

Northumbria University Tissue Bank Operation Manual

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1 Introduction

This manual should be read in conjunction with the Use of Human Tissue Policy and the Tissue Bank Guide which define relevant material and provide guidance on obtaining consent for use and storage of relevant material.

The Northumbria University Tissue Bank securely houses the human tissue taken, stored and used in the University's teaching, research and enterprise activities. The Tissue bank, activities and governance of the Tissue bank do not include the University Anatomy Facility which is governed by its own manuals and procedures.

The use of the Tissue Bank and the material is overseen by Ms A Cassells, the Designated Individual (DI) under the Human Tissue Act (2004).

This document covers the use and security of the Tissue Bank. The manual is an overview of the controls used in maintaining security of the Tissue Bank and the material it contains. It also provides guidelines on the procedures and policies governing the use of the Tissue Bank and lays out the responsibilities of individuals associated with the Tissue Bank.

Staff guides for those people using the Tissue Bank are also available online and in hard copy from Persons Designated.

Version 3.4 of this manual has been prepared post inspection by the HTA in January 2022.

2 Documentation

2.1 General

1. A quality system has been established, documented and is maintained as a means of ensuring that use of the bank conforms to specified requirements. It comprises:
 - An institutional policy on Human Tissue Use
 - Operational manual and guides
 - Quality procedures
 - Codes of Practice
 - Records of such items as samples, training and incidents
2. Documentation must be approved by the DI prior to issue. The DI must ensure that:
 - relevant versions of appropriate documents are readily available
 - invalid or obsolete documents are removed from all points of issue or use to prevent unintended use
 - any obsolete documents are retained by the DI for 3 years. These obsolete records should be available for any HTA inspection.
3. There are documented procedures for the maintenance of records (**section 2.6**)
4. Records of all adverse incident investigations must be maintained and must include a description of incident, any control number used, the nature of the incident, the corrective or preventive action implemented, and the report to the faculty Research Ethics Committee.

2.2 Controlled Documents

1. The following types of documents are controlled documents:
 - The Operation Manual
 - Guides and Codes of Practice
 - Operation forms
2. Controlled documents must be identified with
 - A unique identifier
 - The identity of the author
 - The version number for the document
 - The issue date for the document
 - The review date for the document

2.3 Changes to controlled documentation

1. Changes to current documentation can be requested by any employee. The DI will make an initial check to ensure proposed changes comply with HTA licensing requirements.
2. Proposed changes to documentation must be reviewed by the Faculty Research Ethics Committee and approved by the DI
3. New versions of documentation should be electronically stored by the DI with previous versions suitably archived. New documents should be marked with updated version numbers and approval date.
4. Printed versions of new documentation must be authorised, dated and signed by the DI.
5. The new documentation must be distributed to all staff associated with the bank and suitable training provided in new procedures if necessary - training records must be updated and maintained
6. The new documentation must be added to the Manual and a hard copy placed in the bank where it can be accessed by all users
7. Invalid or obsolete hard copies of documents must be removed by the DI from all points of issue to prevent unintended use. An up to date distribution list of controlled documents (and version number) should be maintained.
8. Electronic archives of documentation should be maintained by the DI.

2.4 Review of documentation

1. All controlled documents should be reviewed for continued suitability as circumstances dictate but at least annually in January (in line with **appendix 5**)

2. Required changes to documentation should follow the procedure in **section 2.3**

2.5 Controlled Records

1. The following types of documents are controlled records:
- Tissue Sample Logs
 - Studies list
 - Records of adverse incidents and corrective actions
 - Training records
 - Signed Principal Investigator compliance declarations
 - Signed consent forms

2.6 Maintenance of records

All controlled records must be stored to ensure protection from loss, damage or deterioration. Electronic records should be held by both DI and Technical Manager.

The DI is responsible for ensuring that controlled records are maintained in accordance with the requirements of this Procedure

Tissue Storage Logs held in the bank should be scanned into PC by the DI every 6 months on audit

Documents generated by the procedures involved in work with Human Tissue.

Generating and maintaining these records is the responsibility of the person named below. Copies of these records may be filed by more than one person while a study is underway

- | | |
|----------------------------------------------------------|-------------------------|
| • Tissue Sample Log | Individual Investigator |
| • Declaration by Principal Investigator | Principal Investigator |
| • Consent SOP & form for Tissue Use, Removal and Storage | Principal Investigator |

Location of documents generated by the procedures involved in work with Human Tissue.

The primary copy of these records is stored as follows

- | | |
|----------------------------------------------------|-----------------------|
| • Tissue Sample Log | Tissue Bank File |
| • Declaration by Principal Investigator | DI office |
| • Consent form for Tissue Use, Removal and Storage | PI office (sole copy) |
| • Consent SOP for study | Investigator |

Archiving records generated by the procedures involved in work with Human Tissue.

Archiving these records is the responsibility of the person named below.

