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HUMAN TISSUE IN CLINICAL RESEARCH MANAGEMENT PROCEDURE

Introduction and Aim

This document has been developed to support Cardiff and Vale University Health Board (CAVUHB) Research Governance Policy UHB 099. Cardiff and Vale UHB has a Duty of Care to any patient who has donated tissue, blood or other human biological material for research purposes - to ensure that the tissue is treated with respect and is handled in accordance with the appropriate legislation and best practice.

Objectives

The purpose of this document is to detail the University Health Board (CAVUHB) management procedure for Human Tissue in Clinical Research in line with the requirements of the Human Tissue Act. The objective of this procedure is to ensure UHB compliance with the Human Tissue Act 2004 and ethical considerations in relation to research using human tissue. This procedure is an integral part of the CAVUHB's research governance arrangements. This is not a guide covering all aspects of the Human Tissue Act as it relates to research. Researchers working on human tissue are expected to adhere to the legal requirements of the Human Tissue Act and follow best practice on handling, transport and storage and consent as described by the Human Tissue Authority. Detailed guidelines on the regulatory requirements and codes of practice are available from the Human Tissue Authority website at:

https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation

Scope

This procedure applies to all Cardiff and Vale UHB staff, including those with honorary contracts, who are involved in any aspect of human tissue management for the purposes of research or biobanking.

Equality and Health Impact Assessment	An Equality and Health Impact Assessment (EHIA) has been completed and this found there to be no impact
Documents to read alongside this Procedure	Research Governance Policy *UHB 099*
Approved by	Joint Research Governance Group

Accountable Executive or Clinical Board Director	Medical Director
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Disclaimer

If the review date of this document has passed, please ensure that the version you are using is the most up to date either by contacting the document author or the Governance Directorate.

Summary of reviews/amendments

Version Number	Date of Review Approved	Date Published	Summary of Amendments
1	17/07/2019 RGG	17/07/2019	New document to support Research Governance Policy *UHB 099*. On publication the following documents to be withdrawn: • Human Tissue Management Policy UHB 097 • Procedure For Governance & Compliance Audit of Human Tissue For Research Purposes UHB 134 • Procedure for Training in Use of Human Tissue Obtained For Research Purposes UHB 137
2	21/04/2022	06/06/2022	Minor formatting amendments. Updated references to Joint Research Office (JRO). Updated the management arrangements for contacting PIs at the end of study.
3	30/01/2025	07/04/2025	Updated background information and reference to JRO governance oversight of Research Tissue banks
4	16/07/2026	23.07.2026	Updated to align with restructure of CU HTA licensing and oversight arrangements, and to clarify CAVUHB review/approval requirements for research projects and databases involving human tissue.

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1. Background and Context

1.1 The Human Tissue Act (2004)

The full provisions of the Human Tissue Act 2004 (subsequently referred to as the Act) came into force on 1 September 2006, and cover England, Wales and Northern Ireland. The aim of the Act is to provide a legal framework regulating the removal, storage, use and disposal of 'relevant material' from the living and the removal, storage, use and disposal of all tissue from the deceased.

Under Section 53 of the Act 'relevant material' is any material, other than gametes, removed from the body which consists of or includes human cells. HTA references to relevant material specifically do not include:

- embryos created outside the human body
- hair and nails from a living person
- cell lines or other human material created entirely outside the human body
- extracted components that are entirely acellular, such as serum, DNA and RNA

The Human Tissue Authority (HTA) is the governing body set up to regulate activities that come under the Act, and issues licences, carries out inspections of licenced premises and promotes good practice. The HTA expect all persons carrying out activities within the regulatory remit to follow appropriate HTA guidance.

There are four main categories of criminal offences under the Act:

i) Operating without proper consent – by removing, storing or using tissue for scheduled purposes such as research either without explicit consent or for a completely different purpose than the donor agreed to.
ii) Operating without a formal licence appropriate to the nature of the regulated activities
iii) Trafficking or commercial trade in organs for human transplantation
iv) DNA 'Theft'- possessing any human bodily material with the specific intent to undertake non-consensual DNA analysis.

1.2 Defining terminology

The terms 'Research Tissue Bank' (RTB) and 'Biobank' are often used interchangeably in medical research and regulatory oversight. Both describe a structured collection of human biological samples store for future, often unspecified, biomedical research beyond the scope of a single project. RTB is a more formal administrative term used on applications for NHS REC review; biobank is a colloquial and commercial term used widely in scientific literature and public communications. Other related terms are biorepository, bioresource, cell bank, cancer bank and tumour bank.

2. Lawful routes for researchers working with ‘relevant’ human tissue

Biomedical research often requires acquisition and storage of new or existing human tissue samples meeting the definition of ‘relevant’ material. *Cardiff & Vale UHB does not hold a HTA research licence for this purpose.* In order to lawfully obtain and store relevant material for research purposes, researchers must either obtain approvals for the specific research project they are undertaking, or access samples via a licenced research tissue bank.

