Manchester Metropolitan
University

Human Tissue Act 2004

Manchester Metropolitan University Code of Practice

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1. Introduction and Aims of Code of Practice

This University Code of Practice (the 'Code') has been developed by the Human Tissue Act Committee (HTAC) to ensure that the Regulatory Framework in respect of the Human Tissue Act 2004 (the 'HT Act') and the Human Tissue Authority (HTA) Directions, including the HTA Codes of Practice and Guidance (the 'HTA Codes') are successfully implemented into the University's practices, guidance and policies.

The Code provides a resource for anyone working or studying at Manchester Metropolitan University with human organs, tissue and cells (together 'Relevant Material') in an educational or research setting.

It also provides guidance about using DNA from Bodily Material i.e. material which has come from a human body and consists of, or includes, human cells. Bodily Material is a broader definition than Relevant Material, as it includes hair and nails from the living as well as from the deceased, and gametes (human sperm and eggs).

It is important for the University to maintain its HTA licence. If staff or students knowingly breach the Regulatory Framework, or the mandatory provisions of this Code, the University's research and teaching may be jeopardised, and the University could suffer reputational damage.

Staff and students are reminded that failure to comply with the HT Act or this Code may amount to 'misconduct' or 'gross misconduct' and could result in disciplinary action being taken. Failure to adhere with the HT Act can lead to criminal penalties and fines for the individual(s) concerned, the Designated Individual (DI) responsible for the premises in which the activity takes place, and the University.

All those to whom this Code applies should report any known or suspected breaches of this Code, and the relevant misconduct. Members of staff and students are encouraged to raise concerns about potential breaches of the Code and / or suspected relevant misconduct in the first instance with their line manager / supervisor, the DI, or the Research Ethics and Governance team in confidence in line with the University's Public Interest Disclosure Policy. 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.

More information about research misconduct can be obtained from the 'Procedure for the Investigation of Misconduct in Research' which can be found via this link Research integrity | Manchester Metropolitan University (mmu.ac.uk)

2. Part A: Regulatory Framework, Licences and the Designated Individual

i. Regulatory Framework

a) Human Tissue Act 2004

The HT Act provides a framework for regulating the storage and use of Relevant Material from the living, and the removal, storage and use of Relevant Material from the deceased for Scheduled Purposes across England, Wales and Northern Ireland. The HT Act makes consent the fundamental principle in underpinning the lawful retention and use of Relevant Material from the living or the deceased for Scheduled Purposes. Under the provision of the HT Act, consent must be obtained to remove, store or use bodies or Relevant Material for Scheduled Purposes https://www.hta.gov.uk/policies/human-tissue-act-2004.

b) Definition of Relevant Material

The definition of Relevant Material in the HT Act 2004 (excluding human application) is:

1. In this Act, "Relevant Material" means material, other than gametes, which consists of, or includes human cells.

2. In this Act, references to relevant material from a human body do not include:

a) embryos outside the body, or

b) hair and nail from the body of a living person

[Human Tissue Act (2004), [Online: http://www.legislation.gov.uk/ukpga/2004/30/section/53; date last accessed 23rd September 2024]

In order to provide further guidance to supplement this definition, the HTA has produced guidance on whether specific materials fall within the definition of Relevant Material under the HT Act. This list is available online via the following link https://www.hta.gov.uk/policies/relevant-material-under-human-tissue-act-2004

c) HTA Legal Directions

Under the HT Act, the HTA has the power to issue its expected standards (or 'Directions') to establishments. This means that the HTA can issue general Directions to establishments to take into account changes in policy and legislation. The HTA may also make Directions that are specific to a particular establishment. (HTA [online: Home | Human Tissue Authority (hta.gov.uk), date last accessed 23rd September 2024).

d) HTA Codes of Practice and Guiding Principles

The HTA Codes provide interpretation of the HT Act and the HTA Directions. They also give practical guidance to support good practice in important areas of science and medicine.

The HTA codes are provided in the list below; the most up to date versions can be accessed and downloaded from the HTA website https://www.hta.gov.uk/hta-codes-practice-and-standards-0. In addition, the MRC Regulatory Support Centre has produced a series of human tissue legislation summaries in collaboration with the HTA https://mrc.ukri.org/research/facilities-and-resources-for-researchers/regulatory-support-centre/human-tissue/.

