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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 (UHB) 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 material for research purposes to ensure that the tissue is treated with respect and is handled in accordance with the appropriate national legislation and good practice. This procedure has been produced to provide instruction to any individual(s) who has responsibility for human tissue, which has been donated for research purposes, and to any researcher who wishes to gain access to such samples.

Relevant material from a human body according to the Human Tissue Act 2004 is defined as: material which consists of, or includes, human cells. It does not include gametes, embryos outside the human body, or hair and nails from the body of a living person. For the purposes of this procedure relevant material will be referred to as "human tissue".

Objectives

The purpose of this document is to detail the University Health Board (UHB) management procedure for Human Tissue in Clinical Research in line with the requirements of the Human Tissue Authority (HTA).

The objective of this procedure is to ensure the University Health Board (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 UHB'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 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/hta-codes-practice-and-standards-0>

Scope

This procedure applies to all of our staff in all locations including those with honorary contracts.

Equality and Health Impact Assessment

An Equality and Health Impact Assessment (EHIA) has been completed and this found there to be no impact

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| Documents to read alongside this Procedure | Research Governance Policy <i>UHB 099</i> |
| Approved by | Joint Research Governance Group |

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| Accountable Executive or Clinical Board Director | Medical Director |
| Author(s) | Governance Officer HTA – Research |

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 <i>UHB 099</i> . On publication the following documents to be withdrawn: <ul style="list-style-type: none"> • 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 |

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Background

Historically, Cardiff University (CU) has been the holder of the **Human Tissue Authority (HTA)** Licence for all research undertaken on the Heath Park site and Cardiff and Vale University Health Board (CAVUHB) had jointly administered and regulated the activities arising from the Licence. Since CVUHB came off the HTA Licence 9 years ago, there has been a separate process for any CVUHB researchers wanting to store material under the CU HTA Licence; to date, no one has requested access. CU are undergoing a licence restructure, and as such access via this route will no longer be possible and material can only be transferred to a biobank (which has always been an option).

Cardiff University has its' own procedures for the use of human tissue in research, any CVUHB researchers working under CU sponsored studies should refer to the CU HTA Code of Practice and SOPs for Human Tissue Research.

This procedure reflects the current status in relation to tissue held by CAVUHB and outlines responsibilities and actions to be undertaken. This procedure is underpinned by the Research Governance Policy UHB 099.

Human Tissue Act 2004

The Human Tissue Act 2004 covers England, Wales and Northern Ireland. The Act established the Human Tissue Authority (HTA) to regulate activities concerning the removal, storage, use and disposal of human tissue for research, medical treatment, post-mortem examination, education and training, and displays in public, along with giving approval for organ and bone marrow donations from living people. The HTA issues licenses for the storage and use of human tissue, carries out inspections on licensed premises and promotes good practice on all aspects of the handling, use, storage and disposal of human tissue. The Human Tissue Act 2004 made it an offence to store human tissue without a licence and/or recognised Research Ethics Committee approval.

'Relevant Material' under the Act, is any material, other than gametes, removed from the body that consists of or includes human cells. In the Human Tissue Act references to relevant material from a human body do **not** include:

- embryos outside the human body,
- hair and nail from the body of a living person,
- cell lines or any other human material created outside the human body,
- serum, plasma, DNA and RNA.

A list of relevant material can be found in Appendix 1 and Appendix 2 has information on DNA Theft.

Storage of Relevant Material by the UHB

A licence is required to store relevant human material, unless you have ethical approval from an NHS Research Ethics Committee (REC) for a specific research project. A licence is required where tissue is being stored for distribution to other researchers and where tissue samples are imported from outside England, Wales and Northern Ireland.

