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**POLICY ON THE USE AND STORAGE OF HUMAN TISSUE FOR RESEARCH AND EDUCATION**

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

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

*This Policy will be reviewed in 3 years*

## 1. Introduction

This document sets out the policy for managing the use and storage 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 and using human tissue. 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 Policy 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)

The Licence Co-Ordinator for the University is Gwenan Hine, Head of Compliance.

## 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), has to 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 Licence Holder acting on behalf of Bangor 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).

### 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.

### 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 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.

## 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. 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[[4]](#footnote-4).

### 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)[[5]](#footnote-5) 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[[6]](#footnote-6) can be found on the University web pages.

## 5. Monitoring and Audit

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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.

**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 Task Group

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. 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 Task Group.
3. To receive the reports of the DI and each PD at each meeting.
4. Seek and elicit guidance and clarification from internal and external experts, as necessary, on matters of compliance with the HT Act.
5. 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.
6. Defining the training requirements/monitoring training records/supporting ongoing training of those engaged in work under the HTA Licence.
7. Report to the Compliance Task Group and provide updates to the Chemical and Biological Sub Committee
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.bangor.ac.uk/governance-and-compliance/governance.php.en> [↑](#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)