NEWCASTLE UPON TYNE HOSPITALS
HUMAN TISSUE QUALITY MANUAL (RESEARCH)

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

NJRO-TISS-POL-005

Prologue

At The Newcastle upon Tyne Hospitals NHS Foundation Trust, we undertake fundamental translational research in a diverse range of disease areas, to develop innovative new tests, treatments 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 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 at Newcastle Hospitals 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 Newcastle upon Tyne Hospitals 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 Conrad Maxwell Robinson
Designated Individual, Newcastle upon Tyne Hospitals Research Sector Human Tissue Authority licence (Licence no. 12193).

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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 (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.

To enable Newcastle Hospitals to store human tissue on its premises for future research purposes, Newcastle Hospitals holds a Research Licence under the Human Tissue Act (Licence no. 12193). 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 Hospitals 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, Newcastle Hospitals requires that all researchers storing and using 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 are 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 Hospitals to ensure compliance with regulatory requirements and the licensing obligations of the Human Tissue Authority.
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 Newcastle Hospitals reputation in ensuring the highest quality and ethical standards to ensure public confidence in the ethics of scientific research.
e) Demonstrate Newcastle Hospitals 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 Hospitals Research Sector Human Tissue Authority 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 Hospitals 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 Hospitals premises.

3. SCOPE

This Quality Manual applies to all individuals involved in human tissue research on Newcastle Hospitals 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 Newcastle Hospitals Human Tissue Authority Research Licence (Licence no. 12193) and relevant material which is currently in use in research projects, which have been given 'favourable ethical opinion' from an NHS Research Ethics Committee.

It should be noted that this manual relates only to the Research Sector Licence held by Newcastle Hospitals, and not to any other sectors, or organisations. For information related to other Human Tissue Authority licences held in Newcastle please refer to NJRO-TISS-T-030 on the Newcastle Joint Research Office Website.

4. ROLES AND RESPONSIBILITES

4.1. Principal Investigator (PI)

It is the responsibility of all Principal Investigators (PIs) at Newcastle Hospitals to ensure that they have the appropriate approvals, permissions and consent in place to collect and use human tissue for research purposes. Approvals for research studies are obtained from the NHS Health Research Authority (www.hra.nhs.uk).

NHS Health Research Authority (HRA) approval brings together the HRA assessment of governance and legal compliance with the independent ethical opinion by an NHS Research Ethics Committee (REC). HRA approval is for all project-based research involving the NHS and Health and Social Care that is being led from England. Only human tissue which is stored with current HRA approval is exempt from requiring storage under the Human Tissue Act regulations.

PIs are responsible for ensuring that any human tissue 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 Human Tissue Authority licence when it is not part of a current NHS REC approved research study, for example, samples remaining at the end of a clinical trial/NHS REC approved project. Note: Relevant material collected under non-NHS REC approval (e.g. University REC approval, or imported material) must be stored under an HTA Licence.

For information on approved storage locations under Newcastle Hospitals Human Tissue Authority licence, see Section 5.

For samples collected under an NHS REC approved project, it is the responsibly of the PI to ensure that when the approval expires, any remaining samples are appropriately managed. i.e.

- The project specific ethical approval is extended to cover further research.
- The remaining samples are transferred to an NHS REC approved Research Tissue Bank.
- The remaining samples are transferred to an approved storage location under the Human Tissue Act (with the approval of the Designated Individual).
- Samples are transferred away from Newcastle Hospitals premises under appropriate material transfer agreements.
- 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 NHS 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 NHS REC approved Research Tissue Bank CIs under the Newcastle Hospitals Research Licence is provided in NJRO-TISS-T-034

4.3. Clinical Board and Department Responsibilities

Clinical Board and Departments receiving human tissue samples (e.g. for analysis) must ensure due diligence, by ensuring that the PI provides details of the NHS Research Ethics Committee approval when they bring tissue along for analysis. Where tissue is to be stored long-term, managers must ensure that the end date of the ethical approval is known, and donor consent allows this activity, in order to facilitate identification of when samples must be transferred for storage under the Human Tissue Act regulations.

