NEWCASTLE UNIVERSITY

HUMAN TISSUE QUALITY MANUAL (RESEARCH)

The collection, storage and use of human tissue in research at Newcastle University

NJRO-TISS-POL-004

Prologue

At Newcastle University, we undertake fundamental translational research in a diverse range of disease areas, to develop innovative new treatments, tests and medicines to improve human health. In order to do this, we rely on the generosity of donors, including healthy volunteers, who kindly provide their tissue samples for use in research projects. Human tissue samples are a precious gift, and their removal, storage and subsequent use in research projects in Newcastle is carefully controlled to ensure that all the regulations are met, and that donor wishes are respected.

The purpose of this Quality Manual is to set out the quality management system and standards that must be implemented in Newcastle to support human tissue research and to ensure that all samples and donors are treated with the respect and dignity that they deserve. This is irrespective of whether or not it comes under the remit of the University Human Tissue Authority Research Licence and covers tissue use from healthy volunteers and from patients enrolled in research ethics committee approved projects. This is to ensure that all tissue is treated to the same high standards as those recommended by the Human Tissue Authority.

Dr Chris Morris
Designated Individual, Newcastle University Research Sector Human Tissue Authority licence (ref. 12534)

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1. INTRODUCTION

The use of human tissues in medical research in the United Kingdom is strictly regulated.

Human tissue research must be conducted in accordance with the Human Tissue Act (2004), General Data Protection Regulation (GDPR), Data Protection Act (2018) and the NHS Health Research Authority's (HRA) procedures for conducting medical research.

All research must be carefully planned and funded, and approval sought to ensure the research is ethical and appropriate, and compliant with the regulations. Once initiated, research must be carefully managed, ensuring that appropriate and valid consent is in place for all samples and data, maintaining patient confidentiality, dignity and sample traceability through to study closure.

As human tissue is widely used across Newcastle University, the University holds a Research licence under the Act (Licence no. 12534) –which governs the storage of human tissue on University premises for use in future research. This licence, and its requirements, must be understood and respected by all employees who work with human tissues.

This Quality Manual has been produced to provide a comprehensive description of the Quality Policy and Quality Management System adopted at Newcastle University relating to the use of Human Tissues in research.

The Newcastle Joint Research Office website should also be consulted (https://newcastlejro.com/) as a valuable resource for researchers.

2. AIMS

Human tissue is considered to be a precious gift. In order to demonstrate respect for this gift and ensure high quality research, it is paramount that all human samples are acquired lawfully, with appropriate consent, and are stored, handled, used and disposed of respectfully, sensitively and responsibly.

As such, the University requires that all researchers working with human samples, from the living or deceased, strictly abide by the procedures and standards set out in this Quality Manual.

This Quality Manual therefore aims to:

a) Ensure the wishes and consent of donors and their relatives is respected, and their tissues are treated with dignity and in accordance with the appropriate national legislation and good practice.

b) Provide clear rules on the use of human tissue in research at Newcastle University to ensure compliance with regulatory requirements and the licensing obligations of the HTA
c) Maintain an effective Quality Management System in compliance with the Human Tissue Act and the standards and guidance issued by the Human Tissue Authority.
d) Enhance the University's reputation for the delivery of research of the highest quality and ethical standards and ensure public confidence in the ethics of scientific research
e) Demonstrate the University's commitment to defining the quality of its products and services, and ensuring the continuous review and improvement of quality standards to promote process excellence and good ethical practice.

To achieve this, it is imperative that all staff working under the Newcastle University research sector HTA licence understand their responsibilities under the Human Tissue Act, and are accountable for the quality of their work.

This Quality Manual provides researchers with a comprehensive summary of the Newcastle University quality management system relating to human tissue research, providing a clear description of the processes that must be conducted in order to organise, conduct, and document research using human tissue on Newcastle University premises.

3. SCOPE

This Quality Manual applies to all individuals involved in human tissue research on Newcastle University premises, where human tissue is defined in accordance with the Human Tissue Act (2004) as "*material, other than gametes, which consists of, or includes human cells*" – referred to as "relevant material" under the Act.

This includes relevant material held under the University's Human Tissue Authority research licence (ref. 12534) and relevant material which is currently in use in research projects, which have been approved by nationally recognised NHS Research Ethics Committees.

It should be noted that this manual relates only to the Research Sector Licence held by the University, and not to any other sectors, or organisations. For information related to other HTA licences held in Newcastle please refer to NJRO-TISS-T-030.

4. ROLES AND RESPONSIBILITES

4.1. Principal Investigator (PI)

It is the responsibility of all Principal Investigators (PIs) at Newcastle University to ensure that they have the appropriate ethical approval, permissions, and consent in place to collect and use human tissue for research purposes. This may be obtained from a recognised NHS Research Ethics Committee (REC), or from the University Ethics Committee.

