****

**QUALITY DOCUMENT ON THE USE AND STORAGE OF HUMAN TISSUE FOR RESEARCH AND EDUCATION AT BANGOR UNIVERSITY (Licence 12546)**

|  |  |  |
| --- | --- | --- |
| **Date** | **Purpose of Issue/Description of Change** | **Equality Impact Assessment Completed** |
| 30th September 2022 | Initial Issue – Under Review |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Manual Author** | **Senior Responsible Officer** | **Approved By** | **Date** |
| HTA Licence Holder | HTA Designated Individual | HTA Committee | 30th November 2023 |

*This Manual will be reviewed every 3 years*

## 1. Introduction

With a long tradition of academic excellence and a strong focus on the student experience, Bangor University currently hosts around 10,000 students studying a wide variety of subjects in nine Academic Schools. We acknowledge our responsibilities to adhere to all applicable regulatory and licensing standards connected with research and teaching that involves the acquisition, storage, use and disposal of human tissue. Procedures are in place to ensure the University meets the Health and Safety, and Environmental requirements associated with such activities.

This quality document sets out the policy and procedures for managing the acquisition, storage, use and disposal of Human Tissue at Bangor University for research and education purposes. Since the establishment of the Human Tissue Authority (HTA) there have been strict legally binding parameters to follow when storing this material. The Human Tissue Act (HT Act), 2004*[[1]](#footnote-1)* provides a framework for regulating the storage and use of human organs and tissue from the living, and the removal, storage and use of tissue and organs from the deceased, for specific health related purposes and public display.

The document is designed to provide researchers with standards and guidelines in relation to the conduct of high-quality and ethical research involving human tissue. Any activity within the University that involves the use of organs, tissues and cells has to follow strict Standard Conditions. The HT Act makes it an offence to have human tissue, including hair, nail and gametes in this context, with the intention of analysing its DNA without the consent of the individual from whom the tissue came, or of those close to them if they have died.

In order to comply with the HT Act all establishments that have any dealings with human material have to be licensed, with a Designated Individual (DI) identified who takes ultimate responsibility for compliance with the Act.

The DI for the University is Dr Huw Roberts (huw.roberts@bangor.ac.uk), College Manager. The licence holder acting on behalf of Bangor University is Dr Colin Ridyard (mhsa08@bangor.ac.uk)

## 2. Scope

The University has been granted a licence under Section 16 (2) (e) (ii) of the Human Tissue Act 2004 (‘the Act’). The licence authorises the storage of relevant material for the following scheduled purposes:

* 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 University is licensed for Anatomy - license number 12546)

Tissue stored for research purposes is exempt from the licencing requirement if the tissue is:

* Held for a specific NHS Research Ethics Committee-approved research project
* From a person who died over 100 years ago
* Stored pending transfer elsewhere providing it is held for a matter of hours or days and certainly no longer than a week and with approval from the DI or a nominated representative
* Held whilst it is processed with the intention to render the tissue acellular providing the processing takes a matter of hours or days and certainly no longer than a week and with approval from the Research Governance Team
* created outside the human body and which does not involve any application of tissues or cells into humans

## Any activity within the University that involves the use of organs, tissues and cells (including

## saliva, blood etc. which contain cells), must follow strict Standard Conditions and, operate in accordance with Governance Arrangements for Research Ethics Committees (GAfREC)[[2]](#footnote-2). This means researchers must ensure their use of human tissue has been ethically approved through an NHS research ethics committee and the appropriate consent is in place. Researchers wishing to undertake research involving human tissue must consult with the University’s DI prior to the commencement of any research.