The HTA Codes are incorporated by reference into this Code. All staff and students involved in activities using Relevant Material are responsible for reading and applying this University Code.

- Code A: Guiding Principles and the fundamental principle of consent
- Code B: Post-Mortem examination
- Code B: Post-Mortem examination standards and practice
- Code C: Anatomical examination
- Code C: Anatomical examination standards and guidance
- Code D: Public Display
- Code D: Public Display standards and guidance
- Code E: Research
- Code E: Research Standards and guidance
- Code F: Donation of solid organs and tissue for transplantation
- Code G: Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation
- Code of Practice on the Human Transplantation (Wales) Act 2013

The HTA's existence and approach are founded on four guiding principles. These principles are derived from the HT Act, explicitly or implicitly, and actively inform the HTA's overall approach to regulation, Codes of Practice, and licencing standards. The principles should inform the actions of anyone involved in using human material, and therefore anyone undertaking activities falling within the remit of the HTA must give them due regard. Where the principles refer to tissue, they apply equally to entire organs.

The guiding principles and further details are available on the HTA website under the Codes of Practice:

- **Consent** and the wishes of the donor, or where appropriate their nominated representatives or relatives, have primacy when removing, storing and using human tissue.
- **Dignity** should be paramount in the treatment of human tissue and bodies.
- **Quality** should underpin the management of human tissue and bodies.
- **Honesty and openness** should be the foundation of communications in matters pertaining to the use of human tissue and bodies.

[HTA Codes of Practice: Codes of Practice | Human Tissue Authority (hta.gov.uk) (last accessed 23rd September 2024)

e) Human Tissue Regulations in Scotland

There are two pieces of Human Tissue legislation which apply in Scotland:

1. **Human Tissue (Scotland) Act 2006**: This act uses the term 'authorisation' which relates to the principles of consent.
2. **Human Tissue Act 2004:** The HT Act applies to England, Wales and Norther Ireland. However, one section of the HT Act applies to Scotland (Section 45, which regulates DNA analysis)

The Human Tissue (Scotland) Act 2006 sets out provisions for the removal, retention, and use of 'organs, tissue and tissue samples' from the deceased, and which is subsequently used for research. It does not regulate the use of tissue from the living for research. The Human Tissue (Scotland) Act 2006 states that authorisation is needed to remove and use post-mortem tissue and tissue samples for research, unless they are Existing Holdings.

MRC Regulatory Support Centre https://mrc.ukri.org/research/facilities-and-resources-for-researchers/regulatory-support-centre/human-tissue/ [last accessed 23rd September 2024].

f) HFEA

If you intend to work with human gametes (ova or spermatozoa) or embryos (outside the body), while outside the definition of Relevant Material for the purposes of the Human Tissue Act 2004, these materials fall within the remit of the Human Fertilisation and Embryology Act 1990, and are regulated by the Human Fertilisation and Embryology Authority (HFEA) https://www.hfea.gov.uk/

ii. University Arrangements for Compliance with the HT Act

a) HTA Licence

A HTA licence is required to store Relevant Material for Scheduled Purposes specified under the HT Act. Licences cover five sectors: human application, anatomy, post-mortem examination, research and public display. Manchester Metropolitan University is the Licence Holder (the "LH") and the LH representative is Prof. Tim Cable.

The University has one licence. The licence has a Designated Individual (the "DI") who is responsible for compliance with the HT Act. The DI is Prof. Hans Degens.

b) Human Tissue Act Committee (HTAC)

The HTAC was established to provide management oversight of Manchester Metropolitan University's compliance with the HT Act. The HTAC reports to the Research Ethics and Governance Committee (REGC). The HTAC will ensure that there is an ongoing review of HT Act compliance across the University. The HTAC meets on a three-monthly basis or when needed.

c) Training

Training in the principles and application of the HT Act is available via different formats but is predominantly provided via the completion of online training. Tailored training can be provided upon request to the Faculty Persons Designate (the 'PD'), a member of the Research Ethics and Governance team, or the DI. It is expected that members of staff and students intending to, or who are working with Relevant Material, complete at least the MRC e-learning course, that needs to be renewed every 2 years, and can also complete the HRA e-learning courses:

- https://byglearning.co.uk/mrcrsc-lms/course/index.php?categoryid=1
- https://www.hra.nhs.uk/planning-and-improving-research/learning/e-learning/

Staff and students involved in seeking consent must be specifically trained in the implications and essential requirements of taking consent.