Only material which is stored with current ethical approval from a recognised NHS Research Ethics Committee is exempt from requiring storage under the Human Tissue Act regulations. Material obtained following approval of the University Ethics Committees must be stored under HTA regulations.

PIs are responsible for ensuring that any material requiring storage under the Human Tissue Authority licence is stored in approved storage locations, and disclosed to the Designated Individual named on the licence. Relevant material under the Human Tissue Act requires storage under a HTA licence when it is not part of a current NHS REC approved research study (e.g. samples remaining at the end of a clinical trial/REC approved project, imported material, material collected from healthy volunteers).

For information on approved storage locations under the University's HTA licence, see section 5.

For samples collected under the ethical approval of an NHS REC, it is the responsibly of the Principal Investigator to be aware of the end date of the ethical approval, and ensure that when the approval expires, any remaining samples are appropriately managed. i.e.

- The ethical approval is extended to cover further research
- The remaining samples are transferred to an approved storage location under the HTA (with the approval of the Designated Individual) – ensuring appropriate permissions are in place e.g. ethical approval & consent.
- Samples are transferred off Newcastle University premises, or
- Samples are respectfully disposed

In addition, all PIs must ensure that staff working for them are appropriately trained.

4.2. Chief Investigator (CI) of Research Tissue Banks

Each NRES REC approved research tissue bank must assign a Chief Investigator (CI) (otherwise known as "The applicant" or "Research Tissue Bank Manager". A role description is provided in NJRO-TISS-T-021. A list of all current Research Tissue Bank CIs is provided in NJRO-TISS-T-015.

4.3. Institute Manager Responsibilities

Any Institutes receiving human tissue samples must ensure due diligence, by ensuring that the Principal Investigator's within that Institute provide and record full information on material they are transferring into and out of the institute, including use of the Faculty Academic Leavers checklist.

4.4. Human Tissue Authority licence roles

A number of key roles are assigned under the Human Tissue Act. These include

- A Licence Holder (see role description NJRO-TISS-T-017)
- Designated Individual (see role description NJRO-TISS-T-018).
- Persons Designated (see role description NJRO-TISS-T-019).

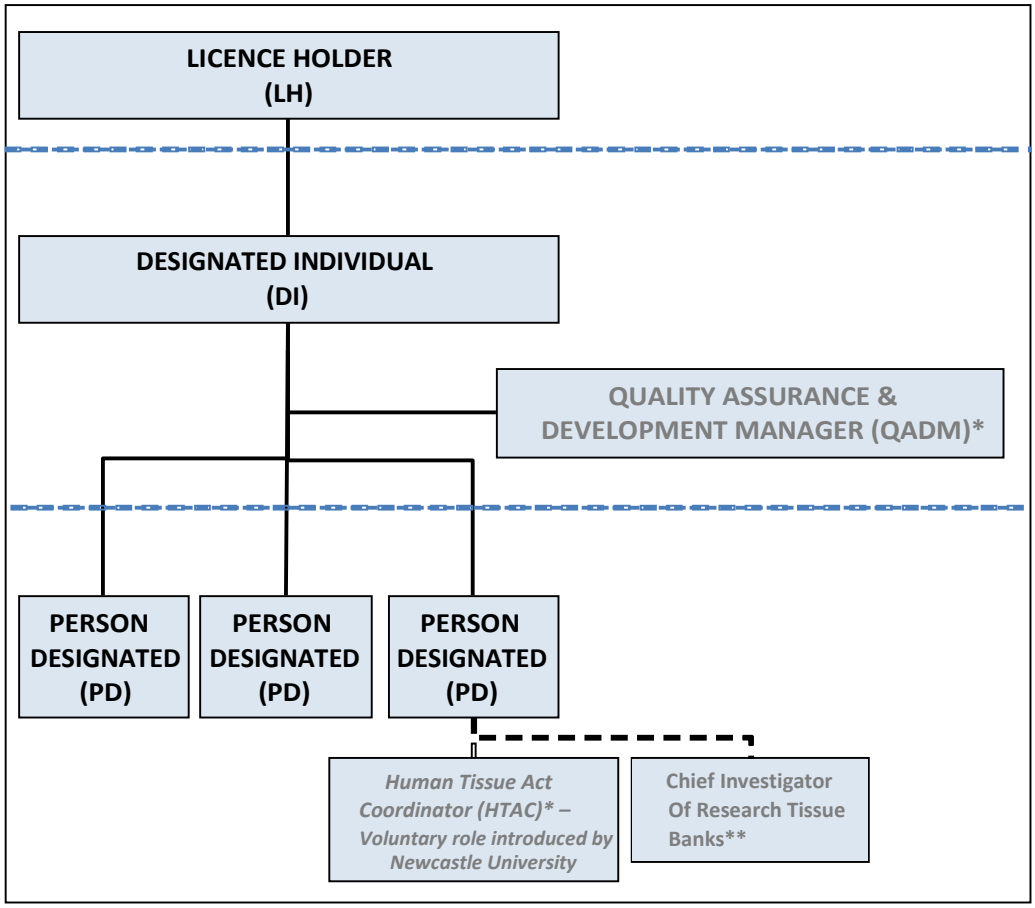
The names and contact details of the Licence Holder and Designated Individual named on the Newcastle University research sector HTA licence (ref. 12534) are provided below.