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------|
| • Tissue Sample Log | Designated Individual |
| • Declaration by Principal Investigator | Designated Individual |
| • Consent SOP & form for Tissue Use, Removal and Storage required by Faculty and University policy | PI to archive or destroy as |

2.7 Computer records

1. The introduction of computerised systems into practices including storage, distribution and quality control does not alter the need to comply with the requirements of this manual. The same criteria and standards apply as to other records.
2. Alternative systems should be available to cope with failures in computerised systems.

3 Sample Control

3.1 Prior to Work Commencing

1. Principal Investigators must notify the Faculty Research Ethics Committee (FREC) of their intention to use human tissue samples in their work prior to any work commencing.
2. Investigators should refer to the Tissue Bank's operation Manual and guides for advice on the taking, storage and use of tissue and will familiarise themselves with the content of the HT Act and the Codes of Practice issued by the Human Tissue Authority. Further information or clarification can be obtained from the DI.
3. Investigators should have undertaken mandatory university ethics training (which includes training on consent).
4. Principal Investigators must ensure that there are protocols and / or SOPs for Investigators (which comply with University Policy) available to cover the following:
 - the source of tissue samples to be used
 - the consent procedures for use of donated tissue samples
 - the anonymisation arrangements for tissue samples if they are to be anonymised
 - the storage arrangements for all tissue samples
 - the arrangements for the recording of the collection and use of tissue samples
4. The Principal Investigator must ensure that the project has been suitably risk assessed, has the appropriate Faculty or University Ethics Committee approval and has been authorised prior to commencing the research.
5. The Principal Investigator should present their signed Declaration of Compliance (**appendix 3**) and proof of the above to the Person Designated (PD) by the DI. If this is complete the Investigator will be issued with a Study Storage Number (SSN).
6. The PD will pass the Declaration, details of the study and SSN to the curator of the tissue bank and DI.

3.2 Sample Storage Numbers (SSN)

1. Each SSN issued to a study must be a unique record of that study.
2. Samples obtained during the study should be suffixed with sequential numbers giving each sample a traceable unique number.
3. The format of the SSN is as follows

A/17/BC01/DE/xx

- The first section is a department identifier (A in the example above).
 - This will either be **A** for Applied Sciences or **P** for Psychology and **S** for Sport
- The second section is an identifier of the year the study was started
 - 17 would refer to 2017
- The third section identifies the Principal Investigator or research group leader and their study number
 - This is in the form of initials of leader and a sequential number depending on the number of studies they have storing samples
- The fourth section identifies the individual investigator
 - This is in the form of initials
- The fifth section is the individual sample identification suffix

3.3 Production of an SOP for consent - relating to taking, storage and use of human tissue

3.3.1 Responsibilities

The PI for the study has overall responsibility for research governance, though they may delegate activities to individual investigators. When doing so an SOP must be used to ensure any consent taken as part of a study involving human tissue use (regulated by HT Act) is valid. The PI should produce a specific SOP for obtaining consent for their study which includes references to the below (as appropriate)

It is the responsibility of all research workers to work to the procedures outlined in the study specific SOP and in the Operating Manual. All workers should inform the DI of any difficulties in the process of obtaining and recording consent.

Consent materials and procedures (SOPs) will be reviewed as part of an annual paperwork audit

3.3.2 Materials

Each study must have a specific

- FREC clearance letter or email
- Participant information sheet (version controlled)
- Consent form (version controlled)
- Sample Storage Number
- Tissue Sample Log and
- SOP for consent taking

3.3.3 Persons Taking Consent

- must have received mandatory ethics training, which includes consent taking
- must have received an induction into the use of the Human Tissue Bank
- must be comfortable with the process of taking consent for the study and
- must understand any issues around ensuring consent for the study is valid.

3.3.4 The participant information sheet

- Participants must be provided written information about the study in an appropriate format.
- Participants must be allowed sufficient time to read and understand the info. The amount of time required may vary depending on the nature of the study.
- Information sheets should provide sufficient information that participants understand
 - why the study is being undertaken
 - what tissue(s) will be taken
 - what techniques will be used to obtain the tissue(s) and any risks associated with this
 - what the tissue is going to be used for
 - whether the material will be sent to another institution and, if so, for what purposes,
 - how the material is going to be disposed of
 - their rights to withdraw consent
- Information sheets should include investigator's contact details
- Investigators must ensure that the most up to date version of info sheet is being used.
- The investigator must be able to answer any questions from participants arising from the info sheet.

3.3.5 Initial participant meeting

- The investigator must answer any questions from participants arising from the info sheet.
- The investigator must reiterate key information relating to human material orally. This should include
 - What will happen to the participant during the taking of the material
 - What will happen to the material and how it will be stored
 - Any anonymization of material, or records, and what this means for the participant's ability to withdraw consent
 - Whether the material is going to be sent elsewhere for analysis
- The investigator should reiterate the participant's right to withdraw their consent, timescales for withdrawal and what that would mean in terms of material taken.