Other useful resources include:

- Manchester Metropolitan University Data Protection training https://moodle.mmu.ac.uk/course/view.php?id=101387
- MRC Regulatory Support Centre (hosted by UKRI) 'Using Human Samples in Research'

All staff and students working with Relevant Material must keep a record of the training they have received relevant to that work. Any evidence of successful HT Act training completed should be forwarded to the DI.

iii. What Do I Need to Know About Licences and Consent?

Where a member of the University's staff or any students intend to undertake work or research involving the storage and use of Relevant Material from the living, or the removal, storage and use of Relevant Material from the deceased, they must consider the following:

i. whether there is a requirement to be licensed;
ii. the requirements for consent.

Flow charts available in the HTA Codes will assist in determining Licence and consent requirements: Licensing | Human Tissue Authority (hta.gov.uk) (last accessed 23rd September 2024

3. Part B: Working Under a HTA Licence

i. Introduction

The University licence covers a specific area of the University (Please see the University Research Ethics and Governance Webpages for details of the licence we hold). You may use relevant material for Scheduled Purposes, e.g., research, only on HTA-licenced premises unless exemption applies (Please see part C).

a) Terms of Licence

The University is the LH with defined responsibilities under the HT Act. The original licence is held by the DI.

Copies of the Licence must be displayed at the licenced premises. It is the responsibility of staff and students to note the terms of the Licence.

b) Licence Fees

Licence fees are paid annually, and the current fees are displayed on the HTA website.

ii. The Role of the Designated Individuals

In relation to a licence under the HTA Act, a DI is the person under whose supervision the licenced activity is authorised to be carried out.

a) Appointment and Training of DIs

The appointment of individuals to the role of DI must receive prior approval from the HTA before the role is implemented. Heads of Departments (HoD) must therefore notify the research Ethics and Governance (REG) team (via ethics@mmu.ac.uk) as soon as any changes to DI are intended.

Before a DI can be formally appointed, the HTA needs to approve this change. Once the REG team has been notified, the proposed DI should complete an application form to make changes to the license.' The form which can be accessed via the HTA website: How to make changes to your licence | Human Tissue Authority (hta.gov.uk) . Once completed, it should be sent onto the REG team for review before, and once advised to do so, the form should be submitted.

The HTA provides necessary guidance on necessary training for DI's on the HTA website. Evidence of training should be held by the DI.

The University has a risk management policy (Risk Management Policy - Manchester Met Intranet (mmu.ac.uk))for the assessment of University risks and includes, within the impact scoring matrix, the impact of non-compliance with the Human Tissue Act. Any situations that the HTAC considers might impact on this risk, will be reported to the Pro-Vice-Chancellor Research via the DI.

Where a DI is unable to discharge their duties, the LH representative may make an application to the HTA to vary the licence to substitute the DI. The LH will work closely with the REG team and HoD to put appropriate measures in place if a DI is temporarily unable to oversee licensable activities.

Persons Designated (PD) are considered to be supplementary to that of the DI in the governance framework. PDs assist the DI with developing procedures, as well as reporting incidents and running training. It is the responsibility of the DI to notify the HTA and LH representative of changes to PDs. Before this is done, the REG team should be notified; it should also be reported at the HTAC.

More information can be found on the HTA website: How to make changes to your licence | Human Tissue Authority (hta.gov.uk)

b) Duty of the DI

The HT Act specifies (section 18) that the duty of the DI is:

''It shall be the duty of the designated individual in a licence as the person under whose supervision the licensed activity is authorised to be carried on to secure—

(a) that the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity,

(b) that suitable practices are used in the course of carrying on that activity, and

(c) that the conditions of the licence are complied with.

The HTA has the power to revoke a licence (as detailed in section 2 7(2) of the HT Act), if it is satisfied that the DI has failed to discharge, or is unable because of incapacity to discharge, their duty under section 18 of the HT Act.