Licence Holder:	Newcastle University – Professor David Burn, named for correspondence Faculty of Medical Sciences, Newcastle upon Tyne, NE2 4HH Tel: 0191 208 7003 Email: David.burn@newcastle.ac.uk
Designated Individual:	Dr Chris Morris Edwardson Building, Campus for Ageing and Vitality, Newcastle upon Tyne, NE4 5PL Email: c.m.morris@ncl.ac.uk, Telephone: +44 (0) 191 208 1208
Persons Designated	As the University is spread over a wide campus, the DI has gained the valuable support of a number of Persons Designated (PDs) to oversee compliance with the Act in their local area. All PDs must confirm their acceptance of this role by signing the appropriate section of the PD role description form. A signed role acceptance is retained by the NJRO Quality Management Team and should be held locally within each groups Human Tissue Master File. As PDs are subject to change, an up-to-date list of the Persons Designated named on the Newcastle University licence is held in the Human Tissue Master File (NJRO-TISS-T-016). This list is provided to the Human Tissue Authority, and any changes communicated as they arise.

In addition to these compulsory licensing roles, the following additional roles have been implemented at Newcastle University to help ensure compliance with the licence. Names are susceptible to change.

Quality Assurance and Development Manager	Mhairi Anderson Newcastle Joint Research Office, Level 1, Regent Point, Regent Farm Road, Gosforth, Newcastle upon Tyne NE3 3HD Email: Mhairi.anderson@ncl.ac.uk Telephone: +44 (0) 191 282 5501 • Part of the Newcastle Joint Research Office (NJRO) Quality Management Team
Human Tissue Act Coordinators	Named in each groups Master Files, where appointed. HTAC Role Description (NJRO-TISS-T-020).

An organogram of HTA licence roles is provided in Figure 1.



* These roles are non-compulsory roles under the HTA but have been established at Newcastle University to support regulatory compliance.

** Research Tissue Bank Chief Investigators are approved by Research Ethics Committees under NRES which i s distinct from the HTA

Figure 1- Roles and responsibilities overview

4.4.1. Responsibilities of all other staff working under the licence

In addition to the formal roles set out by the Human Tissue Act, and additional assigned roles, it is the responsibility of all staff operating under the University's HTA licence to know their responsibilities under the Act, to treat donated material with dignity and respect, and to protect the privacy of donors and maintain data confidentiality.

Researchers should be aware of cases in which material has to be stored under the licence, must disclose this material to the Persons Designated or Designated Individual, and must store the material appropriately in a suitable designated storage location.

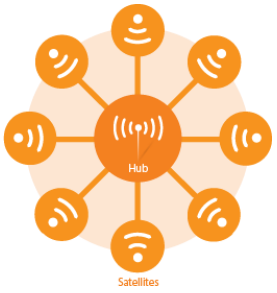
In accordance with the terms and conditions of the University's research HTA licence, the Designated Individual (DI) must be aware of all relevant material stored at the University. This includes all relevant material stored for NHS Research Ethics Committee approved research where a Human Tissue Authority licence is not required for the storage of the material. Therefore, regardless of the method of obtaining tissue, all researchers storing relevant material at the University have a responsibility to disclose this material to the DI.

5. STORING HUMAN TISSUE

5.1. Newcastle University Human Tissue Authority research licence

Newcastle University, has adopted the "hub and satellite model" of licensing under the Human Tissue Authority licensing framework. The main University campus is considered to be the "hub" with 3 geographically remote satellite sites. The details of these licensed premises are provided below. A copy of the HTA licence for each of these premises is provided in **Appendix 1.** A copy of the HTA licence for each premises should be displayed prominently in each location.