## 3. Responsibilities

### a) The University as Licence Holder

As well as maintaining the appropriate Licence from the Human Tissue Authority, the University is responsible for ensuring that correct standard operating procedures (SoPs) are in place for the procurement, storage, use and disposal of relevant human material in accordance with the requirements of the HT Act. Bangor University is responsible for ensuring its staff work in line with HT Act standards and follow the approved Codes of Practice on the HTA website[[3]](#footnote-3). The licence holder acting on behalf of Bangor University is Dr Colin Ridyard (mhsa08@bangor.ac.uk)

### b) Designated Individual (DI)

### As well as providing guidance, the Designated Individual (DI) will be responsible and accountable for compliance with the HT Act and for nominating person designates (PDs) and other staff to the HT Management Committee (see Appendix 1). The DI has the added responsibility to consider and decide on the best solutions and/or courses of action for any HT- related challenges if a solution cannot be found. The DI for the University is Dr Huw Roberts (huw.roberts@bangor.ac.uk), College Manager.

### c) Person Designate (PD)

A Person Designate (PD) is appointed by the DI and acts on their behalf in their local Department or School environment. They are responsible and accountable to the DI for compliance with the HT Act and ensuring all researchers handling HT are suitably trained. PDs are also responsible for assisting in monitoring the storage and use of human material in the departments within their School or College.

### d) Principle Investigator (PI)

For research projects sponsored by Bangor University it is the responsibility of the Principal Investigator (PI) to ensure research staff are adequately trained by the PD, adhere to this policy and report any human tissue-related incidents to the DI. Similarly, for external projects, it is the responsibility of the external Principal Investigator (PI) to consult with the DI to ensure Bangor University research staff are adequately trained by the PD, adhere to this policy and report any human tissue-related incidents.

### e) Researchers

All personnel engaged with HT-related research have a duty to consider how the work they undertake, host or support affects society and the wider research community. Their commitments to the HTA Codes of Practice as set out in this policy will demonstrate to the public, government, funders, third sector, business and international partners that they can continue to have confidence in HT-related research produced in Bangor University and enhance the University’s reputation for high-quality and ethical research.

All staff with responsibility must ensure HTA licensable activity is carried out to the highest standards in accordance with current legislation and national guidance including: HTA Codes of Practice and Standards[[4]](#footnote-4) with particular reference to [Code of Practice A](https://content.hta.gov.uk/sites/default/files/2023-06/Code%20A%20-%20Guiding%20principles%20and%20the%20fundamental%20principle%20of%20consent.pdf): Guiding principles and the Fundamental Principle of Consent and [Code of Practice E](https://content.hta.gov.uk/sites/default/files/2023-06/Code%20E%20-%20Research.pdf): Research Standards and Guidance. So that the required level of HT-related quality assurance is achieved and sustained, Bangor University will establish a University HTA Management Committee which will:

* Control and manage all aspects of HTA Licensable activities.
* Report at least once a year to the University Research Governance and Ethics Committee on HTA Licensable activities.
* Set quality objectives to implement and maintain the system.
* Train the appropriate staff in sufficient numbers and students to ensure they are familiar with the system and the HTA Licensable activities and that this is recorded.
* Undertake internal audits of the system to monitor compliance and maintain a regime of continuous improvement of the system.

## 4. Related Policies

The University’s webpage (Governance Services) list current versions of policies that are relevant to the HT Act. These will be reviewed and revised regularly as part of the University’s report for the Concordat to Support Research Integrity. The Research Integrity Policy does not apply to work routinely done as part of a course module or other coursework. This is covered by the Academic Integrity Procedure.

### a) Research Ethics Policy

Any activity within the University that involves the use of organs, tissues and cells (including

saliva, blood etc. which contain cells), has to follow strict Standard Conditions and, in accordance with GAfREC must have been ethically approved through an NHS research ethics committee. The University Research Ethics Policy can be found on the Governance Services web pages[[5]](#footnote-5).

### b) Public Interest Disclosure (Whistleblowing)

This Policy provides avenues for members of the University to raise serious concerns, disclose information in circumstances which the individual believes shows malpractice (including breaches of the HT Act), and receive feedback on any action taken without fear of adverse repercussions. The University Policy on Public Interest Disclosure (Whistleblowing)[[6]](#footnote-6) can be found on the University web pages.

