the study had donor consent that was generic and enduring.

7.2 The question should be put to the donor if they will agree that the tissue that is being can be used for future research studies.

7.3 The donor should have the right to decline.

7.4 Alternatively for each study fresh consent should be sought from the donor.

7.5 If no consent can be sought or given then the human tissue should be disposed of as to the wishes of the donor (*i.e.* *returned to the donor*) or with due reverence by the research group.

**8 Personnel, Premises and Equipment**

* 1. **Responsibilities of Individuals using Human Tissue**

8.1.1 Principal Investigators(PIs) – it is the responsibility of PIs to ensure that any proposed research studies or teaching activities involving human tissue have appropriate ethical committee approval and that the acquisition, storage, use and disposal of the tissue is undertaken in accordance with the procedures within this quality manual.

* + 1. Additionally it is the responsibility of PIs to ensure that all staff engaged in such activities have undertaken appropriate training to allow them to comply with the requirements of this quality manual.
    2. Co-investigators, Teaching and Technical Staff– it is the responsibility of co-investigators, teaching and technical staff to ensure that all work that they undertake using human tissue is carried out in accordance with the procedures within this quality manual.
  1. **Ethical Approval**

8.2.1 Any proposed research studies or teaching activities involving human tissue require appropriate ethical committee approval. Proposals should be submitted to and approved by the University Ethics Committee following the procedure set out at the University website [www.mmu.ac.uk/rke/](http://www.mmu.ac.uk/rke/)

The website contains ethical information for both staff and students and appropriate ethical forms, which must be submitted to the University Ethics Committee for approval before any work is commenced.

* + 1. As part of the application process applicants are asked if the proposal falls within the Human Tissue Act (2004). If the proposal falls within the Act, or there is uncertainty, the applicant should contact the DI regarding proposed activities under the Act to ensure appropriate consent, compliance procedures and training are in place.
    2. Some research proposals will be subject to approval from an NHS Research Ethics Committee. Guidance on making an application can be found at National Research Ethics Service (NRES) <http://www/nres.npsa.nhs.uk/>
  1. **Premises**

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

Manchester

Laboratories: T3.01, T3.01A, T3.01B, T3.01D 1st floor IRM suite of Laboratories T1.07-T1.19

Cheshire

Biochemistry Laboratory

* + 1. Access to these facilities is restricted to authorised University personnel only in line with University policy.
    2. The laboratories operate according to Good Laboratory Practice.

PIs must ensure that all staff working with human tissue have received appropriate training to meet the compliance requirements.

* + 1. Each laboratory/research group should have a clear policy/protocol to follow which covers laboratory cleaning and decontamination for areas where human tissue samples are used and stored.

**9 Transport of Tissue**

**9.1 Human Tissue Sample**

9.1.1 Transport of human tissue to and from the University must only be undertaken with licensed establishments and be the subject of a Material Transfer Agreement.

9.1.2 Procedures for the transport of tissue to and from the University are outlined in Standard Operating Procedure MMUHTA004– Transport of Human Tissue.

9.1.3 All human tissue should be packed into a sealed container prior to transport and labelled with the following information:

Human Tissue Sample

Sample Reference Number:

Tissue Type:

Details of medium/preservative if applicable:

Date of packing:

UN 3373 warning label

9.1.4 If applicable it should be labelled with hazard warning labels relating to the medium/preservative.

9.1.5 The container should then be packed into a box and labelled with an approved human tissue sample hazard-warning label – UN 3373.

9.1.6 If applicable the box should additionally be labelled with any required hazard warning labels relating to the medium/preservative.

9.1.7 Containers, boxes and labels for human tissue transfer can be purchased from general laboratory suppliers.

**9.2 Transport of human tissue to and from the University by Couriers**

9.2.1 It is important that researchers check that the Courier SOP’s are in place to ensure compliance with the Human Tissue Act (2004) and any other appropriate legislation, integrity of the sample, security of the sample and the respect for the dignity of the donor.

**9.3 Transport of human tissue to and from the University by Manchester Metropolitan University Staff**

9.3.1 Transport of human tissue University staff can only be undertaken if the risk associated with the transfer has been evaluated as acceptable via a risk assessment. The PI must be satisfied that procedures to be put in place to minimise risk are adequate and that the residual risk is acceptable.

9.3.2 Undertake and document a risk assessment of the proposed method of transport. The risk assessment should include consideration of the following:

* + - * Personal risk to the individual undertaking the transfer
      * Risk to the public during transfer (chemical and biological hazard)
      * Integrity of the sample
      * Patient confidentiality
      * Individuals involved in the transfer of human tissue are reminded that transfers should respect the dignity of the donor.

**10. Disposal of Human Tissue**

10.1 Once human tissue has been identified for disposal, either because it is no longer viable following use in experiments or the project for which it has been stored has been completed, it should be transferred to storage prior to disposal.