- **Hub Site:**
  Newcastle University
  Faculty of Medical Sciences
  The Medical School Newcastle upon Tyne
  NE2 4HH
  Tel: 0191 208 7003
  Professor David Burn (for correspondence)



- **Satellite Premises:**

Edwardson Building Campus for Ageing and Vitality Newcastle University Newcastle upon Tyne NE4 5PL United Kingdom	Institute of Transplantation and Northern Centre for Cancer Care Freeman Hospital Freeman Road High Heaton Newcastle Upon Tyne NE7 7DN	International Centre for Life Newcastle University Central Parkway Newcastle upon Tyne NE1 3BZ
Tel: +44 (0) 191 248 1300 Correspondence to: Debbie Lett (Debbie.Lett@ncl.ac.uk).	Tel: +44 (0)191 233 6161 (Switchboard) Correspondence to: Dr Chris Ward (chris.ward@ncl.ac.uk).	Correspondence to: Daniel Cox (Daniel.Cox@ncl.ac.uk).

5.2. Approved storage locations

Relevant material requiring storage on Newcastle University premises under the Human Tissue Authority licence may only be stored at preapproved locations within the hub and satellites. These locations must be approved by the Designated Individual and are audited on a regular basis by the NJRO Quality Management Team, or appropriate delegate. Where any staff believe human tissue is stored in unapproved storage locations, they should contact the Designated Individual immediately.

An up-to-date copy of the approved storage locations is provided in the Newcastle University Human Tissue Authority licence organogram (NJRO-TISS-T-014).

5.3. Activities covered by the licence

The licensed activity named on the Newcastle University research HTA licence (ref. 12534) is:

"Storage of a relevant material for a number of scheduled purposes"

The scheduled purposes listed on the licence are:

- 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 related to human health
- Performance Assessment
- Public Health monitoring
- Quality Assurance

It should therefore be noted that:

- This licence is for the "**Storage**" of relevant material for research, and does not license the research itself.

- For researchers to use the tissue stored at Newcastle University, Research Ethics Committee (REC) approval is required.

- Material may be stored for a range of scheduled purposes, such as, public display or determining the cause of death ("scheduled purposes"). However to physically conduct these activities, the appropriate licence would be required (e.g. material may be stored for public display in accordance with the Newcastle University licence, however to publically display the material, a public display HTA licence would be required. For further information, please refer to the Human Tissue in Research Manual).

Any researcher who wishes to store a tissue for a purpose not listed above must contact the Designated Individual or Quality Assurance & Development Manager for advice.

5.4. Sample tracking

To meet its regulatory responsibilities under the Act, Newcastle University has invested in the "Achiever" Medical Sample Tracking Software, from the vendor Interactive Software (ISL).

Achiever is a configurable and scalable laboratory information management system (LIMS) specifically designed to assist academic research institutions to successfully manage human tissue within their biobanks and biorepositories whilst ensuring compliance with appropriate regulations including the Human Tissue Act (2004). The system is maintained by NUIT, and has been configured to meet the requirements of the Newcastle University.

The Achiever software assigns tissues with a unique sample number, a key requirement of the Act, and provides quick and easy regulatory reporting, and audit trail and full traceability to donor consent records.

It is mandatory that all research groups storing relevant material under the University research sector HTA licence use the Achiever software to track relevant material, unless an alternative regulatory compliant system is approved (refer to NJRO-TISS-T-029 for requests to use alternative systems). For a copy of the official mandate, please refer to NJRO-TISS-POL-002.

6. THE QUALITY MANAGEMENT SYSTEM (QMS)

To promote high quality standards for human tissue research in Newcastle, a tiered Quality Management System (QMS) has been implemented, as shown in Figure 2.

- External regulations – all staff must comply with standards set by external regulators, including the Human Tissue Authority (HTA) and Health Research Authority (i.e. research ethics).
- Institutional policies and procedures must be followed by all University students and staff.
- Any staff involved in human tissue research must also follow the Newcastle Joint Research Office (NJRO) quality management system. This includes a range of bespoke human tissue related documents, denoted "NJRO-TISS-".
- Compliance with these standards must then be supported with local policies and procedures, which must be implemented at a local level to describe each research group's specific procedures within their environment.

It is the responsibility of all staff to ensure that they are appropriately trained and training is recorded. A clear training and induction process and performance review system should be implemented to identify training requirements and to regularly review training needs. Further information on each component of the QMS is provided overleaf.

