Human Tissue Master File

NJRO-TISS-SOP-010

Contents

1. Background/Introduction

Newcastle University and Newcastle Hospitals each hold a research sector Human Tissue Authority licence (ref. 12534 and ref. 12193, respectively). This licence authorises the storage of "relevant material" (material, other than gametes, that consists of, or includes human cells) which has come from a human body for research in connection with disorders, or the functioning, of the human body.

It is a requirement under The Act that there is a systematic and planned approach to the management of records and all documents should be made readily available to staff. In addition, the Confederation of Cancer Biobanks (CCB) Biobank Quality Standards, developed to promote high quality standards in biobanks, recommends that organisations have:

- A description of the organisational structure
- Clear roles and responsibilities
- A master list of quality documents
- A capital asset register or equipment database which is used to record the cleaning, maintenance, repair, quality assurance, validation, calibration and monitoring events for all critical equipment.
- Copies of governance documents e.g. study protocols, consent forms, patient information leaflets, ethics applications, correspondence and approvals.
- Logs of adverse event, meetings and audits

In order to capture this information in one place, a "Human Tissue Master File" has been implemented in Newcastle for all groups working under the Human Tissue Authority research licence.

The Human Tissue Master File is a file containing a core set of documents relating to the Human Tissue Authority licence that must be populated and held by research groups operating under the licence. These documents detail both the organisational and local set-up.

A Human Tissue Master File must be held by all research tissue banks. This aims to produce a consistent and harmonised approach to documentation which can readily be presented on request to demonstrate regulatory compliance.

2. Purpose

The purpose of this SOP is to provide staff working under a Human Tissue Authority research licence within Newcastle Hospitals and Newcastle University with information on how to set up, store and maintain the Human Tissue Master File.

The purpose of the Human Tissue Master File is to deliver a consistent approach to presenting human tissue related information on the organisational and local structure, staffing, governance, premises, facilities and equipment and local procedures. A number of templates are provided herein to support a harmonised, consistent approach. However each group may use their own templates, provided they capture the required information.

3. Scope of Document

This SOP applies to any personnel working under the Newcastle University or Newcastle Hospitals Human Tissue Authority research licence. This includes Persons Designated, Chief Investigators of National Research Ethics Service (NRES) Research Ethics Committee (REC) approved research tissue banks, and local collaborators (e.g. Principle Investigators, laboratory staff, tissue collection centres).

As it is a regulatory requirement that NRES REC approved research tissue banks which only store non-relevant (non-cellular material, such as DNA or cell lines) store material on Human Tissue Authority licensed premises, a Human Tissue Master File must also be held by these banks.

A Human Tissue Master File does not relate to Clinical Trials and should not be used to replace regulatory requirements for Site Files. However, where material is collected in the clinic for a Research Tissue Bank, each collection site should have its own Site File detailing the study set-up, in line with clinical/NHS requirements. This may be adapted to include information set out in this SOP.

In addition, the Human Tissue Master File may be adapted to include information relating to the clinic e.g. recruitment logs, copies of signed consent forms (etc.) provided these are stored appropriately, in compliance with General Data Protection Regulations (GDPR).

4. Definitions

CCB	Confederation of Cancer Biobanks
Designated Individual (DI)	The individual named on the Human Tissue Authority Licence who has ultimate legal responsibility for compliance with the Act.
HTA	Human Tissue Act
Human Tissue Authority	The governing body set up to regulate activities that come under the Human Tissue Act.

NJRO	Newcastle Joint Research Office
NRES	National Research Ethics Service
Person Designated (PD)	A person named on the Human Tissue Authority licence who supports the Designated Individual by directing others in relation to the Human Tissue Act within their local environment
PI	Principle Investigator
REC	Research Ethics Committee
RTB	Research Tissue Bank
SOP	Standard Operating Procedure

5. Roles & Responsibilities

It is the responsibility of each Research Tissue Bank (RTB) Chief Investigator to implement a Human Tissue Master File for their Research tissue bank and keep this up to date. This includes for NRES REC approved research tissue banks, and University Ethics Committee approved research tissue banks.