### c) Research Integrity Policy

This Policy outlines the five key principles of the Concordat to Support Research Integrity which are backed by the major UK research funders. The Policy and the Concordat apply to all University staff and students involved in HT research on behalf of Bangor University and are designed to provide researchers with standards and guidelines in relation to the conduct of high-quality and ethical research. The University Policy on Research Integrity[[7]](#footnote-7) can be found on the University web pages.

## 5. Monitoring and Audit

## 

The University requires all staff and students working with HT to be suitably trained in procurement, handling, use and disposal of HT and maintaining accurate records of HT and to have these available for audit purposes. An annual return of human material will be led by the PDs in order to gain an overall view of the material being stored on University premises and the purpose of the storage of the material. PDs are responsible for assisting in

monitoring the storage and use of human material in the departments within their School or College.

The HTA Management Committee will conduct an unannounced internal audit at least once per year. The frequency of the audit may be increased at the discretion of the Committee (e.g. following a rise in relevant adverse incidents). Non-compliance issues will be brought to the attention of the person responsible, documented, and subject to timely corrective action.

## 6. Management Review

## 

## The HTA Management Committee will review the suitability and effectiveness of the Quality Management System biennially or sooner if deemed necessary by the DI.

## This review will consider the effectiveness of the Quality Management System and whether it is achieving its function of ensuring HTA Licensable activities are being carried out to the highest standards in accordance with HTA guidelines; in particular, it will look at:

* Cases of non-compliance and any recommendations of corrective action.
* Complaints received and if an appropriate response was given.
* Any systemic weaknesses.
* Evaluate possible improvement opportunities.
* Examine the effectiveness of any previous corrective actions.
* Documentation that has reached its review date.
* Whether it fully covers the scope of research within the University.

## 7. Governance Structure

## 

The DI will communicate with the HTA regarding the licence on behalf of the License Holder (Bangor University). During periods of absence, the DI may be deputised by the Licence Holder acting on behalf of Bangor University. The University HTA Management Committee will meet biannually but may be convened by the Chair or DI at any time should the need arise. The University HTA Management Committee reports to the Research Governance and Ethics Committee on research matters and to the Compliance Committee on procedural matters.

## 8. General Provision

## 

Human tissue stored under Bangor University’s HTA licence will be subject to a high level of control at all points, from acquisition through to disposal. Samples will be stored in suitably appropriate facilities to ensure the continued high quality of the sample, provide suitably restricted access to them and ensure they are used in a legitimate way.

* All activities falling under the HTA Licence will adhere to the Guiding principles outlined in [Code of Practice A](https://content.hta.gov.uk/sites/default/files/2023-06/Code%20A%20-%20Guiding%20principles%20and%20the%20fundamental%20principle%20of%20consent.pdf): Guiding principles and the Fundamental Principle of Consent; namely: a) consent; b) dignity; c) quality; and d) honesty and openness.
* Stored human tissue samples will be coded with a unique identifier and no information directly revealing the identity of the participant will be present on the stored sample.
* Human tissue samples will be tracked and traceable from acquisition to complete use, anonymisation or destruction.
* Where identities are provided, for example in gifted samples, access to information linking the code and the participant identity will be controlled.
* Suitably qualified and trained staff will manage the stored samples.
* Non-preserved or non-processed human biological samples and biofluids present a potential biohazard. This risk will be minimised by only using tissue from participants known not to be in high-risk groups (according to the World Health Organisation criteria).
* Unless otherwise regulated by law, the University will classify human tissue samples as gifts, the acquisition, storage, use and disposal of which are conditional and subject to prior consent from the donors.
* HTA licensable human tissue samples under the safekeeping of the University will have a chain of custody to include a record of use. This will provide assurance that they were used according to the informed consent and enable the University to trace the sample (up to the point of use, anonymisation or destruction), should a donor withdraw consent.
* Contingency plans are in place regarding the planned location of storage in the event of facility or appliance failure.
* Material transfer agreements for samples acquired either through collaborative research or commercial arrangement will include safeguards to ensure the sample collection and chain of custody complied with the Human Tissue Act and HTA policies and guidelines.
* The HTA Management Committee will carry out annual risk assessments to review the Quality Management System status with reference to future development and/or changes in research activity and scope within the University (and update the system to reflect such activity).