A person should not undertake the role of DI unless they are in a position to discharge their duties under section 18 of the HT Act. DIs need to have a knowledge and understanding of the HT Act and the HTA Codes. They should demonstrate managerial capability, ensuring development and implementation of quality management systems and supervising responsibility to effect change, in order to ensure compliance with the HT Act.

The Heads of Departments (HoD) need to have a general understanding of the responsibilities of the DI's within their Faculty in order to ensure that the DI has the authority and support from them to fulfil their duties under the HT Act and associated HTA Codes.

c) Authority of DIs

DIs are authorised to give instruction and directions to all those using relevant material, including staff more senior to themselves, and students, as necessary in order to ensure compliance with the conditions of the licence. Should occasions arise where compliance with such instructions and directions are not adhered to, those individuals may be prevented from undertaking any activity with relevant material immediately and in the future. This may also result in an investigation of research misconduct or gross misconduct resulting in disciplinary action for the individual(s).

A breach of duty by a DI can result in serious penalties including fines, up to 3 years imprisonment or both [HT Act section 25).

d) Insurance and Indemnities for DIs

DIs are personally responsible for compliance with the HT Act in the area(s) for which they are licenced.

Offences under the HT Act and HTA regulations include:

- Removing, storing or using Relevant Material for Scheduled Purposes on unlicensed premises.
- Removing, storing or using relevant Material for Scheduled Purposes without appropriate consent for that purpose.
- Trafficking in human tissue for transplantation purposes.
- Carrying out licensable activities without holding a licence from the HTA (with lower penalties for related lesser offences such as failing to produce records or obstructing the HTA in carrying out its power or responsibilities).
- Having Human tissue, including hair, nail and gametes, with the intention of its DNA being analysed without the consent of the person from whom the tissue came or of those close to them if they have died.

If a person is found to have committed any of these offences, penalties range from a term of imprisonment (not exceeding 3 years), a fine, or both.

[Human Tissue Authority 2020, https://www.hta.gov.uk/policies/human-tissue-act-2004, accessed online 23rd September 2024)

e) Insurance and Indemnities for Manchester Metropolitan University Staff and Students using Relevant Material

Manchester Metropolitan University holds insurance for DIs and all other staff and students working with Relevant Material within the University. The insurance arrangements provide no specific protection for DIs; the insurance is generally applicable in the same way for everyone.

The University holds insurance to protect itself and any individual acting on its behalf.

This insurance provides protection against costs relating to defence against civil or criminal actions and any awards of damage for a civil action where liability is found.

The insurance does not protect against fines, penalties or criminal sanctions (such as imprisonment).

The insurer will not protect any individual that has knowingly performed an intentionally criminal act but may continue to insure the University if it has taken reasonable steps to manage and control the task.

Work that is carried our outside of the United Kingdom may not be protected in the same way, and specific clarifications should be sought if this is relevant.

Should a case arise where a DI is alleged to have committed an offence under the HT Act, the REG Team, LH and insurance team should be informed immediately or within 24 hours.

iii. Standards of Compliance Required by the HTA

Biannually, the HTA requests that DIs complete a compliance update. The information collected is used to maintain their regulatory oversight, guide their regulatory approach and to inform their risk profiling and scheduling of site visits.

There are several categories which are considered to assess compliance, and are included in the compliance audit:

a) Consent

One of the main principles established by the HT act is the requirement for appropriate and valid consent for Scheduled Purposes. The HTA Code of Practice A (Consent) describes if consent is required for the storage of relevant material.

The consent standards require users of Relevant Material to be able to demonstrate that their processes for seeking and gaining consent comply with the HT Act and the relevant HTA Codes of Practice. The standards also cover the documentation and information used to support the establishment's procedures, and to ensure that staff involved in seeking consent are suitably trained and equipped for the task.