3.3.6 Taking Consent

- Prior to the participant signing the consent form the Investigator must ensure
 - participant understanding and
 - the participant is not feeling under duress to take part.
- The investigator must ensure the most up to date version of consent form is being used.
- The investigator should then have participant sign the consent form and sign and date consent form themselves as investigator
- The participant should retain a copy of the consent form and information sheet.
- Tissue samples from the deceased must only be used in research when appropriate consent has been obtained from an individual who had a 'qualifying relationship' with the deceased or if the individual give his/her consent whilst living and with capacity to consent.
- In any case where the investigator has concerns about the capacity of the participant to provide appropriate consent the University Research Ethics & Governance Handbook should be consulted and the DI should be notified.

3.3.7 Revoking Consent – Withdrawal from a study

- Participants wishing to revoke consent must do so in writing (or email) to the investigator named on the information sheet or the PI
- If material is still held in the bank, and identifiable, it must be identified and disposed of in line with **section 3.6**
- A copy of the letter revoking consent should be attached to the original consent form and a note made by the investigator to indicate the date the material was disposed of
- If the material has been anonymized or analysed, the participant should be informed that their material has already been used and that it is impossible to extract their data from the study
- If the material has been sent to another institution every effort should be made to have the material be disposed of rather than used

3.3.8 Storage of Consent Forms

- Signed consent forms should be stored in accordance with University policy and guidelines in the Research Governance Handbook and the Data Protection policy
- Signed forms should be stored securely
- Signed forms should be held for a suitable period of time (usually three years) after the end of the study.
- Signed consent forms should be stored in a manner that allows for audit and review
- If the PI leaves the University they should make arrangements to hand over consent paperwork to an appointed and appropriate replacement

3.4 During the conduct of the work

1. Investigators must ensure all tissue samples taken and kept in storage for the purposes of a research project are appropriately labelled upon collection of the sample
2. Investigators must maintain a record of the tissue samples they receive during the conduct of a research project in order that the origin, storage location, use and final destination of tissue samples collected as part of the research can be traced. A copy of a Tissue Sample Log must be kept by the investigator. Traceability of tissue samples is a requirement of the HT Act.
3. Samples removed from the bank for analysis or other work must be returned to the bank within 48 hours or be disposed of through an authorised route. The study's Tissue Sample Log in the bank should clearly state the destination of any sample moved from the Bank

3.5 Following the end of the work

1. The Principal Investigator must inform the DI of the end of the study and the final destination of the samples stored for the study.
2. The Investigator must ensure that any tissue samples remaining following the end of the study are disposed of in line with consent received - either
 - disposed of as **section 3.6** and in accordance with the Codes of Practice of the HTA,
 - retained in the Tissue bank for further research study or
 - passed to another institution for further testing.
3. Tissue samples not destroyed following the end of a project may remain stored in the licensed tissue bank only if specific consent had been obtained to allow further storage after the initial study had

finished. Tissue samples should not be stored indefinitely with no clear intention of use. Continued storage should be reviewed after three years.

4. Tissue samples that were collected specifically for testing in another institution may only be passed to that named institution. Specific consent must have been obtained to allow samples to be passed to an outside institution. Procedures on material transfer (**section 3.7**) should be followed when transferring tissue to another institution. Where a third party is used to transport the material to another institution the Principal Investigator should ensure the correct means of storage and movement are used.
5. Investigators who have obtained appropriate consent and wish to retain tissue samples following the closure of a research project must ensure that the samples are stored in the designated tissue bank within the University. No standalone tissue banks will be allowed in Northumbria University.
6. After samples have ceased to be stored in the Tissue Bank the Principal Investigator should archive or destroy the consent forms as required by Faculty and University policy.

3.6 Disposal of Human Tissue

1. All human tissue material should be autoclaved prior to disposal
2. Human tissue material being disposed of via the clinical waste route should not be mixed with special or hazardous wastes (significantly chemically contaminated waste should go to the special waste disposal route).
3. Human tissue material going in the clinical waste container should be in appropriately labelled yellow clinical waste bags or appropriately labelled sharps boxes. Bags for the clinical waste container should be
 - Handled wearing gloves
 - Double bagged, where appropriate, and tied shut
 - No more than 9kg in weight
 - Labelled with
 - University post code
 - University name
 - School name
 - Lab number
4. Free of any items likely to cause a puncture of the bag* (the contractor will refuse to take any container with loose material in it).
 - *Items such as metal blades, glass slides or pipettes, hard plastic pipette tips, wooden sticks should all go into sharps boxes and then be placed in the clinical waste container.
5. The Clinical Waste Container to be used for the disposal of human tissue material is located in Ellison yard. This is a lockable container; the key is held outside Ellison Building EBA505.
6. Users of the container must ensure that it is locked after use.

3.7 Transfer of Human Tissue to, or from, the University

1. Guidance on drafting or reviewing Material Transfer Agreements (MTAs) should be sought from the University Legal Office
2. Material obtained through an MTA with another institution must be stored in the Tissue Bank in accordance with the procedures laid out in this Operating Manual
3. Human tissue transferred from Northumbria must be subject to an MTA with the receiving organisation, which ensures
 - i. Material will be transported safely using a qualified courier service
 - ii. Material will be stored at the recipient institution in accordance with the terms of the Human Tissue Act
 - iii. Material will only be used for, or analysed for, purposes for which consent has been given
 - iv. Material will be disposed of safely and appropriately after use or analysis.