2.1. Storage for a specific REC-approved project without HTA licencing

Relevant material can be obtained, stored and used for research purposes without a HTA licence where there is project-specific favourable opinion from an NHS REC and all conditions of that ethical opinion are met. Storage is limited to the duration of the REC favourable opinion for the project and is for the specific purpose only, as opposed to building a general repository. At the end of the project any remaining tissue samples still considered ‘relevant’ under the Act must be disposed of, or where consent allows, transferred to an approved RTB or used immediately in another ethically approved study.

2.2. Sample storage and access under a HTA licence covering biobanking activities

Storing new samples: Tissue is collected in NHS settings (with consent or a valid legal exemption) and transferred to a licenced RTB as part of a new or existing prospective collection. Samples may then be stored long-term for future unspecified research purposes in multiple projects.

Accessing stored samples: Researchers may apply to a RTB for access to samples for use under the terms of the RTB’s generic REC approval or for use in a specific REC-approved project. The receiving researcher must work within the scope of their stated project, and at the end of the project any remaining samples must be returned to the RTB or disposed of appropriately, as per prior agreement.

2.3 Operational exemptions

Certain activities do not qualify as ‘storage’ requiring a licence:

- Temporary holdings incidental to transportation, up to a maximum of seven days,
- Holdings prior to processing to render material acellular (e.g. DNA extraction). Once acellular, the samples are no longer relevant material. Such processing must be completed within a maximum of seven days.

Consent exemptions: Consent for the use of tissue from living patients is not legally required if the researcher cannot identify the donor and the project has NHS REC approval. This may, for example, cover secondary use of surplus non-identifiable clinical samples.

3. Governance requirements

Any researcher wishing to use human tissue samples in connection with research should contact Cardiff Joint Research Office (JRO) to discuss specific governance requirements for the proposed work.

3.1 Specific research projects involving human tissue samples derived directly from Cardiff & Vale UHB participants

All research projects involving Cardiff and Vale UHB patients or staff or their samples or data require an assessment of capacity and capability within Cardiff JRO. Where projects involve the use of human tissue samples, this process will include R&D review of documented evidence relating to:

- Favourable opinion from an NHS REC and HRA/HCRW approval
- The type and quantity of tissue samples required
- The process of obtaining consent for collecting and using tissue samples
- The process for collecting, transporting and storing samples
- A description of what will happen to any remaining tissue samples at the end of the project
- A Material Transfer Agreement (MTA) or other appropriate incoming/outgoing agreement if samples are to be transferred between the UHB and another organisation

The JRO will routinely identify and contact all Lead Investigators within the UHB using human tissue samples as part of a REC-approved research project, to remind them of their obligations at the end of the project, and ensure that once the study has been completed, any remaining samples are disposed of appropriately. Alternatively, where consent allows, they may be transferred to an approved RTB or used immediately in another ethically approved study.

3.2 Direct donation of samples to an approved Research Tissue Bank

A Tissue Collection Centre (TCC) is a collaborative site (typically a hospital or other healthcare provider) that procures human biological samples, with or without accompanying patient data, on behalf of an RTB. TCCs operate under strict legal criteria but do not need to apply for their own individual ethical approval or HTA storage licence providing collected tissue is only held ‘incidental to transportation’ and leaves the organisation within seven days. TCCs are not a research site under UK Policy Framework for Health and Social Care Research.

Cardiff and Vale UHB may be asked to act as a TCC, obtaining samples from consenting patients for supply to a licenced RTB/biobanking facility for long-term storage and use in future research. Activities required in the UHB may include obtaining consent from patients, collecting/processing/packaging samples and logging anonymised clinical data to add scientific value to the samples.

Formal confirmation of capacity and capability is not required, but host management review should be completed, Senior Management authorisation should be obtained, and a designated JRO/R&D signatory should approve the contract. The governance

review process for requests to act as a TCC is documented in WI-001-06 ‘Processing Applications for CVUHB to act as a data or tissue collection centre’.

4. Oversight of Cardiff and Vale UHB human tissue samples for research use

4.1. Principles of NHS oversight

Cardiff and Vale UHB oversight of research using UHB-derived samples should be proportionate, risk-based and focused on areas where the NHS retains a clear duty of care or governance interest. Patient-facing activities (such as recruitment, consent and sample collection) must be undertaken by suitably trained staff and compatible with patient care and clinical safety.

The UHB should have assurance that contractual and governance arrangements clearly set out roles and responsibilities, including for sample custody, data controllership, data linkage, release decisions and onward sharing. Legal, regulatory, reputational and operational risks arising from the use of UHB-derived samples must be identified, reviewed and appropriately managed.

The UHB should receive proportionate ongoing assurance while avoiding duplication of HTA, REC or host institution oversight processes, and it should not be necessary to duplicate inspections/audits or have an active role in operational management of RTBs unless invited to do so.

4.2. External assurance from the HTA and NHS RECs

a) HTA licencing - covers storage, handling, traceability, governance, audit, premises and quality systems. A HTA licence is mandatory for any RTB in England, Wales or Northern Ireland which stores relevant material (RTBs physically based in Scotland and/or storing only acellular material such as DNA are exempt).

b) NHS Research Ethics Committee (REC) review for specific research projects provides independent ethical assurance that human tissue is obtained with valid consent and is used, stored, and disposed of in a way that is lawful, proportionate, and aligned with participant expectations within the defined study.