It is the responsibility of each Person Designated to ensure that each RTB stored under their remit has a Human Tissue Master File in place. Each PD is also responsible for holding a Human Tissue Master File for their area, documenting the collections held under their remit, including a list of all collections held without ethical approval in place, and reference to associated RTB Master Files, including their location/holder of the file.

It is the responsibility of the NJRO Quality Management team to update the organisational structure section of the Master File and send all Human Tissue Master File owners new versions of these documents when they are updated.

It is the responsibility of the NJRO Quality Management team to audit compliance with this procedure.

6. Procedures

6.1. Setting up the Human Tissue Master File

All Human Tissue Master Files must be set up in collaboration with the Newcastle Joint Research Office (NJRO) Quality Management Team or suitably trained delegate. This is to ensure the Master File is set-up appropriately, and adapted where required to meet local needs.

All Human Tissue Master Files should be completed using the range of templates, available in Q-Pulse.

Information on how to populate each section is provided overleaf.

6.1.1. Cover page

The first step when creating a Human Tissue Master file is to create a cover page, to be put at the front of the folder. This page must be populated with the bank details, including the name of the bank, its location (building), and ethics number (where applicable) and names of key staff e.g. Chief Investigator, local Person Designated etc.

6.1.2. Contents page

The contents page must then be added to the folder. This contains a list of all of the required documents required to populate the Master File. The contents page should be used as a checklist to populate the folder with all the required documents.

Please note, that with the exception of section 1, this contents page is fully editable, and can be adapted to include any other documents that each local group may wish to add to the Master File.

Where documents from the contents page are not added to the Master File, a File Note should be included to justify the omission. This should be conducted in discussion with the NJRO Quality Management team to ensure an appropriate approach is adopted.

Once complete the contents list should be printed and added to the front of the Master File behind the cover page.

6.1.3. Section 1 - Organisational structure

All documents relating to the organisational structure are prepared and controlled by the NJRO Quality Assurance Management team and approved by the Designated Individual (DI) under each research licence. This section of the Master File cannot be edited by anyone other than the Quality Management team.

This includes an organisational chart, role descriptions for each of the key roles operating under the Human Tissue Authority licence, a list of staff named on the licence, and a list of NRES REC Approved Research Tissue Banks for each institution.

These documents should all be printed and added to the study file in the order indicated on the contents page.

Should any of these documents ever change, the NJRO Quality Assurance Management team will update these documents and inform each group to update the physical version of their Human Tissue Master File accordingly (i.e. remove out of date copies, and replace with new versions).

It is then the responsibility of the holder of the Human Tissue Master Files to keep these up to date.

If any errors are identified in these documents, the NJRO Quality Assurance Management team should be promptly informed.

6.1.4. Section 2 - Local Structure

The person responsible for setting up the Human Tissue Master File must populate the "Local Structure" section of the folder following the contents page. This provides information on the premises and staffing, including a section to add any related training certificates.

Where material is stored under the Human Tissue Act in more than one pre-approved location, copies of all of the relevant Human Tissue Authority licences must be printed and added to the folder for each location (e.g. hubs and satellites).

A copy of a local staff organogram should be provided, where available.

CVs should be added to the file for all key staff working at the bank.

- All staff working under the Act must have up-to-date Human Tissue Act training (every 3 years). A copy of HTA training certificates should be added to the folder for all key staff.

- For staff taking consent, copies of GCP training certificates must also be included.

Where staff training records are stored elsewhere (e.g. in individual staff training record files), the location of these records should be added in a file note. However it is highly recommended to hold copies of these certificates centrally in the Master File for ease of auditing in relation to the Act.

6.1.5. Section 3 – Ethics documentation

This section applies to NRES REC approved research tissue banks only. Research tissue banks storing samples without REC approval may leave this section blank.

The current version of ethics documentation associated with the bank should be printed and added to the Human Tissue Master File. If this is not feasible due to the volume of documentation, a file note should be added to indicate the electronic storage location of these documents for audit.