4. Human tissue transferred to Northumbria must be subject to an MTA with the custodian organisation, which ensures
 - i. Material will be transported safely using a qualified courier service
 - ii. Material has been obtained at the custodian institution in accordance with the terms of the Human Tissue Act, in particular the requirement for informed consent
 - iii. Material will only be used at Northumbria for purposes for, for which consent has been obtained at the custodian institution
 - iv. Material will be stored, disposed of or returned to the custodian institution after use in line with the consent obtained by the custodian institution

3.8 Internal audit

1. All samples will be audited by the DI on a 6 monthly basis (**appendix 5**)
2. Audit records (**appendix 4**) and reports must be maintained according to the maintenance of records procedure (**section 2.6**). They should contain all the observations made during the inspection and, where applicable, proposals for corrective measures. Statements about the action that is subsequently taken should also be recorded.
3. Using the inventory and location records verify the following:
 - the presence of the sample
 - the accuracy of the sample description on the inventory and other documentation
 - the accuracy of the location information
 - traceability of sample to consent received
4. The audit can also be used as an opportunity to:
 - reassess the environmental, storage and security needs of samples
 - update labelling and marking of samples
 - carry out a condition check of samples
 - to determine if the sample should remain in storage or be subject to disposal
 - scan in to PC the current Tissue Sample logs
5. After an audit the sample record should be marked with the following information:
 - the date of audit
 - the name of the person checking the sample and its information
 - any discrepancies including errors in identification number, description, etc.
6. The DI must check with the Principal Investigator that the samples can be traced to the relevant consent form where applicable
7. Consent materials and procedures (SOPs) will be reviewed as part of an annual paperwork audit
8. All documented non-conformances found during the audit require a corrective action. Actions must be taken without undue delay to eliminate detected nonconformities and their causes. Actions should be commensurate with the level of non-conformance identified.
9. If the audit highlights a flaw in a procedure (e.g. inaccurate movement control resulting in samples being mislaid), it is important that the relevant procedure be reviewed, revised or reinforced as required. It is then advisable to re-audit affected samples to ensure that the procedure is working effectively.
10. The type and frequency of adverse incidents, complaints and the effectiveness of corrective and preventive action must be reviewed by the DI to ensure that the quality system is effective and suitable.
11. Audit and adverse incident reports should be presented at FREC by the DI

4 Tissue Bank Control

4.1 Use of the Tissue Bank

1. The Tissue Bank is a part of Northumbria University and hence is covered by the University's Safety Policy. In addition to these there are some specific regulations below.
2. Use of the Tissue Bank by researcher or research group MUST be authorized by the DI.
3. No sample storage number may be issued without the required paperwork associated with the project being completed
 - a. consent information,
 - b. ethical clearance
 - c. safety assessments
 - d. Principal Investigator declaration
4. Use of the Tissue Bank is supervised by the DI or persons designated by them in their absence.
5. The Tissue Bank is only available for use at the advertised times - normally weekdays (not Bank or statutory Holidays) - and may not be available during some advertised times in the event of illness or absence of designated staff.
6. All staff must be aware of current health and safety legislation and guidance, and will receive training to enable them to work safely.
7. Access to the stored material in the Tissue Bank is restricted to those who are named on the study's Tissue Sample Log.

Procedure for sample drop off

8. Email the Tissue Bank Curator deputy (gavin.cowper@northumbria.ac.uk) at least 24 hours in advance of the requested time for sample drop off - either 09:30am or 3pm (Mon-Fri)
9. Once appointment has been confirmed bring along a sealable **storage box** with the study number written on the box and on the lid with permanent pen. If more than one box is required, then label boxes with number 1 of 2 etc
 - a. Ensure all samples in the box are **labelled** with the following
 - b. Study storage number
 - c. Numerical number 1, 2, 3 etc
10. Records of, access to, and movement of, material from the bank must be updated on the Tissue Sample Log immediately.
11. All personnel must use hand washing facilities after working with the material.
12. The following practices are prohibited in the Tissue Bank lab area: - eating, drinking, smoking, chewing, and the storage of food, drink, smoking materials or personal medication

4.2 Transport of Samples

1. Equipment for the storage and in house transport of the tissue material must be suitable for its intended use.
 - a. All material transported to and from the Tissue Bank must be done so with the due regard for safety of others.
 - b. Material transported to and from the bank should be in containers that prevent leaks to the environment – use of sealable plastic boxes, “cool bags” etc are recommended

4.3 Cleaning / Maintenance of the Freezers

1. The bank should be defrosted when necessary and at least annually.
2. The freezers in the Bank should have their temperature monitored and recorded. If there is a trend upwards in temperature filters should be cleaned and the freezers defrosted and cleaned. If the temperature does not stabilise after cleaning, then an engineer should be called for.