## 9. Training Provision

## 

The HTA Codes provide practical clarification of the HT Act and HTA Directions and can be downloaded from the HTA website: [HTA Codes, standards and guidance](https://www.hta.gov.uk/guidance-professionals/codes-practice). The Medical Research Council (MRC) have in collaboration with the HTA produced a series of human tissue legislation summaries which can be found at: [MRC guidance for using human samples in research](https://www.ukri.org/councils/mrc/facilities-and-resources/find-an-mrc-facility-or-resource/mrc-regulatory-support-centre/using-human-samples-in-research/). In addition, it is strongly recommended that members of staff and students working with Relevant Material also complete the MRC and HRA e-learning courses on:

1. [MRC e-learning](https://byglearning.com/mrcrsc-lms/course/index.php?categoryid=1)
2. [HRA e-learning](https://www.hra.nhs.uk/planning-and-improving-research/learning/e-learning/)

Legal Services and Compliance can provide tailored training if requested by DI or PDs.

**APPENDIX 1**

**Terms of Reference for the University HTA Management Committee**

The University HTA Management Committee is the main Committee at Bangor

University for the consideration of research governance and ethical issues in relation to the HT Act. The Committee will monitor compliance with legislative requirements by receiving a brief annual report from the DI, each PD, the Head of Anatomy and all PIs involved with HT-related research.

Composition

**Chair:** Bangor University Licence Holder

**Ex**-**officio**:

Chairs of Academic Ethics Committees within the College of Human Sciences

Member of Compliance Committee

Principle Investigators involved with HT-related research

H&S Officer for College

**Appointed**:

Designated Individual

All Person Designates

Head of Anatomy

Technical Representative

**Terms of Reference**

1. Review the status of the Licence on an annual basis prior to renewal to ensure it is fit for purpose and establish any changes needed.
2. Carry out annual risk assessments to review the Quality Management System
3. To establish a general framework of policies and standard operating procedures (SoPs) as required by the Licence and to keep such policies and SoPs updated as necessary, recommending their approval to the Compliance Committee.
4. To receive the reports of the DI and each PD at each meeting and where concerns arise escalate to the Compliance Committee.
5. Seek and elicit guidance and clarification from internal and external experts, as necessary, on matters of compliance with the HT Act.
6. Arrange and oversee all HT-related Internal and External Audit Programme across all licensable sectors and monitor their effectiveness and review and implement any required actions therefrom.
7. Defining the training requirements/monitoring training records/supporting ongoing training of those engaged in work under the HTA Licence.
8. Prepare reports for other University Committees as and when required.

1. <https://www.hta.gov.uk/guidance-professionals/hta-legislation/human-tissue-act-2004> [↑](#footnote-ref-1)
2. <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/governance-arrangement-research-ethics-committees/> [↑](#footnote-ref-2)
3. <https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation/codes-practice> [↑](#footnote-ref-3)
4. <https://www.hta.gov.uk/codes> [↑](#footnote-ref-4)
5. <https://www.bangor.ac.uk/governance-and-compliance/governance.php.en> [↑](#footnote-ref-5)
6. <https://www.bangor.ac.uk/governance-and-compliance/governance.php.en> [↑](#footnote-ref-6)
7. <https://www.bangor.ac.uk/governance-and-compliance/governance.php.en> [↑](#footnote-ref-7)