10.2 Unless otherwise stated or material requires another form of containerisation (seek advice from DI or deputies) all relevant material (human tissue) should be placed in a yellow Biohazard bag.

10.3 The bag should be sealed with zip ties or tied in a knot and placed in the appropriate disposal freezer MMUHTA007. The freezer should be kept locked at all times. This freezer is used for the disposal of human tissue and all samples stored will be incinerated.

10.4 The bag should be labelled with following information:

* Human Tissue Samples for Disposal
* Project Reference Number
* Sample Reference Number(s)
* Custodian
* Contact Details of Custodian

10.5 Prior to appointed disposal contractors collecting the waste, technical staff will remove samples from the freezer to the appropriate clinical incineration bin.

10.6 A copy of the signed waste consignment note from the University appointed contractors for disposal should be forwarded to the appropriate technical staff who will allocate a unique number, and all samples that have been collected will be tagged as part of their disposal record and transfer consignment.

10.7 The consignment note should be filed and retained for audit inspection.

10.8 Details of the disposal consignment will be recorded on Procura.

10.9 When tissue disposal is undertaken at the end of a project, the PI should inform the organisation from which the tissue originated in writing if this is required as part of the MTA. When this is the case a copy of the letter should be filed as a part the project record. A copy of this record should be sent to the relevant Research Administrative team to keep on file for audit purposes.

10.12 If material is being returned at the request of the donor then a material transfer form should be completed.

**11 Cleaning and decontamination**

11.1 Procedures for cleaning and decontamination of areas where human tissue is

stored and used are outlined in Standard Operation Procedure MMUHTA005

**12 Training**

12.1Procedures for the development and documentation of training programmes and records are outlined in Standard Operating Procedure MMUHTA008 Training Programmes and Records.

12.2 All staff proposing to undertake research 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 appropriate training courses where required.

12.3 Training requirements will be determined according to the role of the individual within the proposed programme of work and ascertained via a checklist.

12.4 The DI will identify training requirements for PIs.

PIs will identify training requirements for the research team.

12.5 Training records relating to the use of human tissue for research will form part of an individual’s overall training record. Access to records will be required as part of internal University audits or during inspections by external regulatory authorities.

**13 Audits**

**13.1 Internal Audit**

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

13.1.2 Audits will be undertaken by the DI or Deputy and will comprise of a documentation review and laboratory visit.

13.1.3 Documents for audit will include:

* Ethics Committee Application and Approval
* Freezer logs and maintenance records
* Material Transfer Agreements
* Consent Forms (if appropriate)
* Risk assessments undertaken to ensure compliance with SOPs
* Documentation of Transfer of Tissue to and from the University
* Tissue storage records
* Documentation of the issue and return of stored tissue
* Tissue disposal records
* Adverse event forms (if appropriate)
* Training records

13.1.4 PIs should establish a records management procedure prior to commencing a project which identifies where documents are to be held and who, if appropriate has delegated responsibility for the records/documents*.*

13.1.5 If individual subject information is collected as part of a project procedures must be put in place to ensure that confidentiality is maintained.

13.1.6 The internal audit protocol is outlined in Standard Operating Procedure MMUHTA 009 Internal Audit.

**13.2 External Audit**

13.2.1 All projects, which fall within the Human Tissue Act (2004) and are undertaken under the terms of the Manchester Metropolitan University Human Tissue Act Licence may also be subject to audit/inspection by the Human Tissue Authority

**14 Complaints**

14.1 Any complaints in relation to the storage and use of human tissue in Manchester Metropolitan University should be made in writing to the DI.

14.2 The complaint will then be investigated by the DI. If appropriate, action will be taken to resolve the issue raised by the complainant.

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

14.4 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 of Documents**

15.1 On completion of studies using human tissue all documentation relating to the study should be packed into archive boxes and labelled with the following information:

* Study Title
* Reference Numbers relating to the study, for example, ethics committee references numbers
* Principal Investigator
* Start Date Completion Date

15.2 The archive material should then be transferred to the DI for storage in the central archive. All materials will be kept for a period of 15years.

**16 Governance**

16.1 Governance of the acquisition, storage, use and disposal of human tissue in Manchester Metropolitan University is overseen by the Designated Individual (DI): Professor William Gilmore

16.2 Terms of Reference

* To ensure the University is compliant with the requirements of the Human Tissue Act (2004)
* To establish governance and operational structures within the University to ensure compliance, and to monitor the effectiveness of those structures
* To keep under review national and international directives on human tissue
* To maintain central records relating to the acquisition, storage, use and disposal of human tissue within Manchester Metropolitan University

16.3 Frequency of Meetings

Annually, and additionally as required to ensure the terms of reference are met.

1. [↑](#endnote-ref-1)