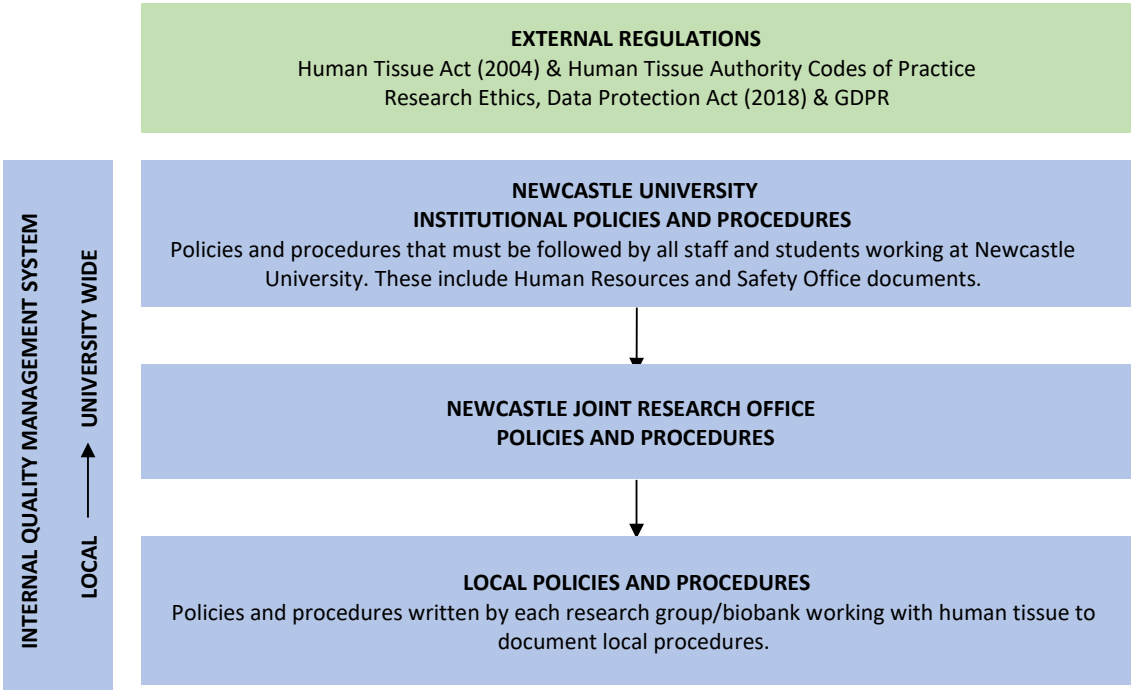


Figure 2- Newcastle University QMS Structure

6.1. External Regulations

It is the responsibility of all staff to ensure that they comply with external regulations in relation to human tissue research, including the standards set under the Human Tissue Act (2004) and associated Codes of Practice, Data Protection Act (2018) and General Data Protection Regulations (GDPR) and terms and conditions of ethical approval, granted by the Health Research Authority (HRA) Research Ethics Committees.

The Human Tissue Authority (HTA) is an independent government body which has been established to regulate compliance with the Human Tissue Act.

The HTA has the following objectives:

- To ensure that clear standards are in place for the use of human tissues
- To inspire public and professional confidence in medical research by ensuring that human tissue is used safely and ethically, and with proper consent
- To provide researchers with support and guidance to ensure best practice.

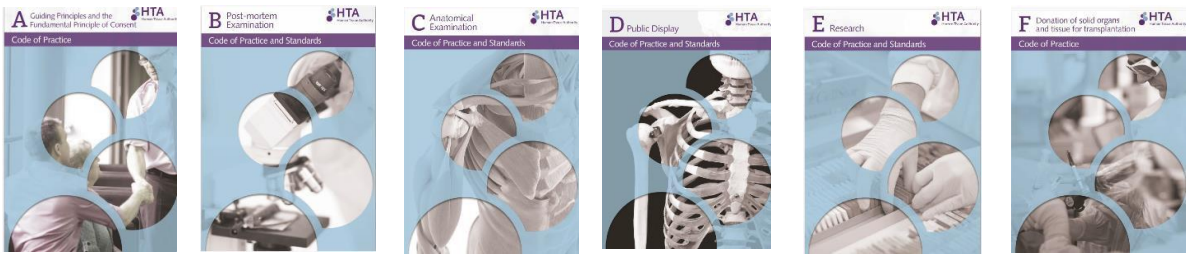
To achieve these objectives the HTA has created a number of codes of practice. The codes of practice provide guidance for researchers and lay down expected standards for each of the sectors the HTA regulates. The codes are designed to support professionals by giving advice and guidance based on real-life experience.

There are currently six Codes of Practice:

Code A -	Guiding principles and the fundamental principal of consent
Code B -	Post-mortem examination
Code C -	Anatomical examination
Code D -	Public display
Code E -	Research
Code F -	Donation of solid organs and tissue for transplantation

These codes have been written to reflect the following principals:

- **Consent** and the wishes of the donor or family have priority when removing, storing and using tissue and organs
- **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 when communicating about the use of human tissue and bodies.