3. When samples are moved from the bank to allow for the defrosting and cleansing of the freezers **section 4.2** must be adhered to, and a log of what was removed, and where it was removed to, should be created. This should be used to ensure all samples are returned after cleaning.

4.4 Security of the Tissue Bank

It is the duty and responsibility of all workers in and visitors to the Tissue Bank to follow the regulations laid down below:

1. The Tissue Bank is only available for use at the advertised times - normally weekdays (not Bank or statutory Holidays) - and may not be available during some advertised times in the event of illness or absence of designated staff.
2. The storage facilities must be locked when not in use.
3. Staff must remain vigilant at all times when the storage facilities are in use.
4. A record (on the Tissue Sample Log) must be left of the deposit or removal of material in the Tissue Bank.
5. If an adverse incident occurs, an adverse incident form must be filled in and filed with the DI. The procedure for dealing with adverse incidents must be followed

4.5 Security of the Stored Material

1. All doors to the storage units must be secured at all times except to permit authorised entry and exit of samples.
2. All samples must be ID'd and catalogued prior to storage in the Tissue Bank.
3. Procedures for traceability must be established, documented and maintained. These procedures must define the extent of traceability and facilitate corrective action.
4. Records of use and movement must be maintained for audit purposes.

5 Adverse Incidents

5.1 Procedure for dealing with Adverse Incidents

1. Adverse Incidents are incidents or “near misses” involving:
 - breaches of security
 - loss of material
 - damage to samples
 - damage to the Tissue Bank
 - injury to personnel
 - accidents involving possible personal contamination from tissue
2. All adverse incidents must be investigated by the DI and relevant University staff. This is in addition to “normal” University accident reporting and investigation procedures.
3. The DI should determine the cause of the non-conformance or potential non-conformance and design the corrective action plan to address.
4. Where appropriate, corrective action should be followed by preventive action to include a review of the causes of the non-conformance and the implementation of appropriate changes to procedures to prevent recurrence.
5. A report on each adverse incident and details of corrective action taken must be made to the Faculty Research Ethics Committee. Principal Investigators whose studies have potentially been affected should be contacted by the DI.
6. Changes to or improvements to security arrangements or operating procedures arising from adverse incidents must be:
 - recorded and the old procedure must be filed
 - signed and authorised by the DI
 - broadcast to all workers associated with the Tissue Bank and suitable training provided in the new procedure if necessary - training records must be updated as per Staff Training SOP
 - added to the Tissue Bank Manuals and a copy placed in the Tissue Bank
7. Collated results of adverse incidents must be reported to the HTA as required by the Human Tissue Act

5.2 Freezer Failure

5.2.1 Responsible Personnel

Estates Services are responsible for

- maintenance of facility infrastructure and services.
- providing back up services in the event of primary service failure (e.g. electricity)

Contact Estate Services Helpdesk ext. 4070

Security Services are responsible for

- attendance at scenes of alarms or adverse incidents.
- for callout of specialist personnel in the event of alarms or adverse incidents out of working hours

Contact Security Office ext. 3200 (emergency)

Specialist Personnel are responsible for

- providing specialist support to Estates or Security Services in the event of an alarm or service failure
- attendance at scene, if called out by security services.
- providing specialist support to efforts to deal with the effects of an adverse incident

Contacts – see below

5.2.2 In the event of power failure to the HTA freezers

1. If power fails to the Human Tissue bank freezer area an alarm system will alert Tissue Bank contacts and Security.
2. Security should check the Tissue Bank in Northumberland NB430 and be prepared to respond to calls from Tissue bank contacts
3. If there has been no contact Security should follow the contact procedure to obtain specialist advice and obtain specialist support to the incident should it be necessary

5.2.3 Contact Procedure

Security will attempt to contact the Primary contact – if no response from this number they will then proceed to secondary contacts returning to Primary contact if no response is received

On receiving a phone call from Security, you should:

- Establish from Security the nature of the incident.
- Decide in consultation with Security how many and what type of staff should be called immediately.
- Contact other relevant staff if required.

5.2.4 Contact Details (In work hours)

Tissue Bank Freezer Area

- | | | |
|-----------------------|-------------------|---------------|
| a. Primary Contact | Ms Amber Cassells | 0780 170 8545 |
| b. Secondary contacts | Mr Gavin Cowper | 0772 025 5911 |
| | Mr Dave Wealleans | 0797 004 7205 |

5.2.5 Contact Details (Out of work hours)

Tissue Bank Freezer Area

- | | | |
|-----------------------|-------------------|---------------|
| a. Primary Contact | Ms Amber Cassells | 0780 170 8545 |
| b. Secondary contacts | Mr Dave Wealleans | 0797 004 7205 |