4.4. Human Tissue Authority Licence Roles

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

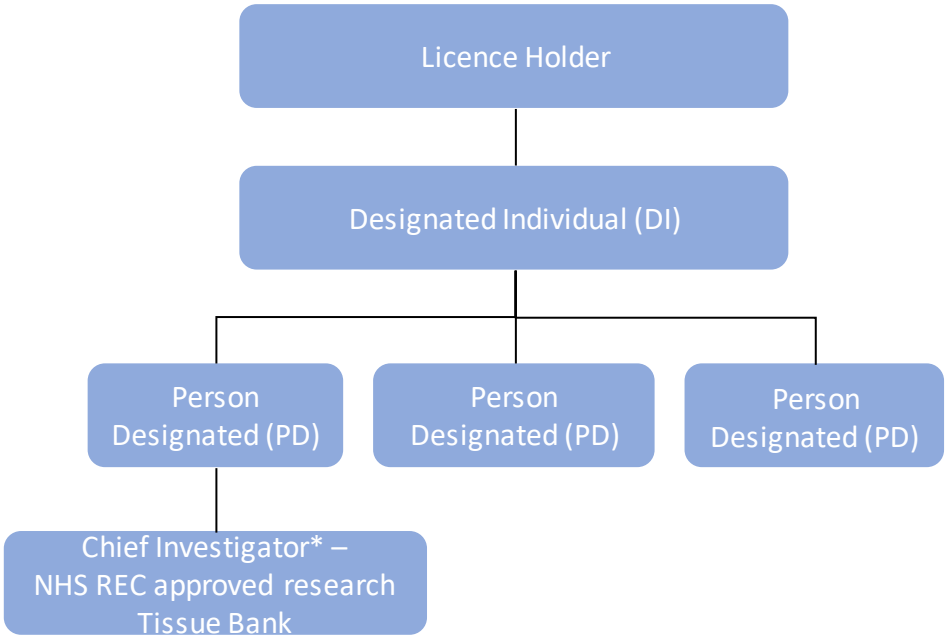
- A Licence Holder (see role description NJRO-TISS-T-017)
- Designated Individual (see role description NJRO-TISS-T-018).
- Persons Designated (see role description NJRO-TISS-T-019).

The names and contact details of the Licence Holder and Designated Individual named on the Newcastle Hospitals Research Sector Human Tissue Authority licence (Licence no. 12193) are provided below.

Licence Holder:	Dr Michael Wright Medical Director The Newcastle upon Tyne Hospitals NHS Foundation Trust Freeman Hospital Freeman Road High Heaton Newcastle upon Tyne NE7 7DN Tel: 0191 213 7222 Email: michael.wright19@nhs.net
Designated Individual:	Dr Conrad Maxwell Robinson Consultant Cellular Pathologist Cellular Pathology New Victoria Wing Royal Victoria Infirmary

	Queen Victoria Road Newcastle upon Tyne NE1 4LP Tel: 0191 282 9807 Email: max.robinson@nhs.net
Persons Designated	As Newcastle Hospitals are spread over a large site, the Designated Individual has gained the valuable support of a number of Persons Designated (PDs) to oversee compliance with the Act in their local area. All PDs 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 Newcastle Joint Research Office 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 PDs named on the Newcastle Hospitals licence is held in the Human Tissue Master File NJRO-TISS-T-036. This list is provided to the Human Tissue Authority, and any changes communicated as they arise.

An organogram of Human Tissue Authority licence roles is provided in Figure 1.



* Research Tissue Bank Chief Investigators are approved by Research Ethics Committees, which are distinct from the Human Tissue Authority

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 Newcastle Hospitals Human Tissue Authority 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 Newcastle Hospitals Human Tissue Authority Research Licence, the Designated Individual must be aware of all relevant material stored at Newcastle Hospitals. 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 Newcastle Hospitals have a responsibility to disclose this material to the Designated Individual.

5. STORING HUMAN TISSUE

5.1. Newcastle Hospitals Human Tissue Authority Research Licence

Newcastle Hospitals has adopted the 'hub and satellite' model of licensing under the Human Tissue Authority licensing framework. The Royal Victoria Infirmary is considered to be the 'hub' with Freeman Hospital, Balliol Offsite Storage Facility and North East Innovation Lab operating as geographically remote satellite sites. The details of these licensed premises are provided below. A copy of the Human Tissue Authority licence for each premises is provided in **Appendix 1.** A copy of the Human Tissue Authority licence for each premise is displayed at each location.