A copy of these codes can be found on the HTA website at the following address alongside an additional document, including the standards against each Code, and guidance: https://www.hta.gov.uk/guidance-professionals/codes-practice

6.2. Institutional Policies and Procedures

It is the responsibility of all staff to ensure they comply with Newcastle University Institutional policies and procedures e.g. Health and Safety, IT. Copies of institutional procedures can be found via the staff home page under the policies tab. These should be identified as part of staff training and induction procedure.

6.3. NJRO Policies and Procedures

The NJRO has adopted a quality management system (QMS) to support research in Newcastle. These documents are either institution specific (Newcastle University or Newcastle Hospitals) or apply jointly to both organisations. This is captured in the scope of each document.

- All documentation can be accessed via the NJRO Q-Pulse system and the NJRO website (https://newcastlejro.com/).
- This QMS includes a number of human tissue specific policies and procedures that must be followed by all staff operating under the Human Tissue Act (2004). These documents are denoted “NJRO-TISS”. These have been written to comply with all external regulations.
- A Master List of all NJRO human tissue quality documents is provided in “NJRO-TISS- T-023”. This document must be held in each groups Human Tissue Master File.

6.4. Local Policies and Procedures

All groups are responsible for ensuring that all aspects of their work are governed by documented policies and procedures as part of a clear governance process, with documented and up-to-date policies and procedures in place, covering all licensable activities.

At a minimum, it is expected that groups have documented procedures covering:

- Document management – the groups approach to managing their quality documents (e.g. standard operating procedures (SOPs) and work instruction), including how these are approved, distributed, training recorded, and archived).
- Consent
- Sample management e.g. collection, transfer, receipt, labelling, specimen preparation, preservation, storage and sample tracking, disposal;
- Staff training and induction – including procedures for visiting staff.
- Premises, Facilities, Equipment management, including temperature monitoring and recording, contingency planning, cleaning and decontamination;

All documents must be written to comply with standards expected under NJRO-GEN-SOP- 020 “Standard Operating Procedures & Work Instructions – Preparation, Review & Approval”.

7. TRAINING

It is the responsibility of all staff to ensure they are appropriately trained for the activities they conduct and demonstrate that they are continually updating their skills. Appropriate training should be identified during the induction process and regularly assessed during annual performance reviews.

All staff operating under the Human Tissue Authority licence must complete Human Tissue Act training, at least every 3 years. Newcastle University have created a Human Tissue Act (2004) E-Learning course for the Research Sector. Newcastle University staff/students can access this training course for free using their NCL login. Collaborators who do not have a Newcastle University email address, but do work to actively collect samples to be transferred to one of Newcastle University’s NRES REC approved Research Tissue Banks, including taking consent and managing the samples in the clinic for transfer for the University, may also access the training for free. Access to the training must be requested by contacting HumanTissueResearch@ncl.ac.uk.

In addition, all staff must be able to demonstrate that they have read the appropriate policies and SOPs applicable to their work, as detailed in section 6. This should be documented in individual training logs.

8. COMMUNICATION

Regular Persons Designated meetings will be held throughout the year, chaired by the QA and Development Manager, or delegate. Meetings will be used to communicate key information and promote knowledge share. If meetings are not possible, information will be shared by joint mailing lists.

It is the responsibility of the Persons Designated to communicate any Human Tissue related information to staff operating in their area. PDs should attend regular PD meetings where ever possible, and send a delegate in their place if they are unable to attend. Information will be shared with the Persons Designated via the PD mailing list: persons-designated-res@newcastle.ac.uk.

In addition, any communication relating to NHS Research Ethics Committee approved research tissue banks will be conducted via the following shared email address: RTBManagers@ncl.ac.uk

The mailing account for each of these shared mailing lists will be maintained by the NJRO Quality Assurance Management Team.

Regular “NJRO Human Tissue in Research“ newsletters will also be issued and should be distributed amongst all teams operating under the licence.

Further information can be found on the following websites:

- Newcastle Biobanks: https://www.ncl.ac.uk/biobanks/
- Newcastle Joint Research Office website: https://newcastlejro.com/

9. GOVERNANCE

Governance of the acquisition, storage, use and disposal of human tissue at Newcastle University under the Human Tissue Act (2004) is overseen by the NJRO Quality Assurance and Development Manager, supporting the Designated Individual (DI) and Licence Holder. Audits are conducted in accordance with NJRO-TISS-SOP-004 with appropriate Corrective Preventive Action (CAPAs) to address any findings.

In the absence of the DI, a Person Designated is delegated to represent the DI – typically the QA and Development Manager.

Where required, issues are escalated to the Designated Individual and/or Licence Holder (as appropriate.