The UHB does not currently hold a HTA Licence. Whilst Cardiff University holds an HTA Research Licence, this is for the sole use of the biobanks hosted by Cardiff

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University; no active research or stored material is permitted under the HTA Licence. Therefore, no researcher can store relevant material unless one of the following exemptions apply:

- A research project using relevant material that has been approved by a recognised research ethics committee (e.g. REC) The relevant material may be stored without a licence for the duration of the project and at the end of the project, the relevant material must either be destroyed or stored on licensed premises. A university ethics committee is not considered to be a recognised research ethics committee for this purpose
- A research project using tissue provided by a REC-approved bank which has generic ethical approval. The recipients do not need to store relevant material under a HTA licence during the period of the research project. On completion of the project, the researcher must return tissue to the bank or destroy it, or the researcher could apply to the RTB for approval for use the tissue in another study.
- Where relevant material is being held with the intention of processing to render the material acellular (e.g. extracted DNA or protein lysates) prior to research. Tissue may be stored without a licence providing that the processing takes a matter of hours or days and certainly no longer than a week.
- The licensing requirements for storage do not include storage which is incidental to transportation. This means that the storage of material while it is being conveyed from one place to another does not need to be licensed. This would normally be a matter of hours or days and no longer than a week. Directorates that supply tissue to research tissue banks will need to be assured that this is satisfied

Acquisition and Importation of New Relevant Material at the UHB

New human tissue samples may be acquired as part of an NHS REC- approved project or from a REC-approved Research Tissue Bank. If a Chief Investigator or a Principal Investigator (PI) is a collaborator on a project using human tissue being led by another institution and for which the UHB is not a sponsor, it is essential that they are aware of the content of any ethics application submitted to an external REC. They have a number of responsibilities:

- ensuring that ethical approval remains in place for the duration of the project
- ensuring that Material Transfer Agreements (MTA) are in place for any incoming/ outgoing tissue transfers
- maintaining relevant and good quality records
- drafting and updating risk assessments
- adverse event reporting
- implementing recommendations made following an internal audit or HTA inspections
- advising the R&D Office when ethical approval of the study ends and confirming that samples have been destroyed or transferred to an organisation that holds a HTA licence.

Research Governance Section of the Research and Development Office

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The Joint Research Office (JRO) has a Research Governance Team that serves the University Health Board (UHB) research community. The team aims to advise on the UK Policy Framework for Health and Social Care Research and the conduct of clinical research, as well as provide an effective research governance environment for researchers. In relation to the Human Tissue Act, the Governance Officer Human Tissue Act – Research, a post holder within the team, supports them.

A research project will require confirmation of capacity and capability from the JRO if the research involves the use of any UHB resource, it's patients, staff, their data, tissue or organs. All projects are reviewed by the JRO prior to confirming capacity and capability. If a project involves the use of tissue samples the review process required will expect to see documented evidence of:

- What tissue samples are required and the quantity.
- What process is to be employed to gain access to the samples.
- Details of consent.
- What the tissue disposal process will be.
- Inclusion of an MTA if samples are to be transferred to an organisation outside of the University Health Board (UHB) as appropriate.

On a quarterly basis the JRO will produce a report to identify all projects due to complete in the following 3 months. CIs and/or PIs will be contacted and asked to confirm that all tissue will be destroyed, once the study has ended. If they intend to retain tissue at the end of the study there are 3 options:

1. Negotiate transfer to premises that hold a HTA licence.
2. Negotiate transfer to a Research Tissue Bank that has a HTA licence.
3. Apply for NHS Ethical approval.

Note: It is no longer possible for researchers (CU or CVUHB) to retain relevant material under an HTA Licence held by Cardiff University; retention of relevant material within Cardiff University is only permitted through one of the biobanks.

Tissue Banks and Biobanks

Some research requires the transfer of tissue samples, blood samples, or samples of other bodily material obtained from University Health Board (UHB) patients to a tissue bank or bio-bank facility. The University Health Board (UHB) has a duty of care to protect its patients by providing a robust system governing how such research tissue is managed. The following process has been established not to hinder research, but to implement a process to provide clarity. It describes the procedure to be followed when transferring a tissue sample(s) from a UHB patient, to a Tissue Bank. The following system is therefore in operation:

- Individual tissue banks are required to be in licensed premises under the Human Tissue Act (2004) and optionally approved as a Research Tissue Bank (RTB) by an NRES committee.
- Samples to be collected for Cardiff University Research Tissue Banks and other Individual tissue banks that receive CAVUHB samples, must be processed such that