- **Hub Site:**

  Licence holder: Dr Michael Wright
  Royal Victoria Infirmary
  Queen Victoria Rd
  Newcastle upon Tyne
  NE1 4LP

  Correspondence to: Max Robinson
  Tel: 0191 282 9807

- **Satellite Premises:**

  Freeman Hospital
  Freeman Road
  High Heaton
  Newcastle upon Tyne
  NE7 7DN

  Balliol Storage Unit 2004/16
  Balliol Business Park
  Benton Lane
  Newcastle upon Tyne
  NE12 8EW

North East Innovation Lab
The Biosphere
Draymans Way
Newcastle Helix
Newcastle upon Tyne
NE4 5BX

Correspondence to: Max Robinson
Tel: 0191 282 9807

5.2. Approved storage locations

Relevant material requiring storage on Newcastle Hospitals premises under the Human Tissue Authority licence may only be stored at approved locations within the hub and satellite sites. These locations must be approved by the Designated Individual and are audited by the Newcastle Joint Research Office 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 Hospitals Human Tissue Authority Licence Organogram (Appendix 3; NJRO-TISS-T-035.)

5.3. Activities covered by the licence

The licensed activity named on the Newcastle Hospitals Human Tissue Authority Research Licence (Licence no. 12193) 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 Hospitals, NHS 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.

Any researcher who wishes to store tissue for a purpose not listed above must contact the Designated Individual for advice.

5.4. Sample tracking

The retrieval and tracking of relevant material for the purposes of research is specific to the approved storage locations, see Newcastle Hospitals Human Tissue Authority Licence Organogram NJRO-TISS-T-035. Approved storage locations currently track samples using password protected spreadsheets (Microsoft Excel, USA) and proprietary biorepository management systems (SLIMS, Agilent Technologies, Inc. USA). Newcastle Hospitals are currently in the process of procuring a new Laboratory Information Management System from CERNER (USA) with auditable sample tracking capabilities that will enhance the tracking of samples across the storage locations and their release for research.

Transfer of relevant material between Newcastle Hospitals and Newcastle University is managed under a Service Level Agreement (NJRO-TISS-SOP-001) and tracked using the Service Level Agreement (SLA) Monitoring Form NJRO-TISS-T-001.

6. THE QUALITY MANAGEMENT SYSTEM

To promote high quality standards for human tissue research at Newcastle Hospitals, a tiered Quality Management System 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 and NHS Health Research Authority (i.e. research ethics).
- Institutional policies and procedures must be followed by all Newcastle Hospitals staff.
- Any staff involved in storage and/or use of human tissue in research must also follow the Newcastle Joint Research Office 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 Quality Management System is provided below.

Figure 2. Newcastle Hospitals Quality Management System.

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 NHS Health Research Authority and associated Research Ethics Committees.

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

The Human Tissue Authority 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 Human Tissue Authority 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 Human Tissue Authority regulates. The codes are designed to support professionals by giving advice and guidance based on real-life experience.

There are currently seven Codes of Practice:

Code A	Guiding principles and the fundamental principle 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
Code G	Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation

These codes have been written to reflect the following principles:

- **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.

The codes can be found on the Human Tissue Authority website at the following address alongside an additional document, including the standards against each code and guidance: https://www.hta.gov.uk/

6.2. Institutional Policies and Procedures

It is the responsibility of all staff to ensure they comply with Newcastle Hospitals Institutional policies and procedures e.g. Health and Safety Operational Policy, Network Security & Access Control Policy etc. These should be identified as part of the staff induction and training procedure.

6.3. Newcastle Joint Research Office Policies and Procedures

The Newcastle Joint Research Office has adopted a Quality Management System to support research in Newcastle. These documents are either institution specific (Newcastle Hospitals or Newcastle University) or apply jointly to both organisations. This is captured in the scope of each document.

- All documentation can be accessed via the Newcastle Joint Research Office Q-Pulse system and the Newcastle Joint Research Office Website https://newcastlejro.com/
- The Quality Management System 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 Newcastle Joint Research Office 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 which may be accessed by Newcastle Hospitals staff. Access to the training can be requested by contacting HumanTissueResearch@ncl.ac.uk

Persons Designated are advised to keep up-to-date with the latest news from the HTA, by subscribing to the e-newsletter. The newsletter is an important source of information providing updates, important guidance and resources plus details of future HTA events.

The HTA has a set of online test questions on governing legislation, which may be a helpful learning tool for both new and existing staff. The tests are non-compulsory, anonymous and you can find the links to each test on The HTA website here: test your knowledge.