Due to the close partnership working between Newcastle University and Newcastle Hospitals, a joint governance framework is in place. To ensure independent governance oversight, the QA and Development Manager reports regularly to the Newcastle Joint Research Office (NJRO) Quality Management Improvement Form (QMIF). Any critical findings identified in internal Human Tissue audits must be approved by this forum prior to the issue of reports. Any other governance issues which require independent review/discussion/peer review are also taken to this group. The QMIF reports into the Newcastle Hospitals Clinical Research Governance Group, which reports directly to the Trust Executive Board.

Within the University, the NUTRCI Executive Board acts as a direct escalation route from the NJRO, which reports into the Faculty Executive Board.

Terms of Reference for all groups are available on request.

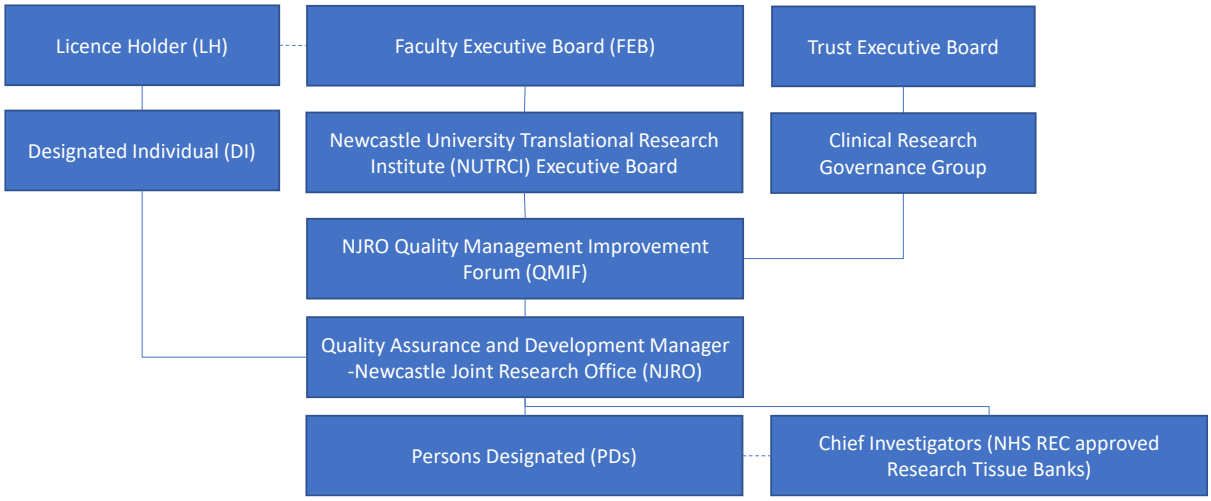


Figure 3- Governance Structure

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Newcastle University

Appendix 1 –Newcastle University HTA Licences

Hub Licence – Main campus

HTA Human Tissue Authority

Licensing Number	**12534**
Licence Holder	**Newcastle University**
Licensed Premises	**Newcastle University** **The Medical School** **Framlington Place** **Newcastle Upon Tyne** **NE2 4HH**
Designated Individual	**Dr Christopher Miles Morris**

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

The licensed activity should be carried on only at the licensed premises specified above, and under the supervision of the Designated Individual.

This licence is subject to the conditions set out in the Annexes accompanying this licence as may be subsequently varied pursuant to an application under paragraph 8 of Schedule 3 to the Human Tissue Act 2004.

This licence is valid from the date specified below and will remain in force until revoked.