Qualifying consent is required to analyse DNA derived from Bodily Material and to use the results. Bodily Material differs from Relevant Material as it includes hair and nails from the living, and gametes. It also refers to processed material such as plasma, serum and saliva obtained by the use of collection kits that lyse cells prior to DNA extraction. This means that if appropriate consent to use Bodily Material has previously been obtained under the HT Act for a Scheduled Purpose, it is not necessary to obtain separate consent where that use also involves DNA analysis provided the consent does not rule-out DNA analysis. However, where samples are being prospectively collected for research

involving DNA analysis, it should be made clear to the donor that their Bodily Material may be used for this purpose, if that is the intention, by, for example, including a reference to the intended DNA analysis in the consent form and participant information sheets.

Records must be kept by the DI for all licensable Relevant Material obtained by staff and students including evidence of consent. It is the responsibility of the researcher, staff or student to keep a record of the whereabouts of signed consent forms and to make them available to the DI via the HTA SharePoint system. Anyone removing, storing or using Relevant Material in circumstances for which the HT Act requires consent must be personally satisfied that relevant consent is in place.

Consent Exclusions

It is lawful for Relevant Material taken from a living person to be stored and used without consent for research purposes, only if:

- **it is an existing holding for a scheduled purpose.** An existing holding is material from the living or deceased that is already stored at the time the HT Act came into force on the 1 September 2006;
- **the research has current ethical approval** from a recognised NHS Research Ethics Committee;

and

- **the Relevant Material is anonymised** and the researcher takes all necessary steps not to identify the person from whose body the Relevant Material has come;

For more information, please see HTA Code E (Research).

If the purpose of storage of Relevant Material from a living person is research, then consent must follow the guidance available via the Health Research Authority (HRA) website http://www.hra-decisiontools.org.uk/consent/examples.html.

Once consent has been obtained, the consent forms must be filed as follows:

- For a specific research study involving participants identified and recruited from the NHS, consent forms should be stored in the patients' clinical notes. For NHS Research Ethics Committee (REC) approved studies where tissue is anonymised and part of an existing holding, consent forms do not need to be stored at Manchester Met. A copy of the NHS ethical approval with the material transfer agreement related to the samples must be stored in the study master file kept securely by the Principal Investigator (PI). A copy should also be uploaded to the HTA SharePoint system in the researcher's designated folder.
- For a specific research study involving healthy volunteers, forms should be stored in accordance with University policies and procedures.

A record and location of the consent forms should be kept by the Principal Investigator, and they must be made available to the DI, REG team, monitors and / or regulators on request.

b) Governance and Quality Systems

It is essential to demonstrate that there is a suitable governance framework, underpinned by clear and controlled documentation, effective audit, staff training and organised record-keeping including an effective system of risk management and suitable systems to deal with adverse events.

c) Documentation Required for the Quality System

The HTA requires the recording of policies and procedures in a quality system which must be identified by version number and managed by a document control system.

HTA guidance for sector specific requirements is available on the HTA website:

Inspection guidance | Human Tissue Authority (hta.gov.uk)

The quality system should contain the documents necessary to demonstrate compliance with the relevant standards and include, but is not limited to, the following:

- Organisation chart listing staff roles and line management structure.
- Internal audit schedules and audit reports.
- Policies (e.g. consent incl. consent documentation, Health and Safety, disposal, ethics, governance, adverse events, complaints).
- Standard Operating Procedures (SOP) including the template to guide the development of the SOP, Document control and storage of records.
- Traceability records for Relevant Material including origin, storage, use, transfer and disposal.
- Job descriptions and training records.
- Risk assessments for critical processes.
- Adverse events and incidents log.
- Complaints log.
- Maintenance contracts, maintenance log, validation and calibration of critical equipment.
- Contingency plans for equipment / site failure.
- Meeting agendas and minutes including systems used to distribute local/national information.
- Agreements e.g. contracts, Material Transfer Agreements, Service Level Agreements, Third Party Agreements.

d) Adverse Events and Risk Assessments

Investigating Adverse Events (AEs) and taking corrective and preventive action is an important part of the risk management process. The purpose is to assure the health and safety of those handling Relevant Material and to avoid loss or damage to Relevant Material. AEs that lead to, or which could have led to ('near-miss') the harm of any individual(s) or loss of relevant material must be reported to Health and Safety. A record must be kept of all AEs together with the outcome of any investigation.

HTA licenced establishments are required to have an internal system for reporting AEs and where necessary instigate an investigation or root cause analysis.