5.2.6 Dealing with loss of power to the Human Tissue bank

1. Determine scope of adverse incident.
2. Fridges / freezers will hold temperature for a number of hours if they are not opened. Only attempt to move samples if the incident is likely to result in critical temperatures being reached.
3. If possible, move samples from affected freezers to other freezers located as below. Follow procedures laid out in section 4.2.
 - a. Fridges (+4°C) – available in NB430 and 423 in Northumberland Building
 - b. Freezers (-20°C) – available in NB430 within Northumberland Building and Ellison A401 and A602
 - c. Freezers (-85°C) – available in NB430 within Northumberland Building and also Ellison A314, A317, A401 and A603
4. If power is off to multiple buildings then attempt to locate samples in cryogenic stores short term – available in Ellison Building A314, A317, A401, A603

6 Governance of the Tissue Bank

6.1 The Designated Individual (DI)

The governance of the Tissue Bank is overseen by the DI reporting to the University Research Ethics Committee. The DI's responsibilities include:

- ensuring all conditions of the HTA license are complied with
- ensuring suitable practices are used in the course of carrying out the HTA licensed activities
- ensuring Persons Designated are suitable persons to participate in the carrying out of HTA licensed activities
- responsibility for all personnel and implementation of the Code of Practice
- keeping up-to-date with new developments, professional guidelines and related research
- conducting regular meetings with research staff, PDs, laboratory manager and faculty managers to review quality and address training needs
- reviewing procedural efficacy, continuity of the audit trail and advising third parties of their responsibilities
- authorising Standard Operating Procedures and other relevant documents
- ensuring corrective and preventative actions are completed

6.2 Persons Designated (PD)

The DI can, with their permission, designate persons to whom the authority of the license applies. These PDs can direct others working in the Tissue Bank(s) in the absence of the DI. The DI is responsible for ensuring PDs are suitable persons to participate in the carrying out of HTA licensed activities.

The PD's responsibilities include:

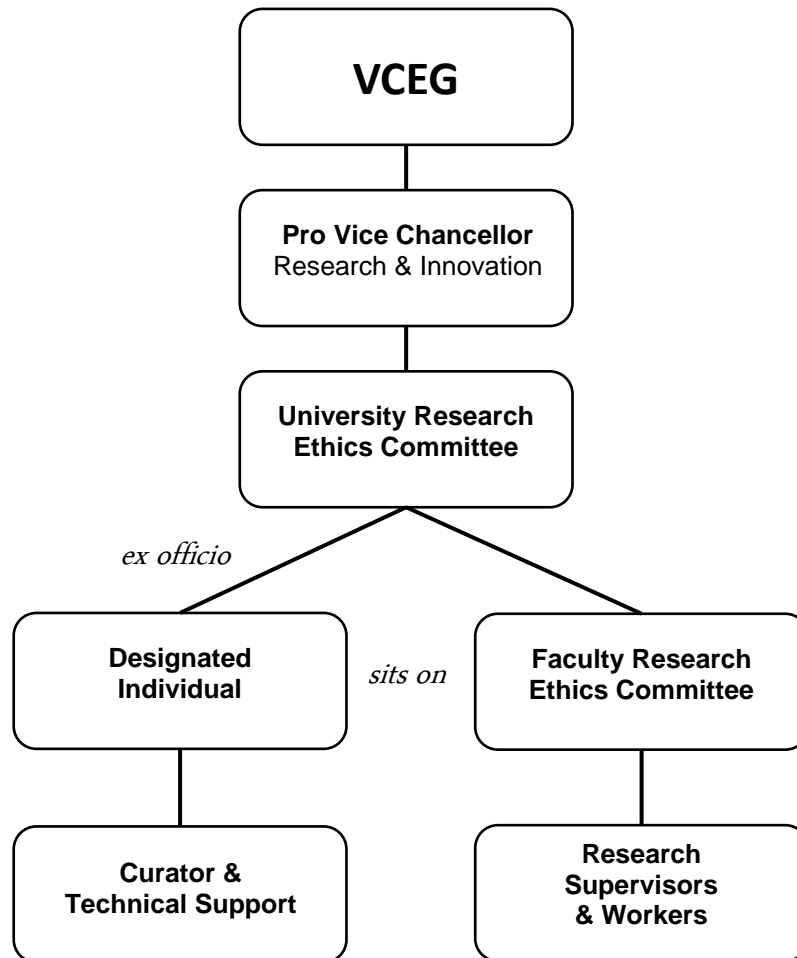
- providing regular input to the review of the quality system
- ensuring that samples are stored and used according to Standard Operating Procedures
- ensuring implementation of the instructions relating to the operation of the Tissue Bank
- retention and maintenance of records
- checking the maintenance and security of premises and samples
- ensuring compliance with training programs

6.3 The Tissue Bank Curator (TC)

The Tissue Bank Manager's responsibilities include:

- arranging and overseeing access to the tissue bank
- performing and acting on internal audit programs
- reviewing procedures at regular intervals
- archiving old documentation
- preparation of Standard Operating Procedures and other relevant documents
- ensuring that process validations are completed
- identification, investigation and monitoring of factors which may affect safety and quality
- checking the maintenance of equipment
- ensuring compliance with training programs