The HTA also offer a number of ELearning modules. Modules are available on the Health Research Authority's learning management platform, including:

- How to ethically review a Research Tissue Bank
    - a guide for Research Ethics Committee (REC) members and is predominantly designed to support REC members with the ethical review of research tissue bank (RTB) applications. However, the module may also be of interest to researchers preparing to submit applications.
- Research Tissue Banks – An introduction
    - designed to help REC members, Research and Development staff, RTB managers, Designated Individuals and other staff be aware of the structure of RTBs, the regulations and ethics behind them
- Research Involving Human Tissue

The Medical Research Council Regulatory Support Centre has e-Learning resources to support HTA compliance. The platform requires registration to access the courses and assessments.

- Research and human tissue legislation
- Research and human tissue legislation assessment – England, Wales & Northern Ireland

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

The Designated Individual (or a delegate) is available for advice and guidance at any time. Persons Designated meetings, chaired by the Designated Individual (or a delegate), will be used to communicate key information, report incidents and share good practice.

It is the responsibility of the Persons Designated to communicate any Human Tissue Act related information to staff operating in their area. Persons Designated should attend Persons Designated meetings wherever possible and send a delegate in their place if they are unable to attend.

Monthly 'Clinical Research Directorate Newsletters' are distributed amongst all teams operating under the licence.

Further information can be found on the Newcastle Joint Research Office website https://newcastlejro.com/

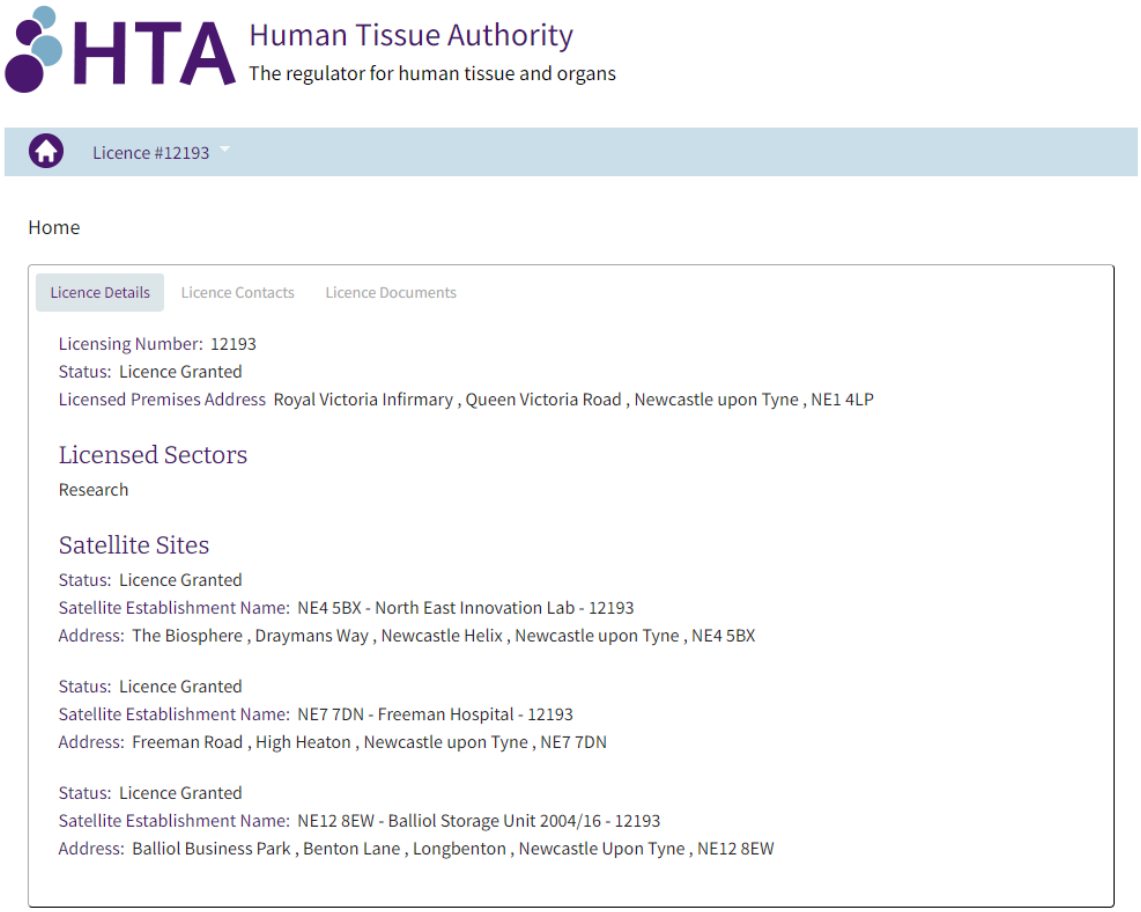
9. GOVERNANCE

Governance of the acquisition, storage, use and disposal of human tissue at Newcastle Hospitals under the Human Tissue Act (2004) is overseen by the Designated Individual, supported by the Newcastle Joint Research Office Quality Management team. Audits will be conducted in accordance with NJRO-TISS-SOP-004 with appropriate Corrective Preventive Action (CAPAs) to address any findings.