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- ❖ An MTA is in place between the UHB and the Research Tissue Bank to acknowledge and oversee the transfer of tissue from the UHB (via the patient) to the RTB and that they accept the conditions of transfer.
- ❖ Directorates that supply tissue to RTBs will need to be assured that the transfer takes a matter of hours or days and certainly no longer than a week, as the UHB does not have a HTA licence.
- ❖ Subsequent research projects that are eligible for portfolio adoption will require confirmation of capacity and capability by R&D.
- ❖ Tissue surplus to requirements will be disposed of according to procedures that meet requirements of the Human Tissue Act (2004).
- ❖ IRAS renewal submitted to JRO who will liaise with the Directorate 2 weeks to comment from JRO and Directorates.
- ❖ Major collection amendments submitted to JRO for review
- ❖ Sample access review committee has CAVUHB oversight
- ❖ RTB Governance group has CAVUHB representation
- ❖ Submission of annual REC report to JRO

Appendix 3 gives further details on current governance oversight arrangements of RTBs managed by Cardiff University for which CAVUHB supplies tissue.

Disposal

Human tissue must be disposed of with respect. Appropriate methods of destruction, storage and arrangements with people involved must be planned and arranged in advance. Risk Assessments of the disposal of human tissue must be made and regularly reviewed.

Acknowledgement:

This document was based on HTA Policies produced by University of Wolverhampton and Nottingham NHS Trust and we are very grateful to use their work as a basis for our document.

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APPENDIX 1

Details on what is considered relevant Material can be found at

[Relevant material under the Human Tissue Act 2004 | Human Tissue Authority](#)

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Appendix 2

DNA Theft

DNA (as opposed to the bodily material from which it originates) is not considered to be relevant material under the Human Tissue Act and can be stored without the need for an HTA Licence. However, the Human Tissue Act does make it an offence to analyse DNA without consent.

It is possible to use the results of DNA analysis without consent, providing the bodily material from which the DNA is extracted:

- is from a living person;

and

- the researcher is not in possession, and not likely to come into possession of information that identifies the person from whom it has come;

and

- the material is used for a specific research project with recognised ethical approval.

Although no offence will be committed in this situation, the HTA recommends that, where practical, consent is obtained.

An offence will be committed where somebody has bodily material intending to analyse its DNA and use the results for research without consent for non-expected purposes (see HTA Code of Practice 1: Consent).

CAVUHB Oversight of Current Research Tissue Banks January 2025

| | CUB (all areas) | SWIFT (Fetal/HD) | WKRTB (Kidney) | WNRTB (Neuro) | WCB (Cancer) | Comment/Rationale |
|---------------------------------------------------------------------------------------------------------------|--------------------|---------------------|-------------------------------|------------------|----------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| IRAS renewal submitted to JRO | Yes | Yes | Yes | Yes | Yes | All renewals to be submitted to JRO for comment. All biobanks to submit to JRO for comment for 2 weeks in parallel with submission to HTA governance group. JRO will link to relevant directorate R&D leads. |
| IRAS renewal submitted to Directorate | No | No | Yes (consent) for approval | No | No | JRO will liaise with the Directorate except in the case of WKRTB where express consent from the Directorate is required. JRO will contact directorates 2 weeks to comment from JRO and Directorates. |
| New Prospective Collection (CUB) Major collection amendments (other RTB) – to JRO review | Yes for approval | No | No | No | Yes via Review and Governance group with UHB represented by Richard Adams. | New Prospective Collection – CVUHB oversight via representation on individual RTB governance committee. JRO to review membership of RTB governance groups Ensure CVUHB rep on CUB governance committee liaises, with a CAV clinician in the relevant field. |
| RTB Governance Group CVUHB Representation | Yes | Yes | Yes | Yes | Yes (Richard Adams) | JRO has reviewed membership to ensure that there are links to the Directorate R&D lead. WCB is the exception but this function is carried out by Richard Adams with an honorary contract with the UHB and a member of the JRO JRGG |
| Sample access review committee CVUHB oversight | Yes | Yes | Yes | Yes | Yes via Richard Adams | <i>–via RTB Governance Group with directorate representation and link to Directorate R&D Lead</i> |

CAVUHB Oversight of Current Research Tissue Banks January 2025

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| Submission of annual REC report to JRO | Yes | Yes | Yes | Yes | Yes | |
| Quarterly reporting to JRO by HTA Manager at JRGG | No | No | No | No | No | Breaches to come in real time to HTA committee which reports quarterly to JRGG |