6.4 Management Organogram



7 Training

Personnel performing work affecting sample quality are deemed competent on the basis of appropriate education, training, skills and experience. The DI is responsible for assessing competence and providing induction and training to workers within the facility

1. All research investigators working with Human Tissue must attend a Northumbria University induction session and mandatory Northumbria University staff ethics training sessions.
2. All employees associated with or using the Tissue Bank must have attended a Tissue Bank Induction session provided by the DI or appropriate PD.
3. Northumbria University building specific roles must be identified and persons undertaking those roles must have attended the appropriate training courses (e.g. fire marshal, first aider)
4. Subject specific training and development requirements for workers in the Tissue Bank are discussed and arranged through the Faculty Research Ethics Committee. The DI can request any staff training or development he feels is essential to maintain the relevance of the skills and knowledge of the staff working in the Tissue Bank. The chair of the Faculty Research Ethics Committee is responsible for ensuring such agreed training takes place.
5. Personnel who carry out specific tasks (DI and PDs) must have appropriate education, training and/or experience.
6. All personnel who are required to perform specialist functions (e.g. manual handling or handling of hazardous substances) must be appropriately trained or supervised by a trained person.
7. Personnel who occasionally work (e.g. maintenance staff) in the Tissue Bank must also be appropriately trained in the use and security requirements of the Tissue Bank.
8. Training records must be maintained and evaluated regularly in accordance with Northumbria University appraisal and training procedures.

8 Human Tissue Authority information and contacts

- **Our Human Tissue License details are**

Licensing Number	12495
Licensed Premises	University of Northumbria at Newcastle Faculty of Health and Life Sciences Room 430 Northumberland Building College Lane Newcastle Upon Tyne NE1 8SG
License Holder	University of Northumbria (Prof D Ford)
Designated Individual	Ms Amber Cassells

This licence is granted under Section 16 (2) (e) (ii) of the Human Tissue Act 2004. This licence authorises the storage of relevant material which has come from a human body for use for the following scheduled purposes:

- Determining the cause of death
- Establishing after a person's death the efficacy of any drug or other treatment administered to him
- Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person)
- Public display
- Research in connection with disorders, or the functioning, of the human body
- Clinical audit
- Education or training relating to human health
- Performance assessment
- Public health monitoring
- Quality assurance

- **HTA general contacts**

<http://www.hta.gov.uk/>

General email enquiries should go to enquiries@hta.gov.uk

Tel: 020 7269 1900 (general)

Direct contact with the HTA should go through the Designated Individual or named License Holder

- **Changes to the License**

Changes to licensed premises or individuals named on the License (Designated Individual, License Holder, Person Designated) should be made to the HTA using their relevant forms and procedures

http://www.hta.gov.uk/licensing/guide_to_licensing_and_application/changes_to_your_licence.cfm

Northumbria University has identified the following people as deputies for the named roles should the role holder be unable to fulfil their duties for an extended period of time.

Designated Individual	Mr Dave Wealleans
License Holder	Prof M Shantz

These individuals will make the relevant changes known to the HTA.

Appendices

A1 Tissue Bank Sample Storage Guide

Prior to sampling

Your supervisor should provide you with a **Study Storage Number** (see over) and you should have had an induction into the use of the Tissue Bank

Procedure for sample drop off

1. The Tissue bank is located in Northumberland Building NB430. This is a laboratory – do not bring food or drink into the lab and do not use mobile phones while in the lab.
 2. Email the Tissue Bank Curator (currently gavin.cowper@northumbria.ac.uk) at least 24 hours in advance of the requested time for sample drop off - either 09.30am or 3pm (Mon-Fri)
 3. Once appointment has been confirmed bring along a sealable **storage box** with the study number written on the box and on the lid with permanent pen. If more than one box is required then label boxes with number 1 of 2 etc
- Clearly label your tissue bank storage container with the **Sample Storage Number**
 - *Samples must be stored in containers– any loose samples will be destroyed*
 - Number your samples sequentially before placing in the storage container
 - *Start at 1, and if samples are stored in batches, continue sequential labelling from the next available number*
 - *A labelling device is provided in the Tissue Bank*
 - *You may wish to also have batch or study info on the sample – this is fine as long as the sequential sample number is separate and clear*
 - Fill in the Tissue Sample Log
 - *All movements of samples in and out of the Tissue Bank must be recorded*
 - *Only people identified, and authorised to do so, on the Tissue Sample Log will be able to store and remove samples from the container*
 - *Ensure the Tissue Sample Log is legible, sample numbers are clear and the number of samples in storage is that indicated on the Tissue Sample Log*
 - *There are additional log sheets kept in the fridge – add page numbers to additional sheets if required.*

A3 Declaration by Principal Investigator

Principal Investigator name	
FREC clearance reference number	
Investigator Name	
Date mandatory ethics training undertaken	
Info Sheet version number in use	
Consent Form version number in use	

I understand the terms and conditions under which Human Tissue is to be used at Northumbria University, particularly my responsibilities under the Human Tissue Use Policy and confirm