In the absence of the Designated Individual, a Person Designated will be delegated to represent the Designated Individual.

Where required, issues will be escalated to the Licence Holder and the Head of the Newcastle Joint Research Office for resolution.

Appendix 1 – Human Tissue Licence Details



HTA Human Tissue Authority
The regulator for human tissue and organs

Licence #12193

Home

Licence Details | Licence Contacts | Licence Documents

Licensing Number: 12193
Status: Licence Granted
Licensed Premises Address Royal Victoria Infirmary , Queen Victoria Road , Newcastle upon Tyne , NE1 4LP

Licensed Sectors

Research

Satellite Sites

Status: Licence Granted
Satellite Establishment Name: NE4 5BX - North East Innovation Lab - 12193
Address: The Biosphere , Draymans Way , Newcastle Helix , Newcastle upon Tyne , NE4 5BX

Status: Licence Granted
Satellite Establishment Name: NE7 7DN - Freeman Hospital - 12193
Address: Freeman Road , High Heaton , Newcastle upon Tyne , NE7 7DN

Status: Licence Granted
Satellite Establishment Name: NE12 8EW - Balliol Storage Unit 2004/16 - 12193
Address: Balliol Business Park , Benton Lane , Longbenton , Newcastle Upon Tyne , NE12 8EW

Hub Licence – Royal Victoria Infirmary

Licensing Number	**12193**
Licence Holder	**Newcastle upon Tyne Hospitals NHS Foundation Trust**
Licensed Premises	**Newcastle upon Tyne Hospitals NHS Foundation Trust** **Royal Victoria Infirmary** **Queen Victoria Road** **Newcastle upon Tyne** **NE1 4LP**
Designated Individual	**Dr Conrad Maxwell Robinson**

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.

.....
Lynne Berry OBE
Chair

.....
Nicolette Harrison
Director of Regulatory Delivery

Valid From **6 April 2020**

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Newcastle University

Satellite Licence 1 – Freeman Hospital

HTA Human Tissue Authority

Licensing Number	**12193**
Licence Holder	**Newcastle upon Tyne Hospitals NHS Foundation Trust**
Licensed Premises	**Freeman Hospital** **Freeman Road** **High Heaton** **Newcastle upon Tyne** **NE7 7DN**
Designated Individual	**Dr Conrad Maxwell Robinson**

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.....
Lynne Berry OBE
Chair

.....
Nicolette Harrison
Director of Regulatory Delivery

Valid From **6 April 2020**

Satellite Licence 2 – Balliol Storage Unit 2004/16

Licensing Number	**12193**
Licence Holder	**Newcastle upon Tyne Hospitals NHS Foundation Trust**
Licensed Premises	**Balliol Storage Unit 2004/16** **Balliol Business Park** **Benton Lane** **Longbenton** **Newcastle Upon Tyne** **NE12 8EW**
Designated Individual	**Dr Conrad Maxwell Robinson**

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

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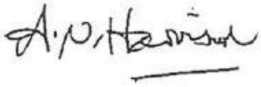
Lynne Berry CBE
Chair



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Nicolette Harrison
Director of Regulation

Valid from: 29 December 2020

Satellite Licence 3 – North East Innovation Lab

HTA Human Tissue Authority

Licensing Number **12193**

Licence Holder **Newcastle upon Tyne Hospitals NHS Foundation Trust**

Licensed Premises **North East Innovation Lab**
The Biosphere
Draymans Way
Newcastle Helix
Newcastle upon Tyne
NE4 5BX

Designated Individual **Dr Conrad Maxwell Robinson**

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

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.....
Lynne Berry CBE
Chair

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Nicolette Harrison
Director of Regulation

Valid from: 11 November 2022

Appendix 2 – Newcastle Hospitals Licence Contacts

NJRO-TISS-T-036

Appendix 3 – Newcastle Hospitals Human Tissue Authority Licence Organogram

NJRO-TISS-T-035

Appendix 4– Newcastle Hospitals NRES REC Approved Research Tissue Banks

NJRO-TISS-T-034