DIs must have a process to ensure awareness of AEs so that proper investigation and reporting can take place. There is an Adverse Event SOP detailing the University process for managing HTA AEs.

There is currently no requirement for organisations in the research sector to report adverse incidents to the HTA, but the HTA do advise DIs to seek advice from them when needed.

Examples of adverse events include:

- Specimen loss.
- Missing or incorrect documentation.
- Security breach(es).
- Abnormalities in storage temperature readings.
- Inappropriate disposal.

There are a number of circumstances that could result in loss or damage to Relevant Material, which should be subject to risk assessment. These may include:

- Transport of samples.
- Use of dangerous instruments / equipment in the preparation of and processing of samples.

- Liquid nitrogen handling;
- Electrical faults / risks e.g. freezer failure.
- Mislabelling of material or loss of label(s).
- Improper storage conditions.
- Misplacement of samples or inaccurate disposal.
- Loss of records or incorrect documentation.
- Malicious damage or theft.
- Accidental damage.
- Fire / Flood damage.

This section of the Code of Practice should be read in conjunction with the following:

- Health Safety and Wellbeing guidance: https://mmuintranet.mmu.ac.uk/Interact/Pages/Section/Default.aspx?section=4637
- Any relevant regulatory alerts from the HTA.

AE advice should be sought at the earliest opportunity from the Research Ethics and Governance team where needed. AE and regular updates should be reported to the HTAC to ensure appropriate preventative procedures are implemented and appropriate lessons are learned.

NHS Research Ethics Committee (REC) approved studies should report any AEs to the Research Ethics and Governance team. Information should be included in the annual progress report to the NHS REC and other regulatory bodies (as appropriate). A record of the AE should be stored in the Study Master File.

e) Internal Audits

The University undertakes internal audits across licenced areas every two years. Objectives of internal audits are to:

- Ensure the activities on the premises comply with the HT Act, the Regulations and the HTA codes.
- Identify good practice that could be shared with others.
- Identify practices that should be changed or improved with a plan for corrective and preventative actions that includes training and resource requirements.

More information can be found in HTA SOP 009, on the Research Ethics and Governance webpages.

Where possible, the audits will mirror HTA inspections in terms of process and scope. The process and completion of the process is managed by the Research Ethics and Governance team and is reported to the HTAC. The HTAC will identify a plan, and oversee any actions identified as part of the audit.

The Pro-Vice-Chancellor for Research and Knowledge Exchange will also receive a report of the outcome of internal HTA audits for information.

f) HTA Inspections

As part of its regulatory function, the HTA carries out inspections of licenced premises. In the majority of cases the University will have due notice of an inspection. The HTA can carry out unannounced inspections. There is no specific schedule for the inspection of licences. Inspections are predominantly risk based or may be triggered by an adverse incident. Following an inspection, the HTA will write a report specifying any non-compliance that must be corrected; reports can also include recommendations. The closure and progress against actions arising from an inspection are managed by the Research Ethics and Governance team and reported to the HTAC.

iv. Traceability

a) Traceability and Records of Stored Relevant Material

Full traceability for the human material for which DIs are responsible, from receipt to final disposal / disposition needs to be demonstrated. HTA inspectors will test this through traceability audits at the University. There is an expectation of a pro-active approach to assure effective traceability throughout the lifetime of the Licence. Traceability steps need to be clear to demonstrate compliance with the HTA's Codes. Traceability of Relevant Material is essential, and records must be kept to document the storage, use and disposal of Relevant Material. Complete and up to date records will need to be available for both internal audits and external HTA inspections.

The DI is responsible for ensuring these are adequate and appropriate with reference to the guidance contained within the relevant HTA Codes.

Records can be in an electronic format (e.g. spreadsheets or databases) or as paper records, with information about a backup system in case either system is jeopardised.

Access-controlled core information required is:

- The origin of the Relevant Material and the date acquired.
- Whether the Relevant Material is:
    - Held with consent.
    - Held under Licence or stored for a defined project under the NHS REC Favourable opinion.
    - From a living or deceased donor.
    - Imported.
- Number of samples, description of tissue / cell type and storage details including location.
- Licence number and /or NHS REC reference, date of REC expiry (for both Manchester Met and NHS REC approved research) and the Principal Investigator.
- Date of use, transfer (including the Material Transfer Agreement [MTA] and disposal.