REC favourable opinion for research tissue banks is on a voluntary basis, but where sought must be from a recognised committee, as defined by the HTA in Paragraph 53 of Code of Practice 9: Research, and cannot be replaced by approval from a university research ethics committee. REC review covers the RTB overarching consent model, governance framework, and access arrangements, enabling human tissue to be stored and reused ethically for future research within defined parameters. Although not mandatory, REC opinion for a RTB confers the significant advantage that it also covers researchers sourcing samples from the RTB at a later stage; there is no requirement to apply for independent project-specific REC approval or a separate HTA licence to store samples for the duration of their project.

4.3. Host organisation assurance for RTBs

Cardiff University (CU) is the UHB's partner organisation in Cardiff JRO, and direct donations of UHB patient samples for biobanking are most often made to Cardiff University hosted RTBs. However, equivalent standards and assurance would be expected from any RTBs hosted by any external organisations.

There are four biobanks hosted under Cardiff University's Biobank and Facility Licence (no. 12422):

- Cardiff University Biobank (CUB)
- South Wales Initiative for Fetal Tissue
- Wales Kidney Research Tissue Bank
- Welsh Neuroscience Research Tissue Bank

In addition, the University hosts the Wales Cancer Bank (licence no. 12107).

It is not anticipated that any further RTBs will be established in Cardiff University as all new collections will be held under Cardiff University Biobank. Cardiff University appoints a Corporate Licence Holder who chairs the Human Tissue Standards Committee, and a Designated Individual responsible for each licence.

Assurance is provided via Cardiff University's Human Tissue Services and HTA Quality Management System, which ensures compliance with the Act and related Codes of Practice via the Code of Practice and Standard Operating Procedures for Human Tissue Research, Biobanking SOP and Biobank and Facility Quality Manual for Human Tissue. Each RTB has a Biobank Manager, as named on the ethical application, who retains overall responsibility for regulatory compliance.

The Biobank and Facility Licence Governance Group, which reports to Human Tissue Standards Committee, includes membership from Cardiff & Vale UHB R&D Office in its Terms of Reference. In addition, when CUB receive applications to access collections which include samples from the UHB, an appropriate UHB stakeholder (normally the clinicians who collected the samples) is always included in the process of project review and approval.

5. Summary of requirements for RTBs receiving direct sample donations from Cardiff and Vale UHB

Governance requirements for specific research projects taking place in the UHB are described in detail in UHB457 Research Governance SOP and UHB448 Obtaining capacity and capability confirmation for research to start.

The following requirements apply equally to all RTBs receiving direct sample donations from Cardiff & Vale UHB, whether hosted by CU or other externally organisations.

5.1 Prior to commencement of sample collection

- Submit all project documentation for JRO review, to include protocol, consent documents and evidence of favourable REC opinion
- Identify a Local Collaborator within the UHB who is willing and able to undertake the required activities, and supported by their Directorate to do so
- Provide an appropriate MTA or other formal contracting arrangement for outgoing samples for signing by an appropriate UHB signatory.

5.2 Amendments (including new prospective collections under CUB)

- Consider early (pre-submission) feasibility discussion with the JRO where the proposed changes impact on NHS activities, risk or resource requirements
- Submit all amendment documentation prior to implementation in Cardiff and Vale UHB, and in parallel to submission to NHS REC for RTBs hosted by Cardiff University
- RTB should confirm if / how the amendment impacts on TCC activities and contracting arrangements
- Evidence of REC favourable opinion for the amendment must be provided where this is required

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5.3 Renewal of REC approval

- **REC favourable opinion of an RTB must be renewed every five years. It is important that ethical approval does not lapse in order to maintain lawful compliance with the Human Tissue Act.**

- As per the process for amendments, the TCC should be provided with the renewal application and supporting documents and advised of any impact on their role in obtaining and supplying samples and data. Early consultation with the JRO prior to REC submission is welcomed.

5.4 Annual Reporting

Reporting to Cardiff and Vale UHB by RTBs receiving samples should make pragmatic use of any pre-existing reports which the RTB prepares for their host organisation or other purposes and take place no less frequently than once a year.

Mandatory minimum data to be submitted:

- Number of Cardiff and Vale UHB patients consented, and types of samples received
- Confirmation of ongoing governance compliance for both the RTB and projects receiving samples
- A report of any complaints received
- A report of any consent withdrawals relating to Cardiff and Vale UHB
- A report of any governance/data breaches, and audit findings or inspection shortfalls and related CAPA plans.

Where available, the following optional information is also desirable:

- Broad types of projects approved for support / sample release (e.g. disease areas, commercial vs academic use, UK vs international use etc)
- Volume of activity supported by the RTB – number of studies supported and number of samples released
- Publications, impacts and other outputs
- Any forward planning information the RTB wishes to share

It is recognised that RTBs hosted by Cardiff University may report some of this information via the Biobank and Facilities Licence Governance Group.