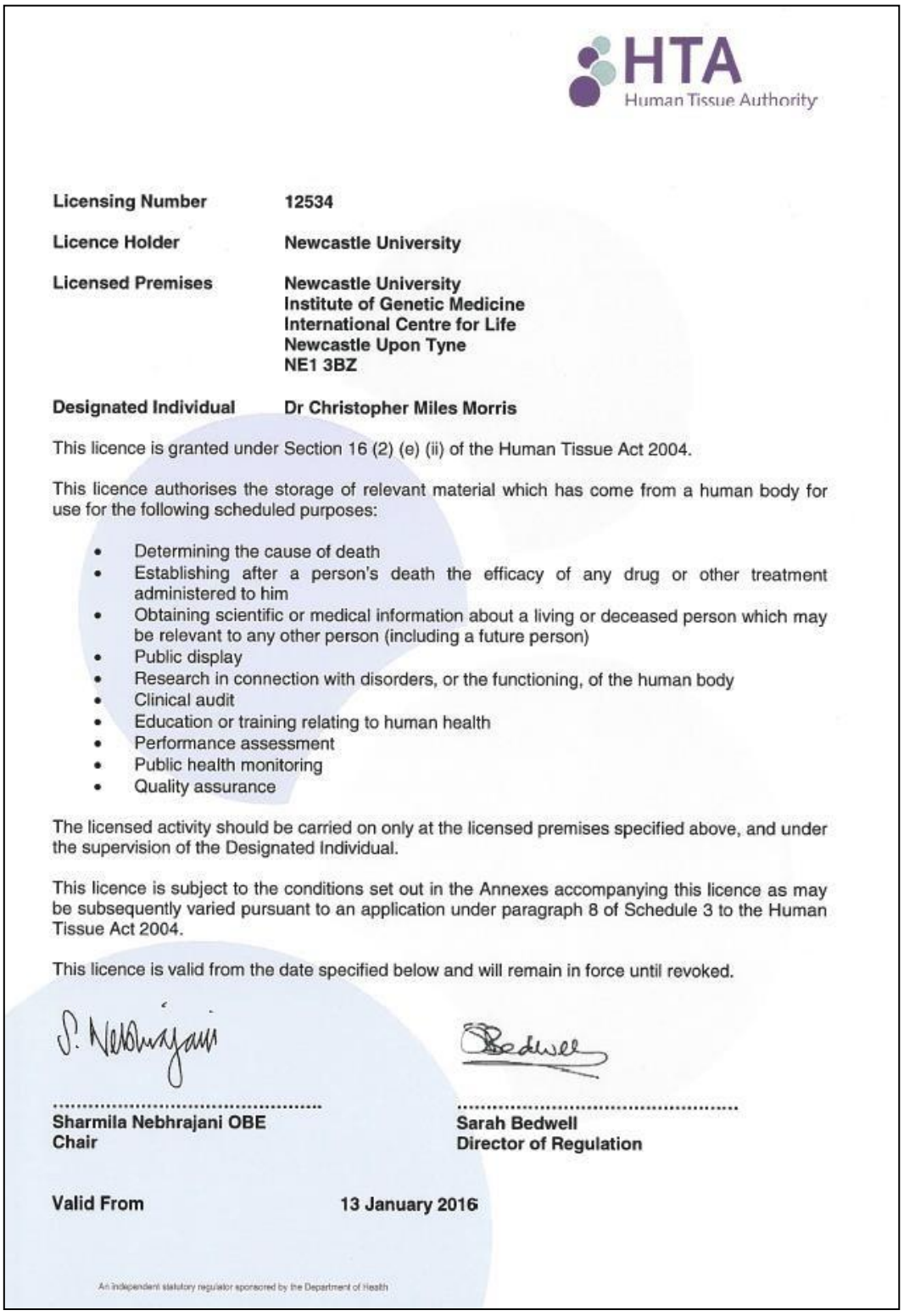
.....
Sharmila Nebhrajani OBE
Chair

.....
Sarah Bedwell
Director of Regulation

Valid From **13 January 2016**

An independent statutory regulator sponsored by the Department of Health

Satellite Licences



HTA
Human Tissue Authority

Licensing Number	**12534**
Licence Holder	**Newcastle University**
Licensed Premises	**Newcastle University** **Institute of Genetic Medicine** **International Centre for Life** **Newcastle Upon Tyne** **NE1 3BZ**
Designated Individual	**Dr Christopher Miles Morris**

This licence is granted under Section 16 (2) (e) (ii) of the Human Tissue Act 2004.

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Director of Regulation

Valid From **13 January 2016**

An independent statutory regulator sponsored by the Department of Health

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Newcastle University

HTA Human Tissue Authority

Licensing Number	**12534**
Licence Holder	**Newcastle University**
Licensed Premises	**Newcastle University** **Institute of Neuroscience, Edwardson Building** **Campus of Ageing and Vitality** **Westgate Road** **Newcastle Upon Tyne** **NE4 5PL**
Designated Individual	**Dr Christopher Miles Morris**

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
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Chair

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Sarah Bedwell
Director of Regulation

Valid From **13 January 2016**

An independent statutory regulator sponsored by the Department of Health

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Newcastle University

HTA Human Tissue Authority

Licensing Number	**12534**
Licence Holder	**Newcastle University**
Licensed Premises	**Freeman Hospital** **Institute of Transplantation and Northern Centre for Cancer Care** **Freeman Road** **High Heaton** **Newcastle Upon Tyne** **NE7 7DN**
Designated Individual	**Dr Christopher Morris**

This licence is granted under Section 16 (2) (e) (ii) of the Human Tissue Act 2004.

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.....
Bill Horne
Chair

.....
Nicolette Harrison
Director of Regulatory Delivery

Valid From **14 March 2019**