Staff and students using relevant material with authorised access are required to make and amend entries in the records kept by the DI, and to keep them up to date and accurate.

b) Transfer of Relevant Material and / or Disposal

Whenever relevant material for Scheduled Purposes is transferred externally it must be documented. The transfer and subsequent storage, use and disposal of tissue must be governed by a Material Transfer Agreement (MTA), which has been approved by the RKE directorate.

A standard MTA is in place for transferring Relevant Material to individuals or organisations outside the University. Please contact the RKE Contracts team for more information about this.

The import (this refers to Relevant Material received from outside of England, Wales and Northern Ireland) of Relevant Material must follow the University Code of Practice; individual guidance can be obtained from the Research Ethics and Governance team.

c) Disposal

For further information relating to the disposal of Relevant Material, please see the HTA SOP 007 'Disposal of Relevant Material' which can be found on the Research Ethics and Governance webpages.

v. Premises, Facilities and Equipment

The University must demonstrate that premises and facilities are appropriate for licenced activities, and are safe, secure and clean. Additionally, the University is required to have systems in place for ongoing monitoring to ensure all key quality specifications are maintained. These standards also cover equipment, ensuring that it is appropriate, suitably maintained and that it does not present an impediment to the staff using it.

4. Part C: Working Under an HTA Licencing Exemption

i. Introduction

A licence is required to collect, use and store Relevant Material for research unless a licence exemption applies. This section details how to work with Relevant Material under an HTA Licencing exemption. If you are working under a licence, please read part B.

Research involving Relevant Material from an NHS REC approved biobank, is considered an HTA licence exemption. Staff and students using Relevant Material from these biobanks should manage samples in line with specifications made in the protocol and ethics application. This includes record keeping, sample transfer, adverse event reporting and disposal. Further information can be found on the HTA licencing exemptions page: Licensing exemptions | Human Tissue Authority (hta.gov.uk) (

ii. Storage Incidental to Transportation

The licencing requirements for storage do not include storage that is incidental to transportation. This means that the storage of material whilst it is being conveyed from one place to another does not need to be licenced. These instances should be no longer than a week.

These exemptions continue to apply under the Human Tissue (Quality and Safety for Human Application) Regulations 2007, which came into force on 5 July 2007. (Licensing exemptions | Human Tissue Authority (hta.gov.uk)[last accessed 23rd September 2024].

iii. Tissue Being Held Prior to Processing

If human tissue is being held while it is processed with the intention to extract DNA or RNA, or other subcellular components that are not relevant material (i.e. rendering the tissue acellular), it is viewed as analogous to the incidental transportation exception. A licence is not required, providing the processing takes place within a matter of hours or days and no longer than a week. Licensing exemptions | Human Tissue Authority (hta.gov.uk) [last accessed 23rd September Apr 2024]

iv. Research and Ethical Approval

An exemption in the HT Act allows for tissue to be stored without a licence for a research project that has appropriate ethics approval [Section 1 (9) of the HT Act 2004]. In addition, consent is not required to store and use tissue from the living for an ethically approved research project if it has been anonymised. More information relating to this can be found in the HTA Code of Practice on research.

The HTA's remit does not include ethical approval of research on human material, which must be applied for using the guidance provided by the Health Research Authority Codes of Practice | Human Tissue Authority (hta.gov.uk) and the General Medical Council (GMC).

Some specific research ethics committees (RECs) have been authorised to give broad ethics approval for research tissue banks, which will then be required to work under NRES standard operating procedures (SOPs). This means that a specified remit of work is permitted without the need for further

individual project-specific approvals. The tissue in these research tissue banks must be stored on HTA-licensed premises. Codes of Practice | Human Tissue Authority (hta.gov.uk)

REC approved banks can provide human tissue to researchers; the recipients of the tissue do not need to store it under an HTA licence during the period of the research project, subject to certain requirements. If the research is not carried out in accordance with these requirements, specific project approval by a recognised research ethics committee will be required or, alternatively, the samples will need to be stored under an HTA licence. Information about the requirements governing the release of tissue can be found on the HRA website: Use of human tissue in research - Health Research Authority (hra.nhs.uk)

v. Licencing Exemptions – Deceased Persons

d) Material More Than 100 Years Old

Storage of material which has come from the body of a deceased person is exempt if the licensed activity relates to the body of a person who died before Section 16 of the HT Act 2004 came into force and at least 100 years have elapsed since the date of the person's death.