The contents page should be used as a guide as to which documents are required. This contents page can be edited to add/remove documents, as required by the bank.

6.1.6. Section 4 – SOPs, Policies and Risk Assessments

This section requires users to add lists of all quality documents used by the bank. This includes:

1. A list of NJRO SOPs that must be followed all staff operating under the Human Tissue Authority research licence. This document must be printed and added to the folder

2. A list of local quality documents that must be followed by all staff working as part of the research tissue bank under the Human Tissue Authority research licence e.g. SOPs, Work Instructions, Policies, Forms, Risk Assessments, and Manuals etc. This list must be created by the local team. A template has been provided (NJRO-TISS-T-024), however if users already have their own lists of quality documents, these may be added to the folder in place of the template

   Hard copies of these quality documents may be printed and added to the folder if desired, however this is not a requirement of the Master File.

- If hard copies of these documents are printed and added to the file, the file owner retains the responsibly for keeping these documents up to date, and removing any out of date versions.
- If hard copies are not added to this folder, the location of these documents (e.g. electronic storage location) should be included on the document list, or as a separate file note.

6.1.7. Section 5 - Premises, Facilities and Equipment

Two templates have been created for section 5, which must be populated and added to the folder.

- The first document relates to creating a capital asset register – i.e. list of all freezers, fridges, and cold rooms etc., used by the group to store material (NJRO-TISS-T-025).
- The second document relates to documenting the details of the groups sample tracking software (NJRO-TISS-T-026).

For Newcastle University staff – where the Achiever sample tracking software is available, but not used, formal authority granted by the Faculty of Medical Sciences (FMS) Steering Group must be added to the folder to authorise the use

Alternative forms may be used to capture this information, however these must be approved by the NJRO Quality Management team, and templates used wherever possible to ensure a consistent and harmonised approach across research tissue banks.

Groups may also wish to store additional information in this section of the folder e.g. relating to safety information, maintenance contracts or PAT testing. Where this is added, the contents page should be updated to capture this information.

6.1.8. Section 6 –Collections/Study list

All research tissue banks should hold a list of all collections currently stored under the Human Tissue Authority licence under their remit. This should include:

- Collection code/ID number (if applicable)
- The collection/study name
- The name of the Principle Investigator/Client (where appropriate)
- Physical storage location of the samples (where multiple locations are used)

In addition, for NRES Research Tissue banks a list of all current/ongoing studies being conducted under the banks ethical approval should be retained in this section of the folder. This should include:

- Study code/ID number (if assigned by the research tissue bank)
- Study Name
- The name of the Principle Investigator
- Date of approval
- Physical storage location of the samples
- Person Designated (where material is stored under the Act)
- Study type e.g. prospective collection, sample release, legacy collection.
- Reference to location of all study documentation (e.g. application to Access Committee, Access Committee review, study set up meeting minutes, release paperwork, etc.).

6.1.9. Section 7 - Staff meetings

Groups may wish to store details of local staff meetings relating to the Human Tissue Authority licence, including minutes and agendas in this section of the folder. If information is stored elsewhere (e.g. electronically), a file note should be added to sign post where this information is held.

6.1.10. Section 8 – Adverse Event Reports

A copy of any adverse event reports relating to the groups operating under the Human Tissue Authority licence, including details of Corrective and Preventative Actions (CAPA) should be added to the folder. Where the researcher wishes to store these elsewhere (e.g. due to customer confidentiality) a file note should be added to indicate where any adverse event reports will be stored.

6.1.11. Section 10 – Audit and Human Tissue Risk Assessments

Any audit reports relating to the group should be added to the folder, including any corrective and preventative actions (CAPA). A human tissue risk assessment for the group should also be added to the folder in this section when completed.

6.2. Oversight

The contents of the Human Tissue Master File will be audited by the NJRO Quality Management team in accordance with NJRO-TISS-SOP-004 using the Human Tissue Master File audit checklist (NJRO-TISS-T-004).

7. References

Code of Practice A – Guiding Principles and the fundamental principles of consent

Code of Practice E: Research

www.hta.gov.uk