- A)** The proposed activities will be carried out under my supervision
Yes No
- B)** The proposed activities have been Risk Assessed, a record has been made of the assessment and control measures required by the assessment, to protect workers, will be utilised
Yes No
- C)** I will follow the guidance and protocols set out in the Policy and associated Guides and Operation Manual
Yes No
- D)** I will ensure the mandatory training relating to ethics and informed consent has been undertaken by those working on this study
Yes No
- E)** I will produce an SOP for the taking of consent for this study and ensure the correct level of informed consent required by the proposed work will be obtained, recorded and stored
Yes No
- F)** I will ensure that all records collected during the proposed work comply with University Policy on Data Protection and participant anonymization
Yes No
- G)** I accept I am responsible for ensuring that the other persons working under my supervision are suitable persons to participate in the carrying out of the proposed activities
Yes No
- H)** I accept that I am responsible for ensuring that suitable practises are used by the persons under my supervision in the course of carrying out the proposed activities
Yes No
- I)** The information provided is true and accurate to the best of my knowledge
Yes No

Signed

Date

Storage Number Issued

A4 Internal Audit Record

Audit date:	
Persons Present:	
Date of report to FREC:	

Study Storage Number	
Project Leader / Principle Investigator	
Investigator (s):	
Recorded number of samples in storage	
Actual number of samples in storage	
Traceability check – Sample ID / Consent form	
Action required?	
Action taken	
Signatures (DI & PI)	

A5 Audit Schedule

January	<p>Documentation review Sample Audit</p> <ul style="list-style-type: none"> • Sample presence • One sample / consent traceability check per study stored • Clarity / legibility of records <p>Scan in current Tissue Sample Logs Report to FREC/ UREC</p>
July	<p>Risk Assessments Review Sample Audit</p> <ul style="list-style-type: none"> • Sample presence • One sample / consent traceability check per study stored • Clarity / legibility of records <p>Scan in current Tissue Sample Logs Report to FREC / UREC</p>

A6 Corrective and Preventative action (CAPA)

Tissue Bank Corrective and Preventative Action (CAPA) record

Action request / required:	
Requested by:	
Assigned to:	

Description of issue	
Investigation report	
C/P Action advised	
Implementation record	
Verification of improvement	

Signatures
Requestor
Investigator
Implementation by
Verification / Designated Individual

A7 Reference Documents

University Policies		Rev #	Date
•	Human Tissue Use Policy	1.2	
•	Research Ethics Policy		
•	Data Protection Policy		
•	Informed Consent Policy		
Manuals			
•	TBOM Northumbria University Tissue Bank Operation Manual	3.2	2016
Guides			
•	TBG 001 Tissue Bank Guide	2.4	2014
•	TBG 002 Tissue Bank Organisation Chart		<i>added to manual 2016</i>
•	TBG 004 Sample Storage Guide	2.0	2014
Operating Forms			
•	TBF 001 CAPA record form	2.0	2016
•	TBF 003 Tissue Sample Log	2.0	2014
•	TBF 004 Declaration by Lead Researcher / Project Supervisor	3.0	2016
•	TBF 010 Audit Record	2.0	2016
Redundant Documents			
•	<i>TBF 002 Internal Audit Plan form</i>		<i>removed 2014</i>
•	<i>TBF 006 Service Supplier Corrective Action Plan form</i>		<i>removed 2014</i>
•	<i>TBF 007 Tissue Bank Quality Management Review Minutes form</i>		<i>removed 2014</i>
•	<i>TBF 008 Employee Training Plan form</i>		<i>removed 2014</i>
•	<i>TBF 009 Internal Audit Record checklist</i>		<i>removed 2014</i>
•	<i>Consent form for Tissue use, removal and storage</i>		<i>removed</i>
	<i>2014</i>		
•	<i>TBQM Northumbria University Tissue Bank Quality Manual</i>		<i>removed 2014</i>
•	<i>TBG 003 Master List of Documents</i>		<i>removed 2014</i>
•	<i>TBG 005 Study List</i>		<i>removed 2014</i>
•	<i>TBSOP 001 Production of an SOP</i>		<i>removed 2014</i>
•	<i>TBSOP 002 The Storage and Use of Human Tissue</i>		<i>added to manual 2014</i>
•	<i>TBSOP 003 Disposal of Human Tissue</i>		<i>added to manual 2014</i>
•	<i>TBSOP 004 Control of Records procedure</i>		<i>added to manual 2014</i>
•	<i>TBSOP 005 Traceability</i>		<i>added to manual 2014</i>
•	<i>TBSOP 006 Response to alarms</i>		<i>added to manual 2014</i>
•	<i>TBSOP 007 Control of Documents procedure</i>		<i>added to manual 2014</i>
•	<i>TBSOP 008 Internal Audit procedure</i>		<i>added to manual 2014</i>
•	<i>TBSOP 009 Corrective and Preventative Action procedure</i>		<i>added to manual 2014</i>
•	<i>TBSOP 010 Adverse Incidents</i>		<i>added to manual 2014</i>