Licensing exemptions | Human Tissue Authority (hta.gov.uk)

e) Archaeological Material

Whilst archaeological material falls outside the legislative requirements of the HT Act, a licence is still required to excavate the material and keep it on University premises.

To apply for a licence, an application form permitting the authority to excavate human remains for archaeological purposes needs to be submitted to the Ministry of Justice (https://www.gov.uk/government/publications/apply-to-excavate-human-remains-for-archaeological-purposes).

Once the licence is in place, a copy should be sent to the DI for their information.

f) Research

Storage of relevant material which has come from the body of a deceased person, is exempt from licensing if the person storing it is intending to use it for the purpose of 'qualifying research' or for a specific research project for which such ethical approval is pending. Qualifying research means research that has been ethically approved by a recognised REC. This can either be a REC established under, and operating to, the standards set out in the governance arrangements issued by the UK Health Departments or an ethics committee recognised by the United Kingdom Ethics Committee Authority (UKECA), to review clinical trials of investigational medicinal products under the Medicines for Human Use (Clinical Trials) Regulations 2004.

Details of all recognised committees and general information about ethical approval can be found on the NRES website.

Licensing exemptions | Human Tissue Authority (hta.gov.uk)

vi. Licensing Exemptions – Living Persons

Under statutory instrument 126, storage of relevant material that has come from the body of a living person is exempted where the person storing it is intending to use it for:

- determining the cause of death;
- establishing after a person's death the efficacy of any drug or treatment administered to him;

- obtaining information which may be relevant to another person;
- public display;
- clinical audit;
- education or training related to human health;
- performance assessment;
- public health monitoring;
- quality assurance;
- qualifying research.

[HTA, Licensing exemptions | Human Tissue Authority (hta.gov.uk) [last accessed 23rd September 2024]

5. Part D: Further Advice and Guidance

In the first instance, please contact the Research Ethics and Governance team or your Faculty PD. Any concerns or problems may be referred to the HTAC or to the LH representative for information.

Contact details:

Research Ethics and Governance Team

Ethics@mmu.ac.uk

Useful links:

Manchester Metropolitan University human tissue webpages

HTA and University Approval | Manchester Metropolitan University (mmu.ac.uk)Manchester Metropolitan University Procedure for the Investigation of Misconduct in Research

Research integrity | Manchester Metropolitan University (mmu.ac.uk)

Human Tissue Authority

https://www.hta.gov.uk/

Human Tissue Authority Codes of Practice

https://www.hta.gov.uk/hta-codes-practice-and-standards-0

Human Tissue Authority information relating to relevant material under the HT Act

https://www.hta.gov.uk/policies/relevant-material-under-human-tissue-act-2004

Human Tissue online training

https://byglearning.co.uk/mrcrsc-lms/course/index.php?categoryid=1

Human Tissue (Scotland) Act 2006

Legislation: http://www.legislation.gov.uk/asp/2006/4/contents

Further guidance: https://mrc.ukri.org/research/facilities-and-resources-for-researchers/regulatory-support-centre/human-tissue/

Human Fertilisation and Embryology Authority (HFEA)

https://www.hfea.gov.uk/

Archaeological material

https://www.gov.uk/government/publications/apply-to-excavate-human-remains-for-archaeological-purposes

For more information about the licence and how and when to apply for a licence, please contact Dr Ben Edwards (B.Edwards@mmu.ac.uk).

Health Research Authority

https://www.hra.nhs.uk/

6. Version Control

Version	Reason for change	Date
V0.2	Updates	11 April 2020
V0.3	Updated in discussion with DI	20 April 2020
V0.4	Updated	12 May 2020
V0.5	Updated	15 May 2020
V1.2	Updated	07 February 2023
V1.3	Updated links and section 4Civ	24 September 2024