University of Leicester Research Governance Office Standard Operating Procedures relating to the Human Tissue Act 2004

SOP HTA-A1002 UoL

Applying for an NHS REC-approved Research Tissue Bank

Version 2.0

Effective Date: 01 December 2024

This SOP will be implemented in line with this document's effective date for all UoL HTA SOPs.

Please note the appendices associated with this SOP may be subject to interim changes. Please ensure that appendices are downloaded from the RGO webpages prior to use to ensure the latest version of the document is being used.

1.0 Introduction

This document has been produced in accordance with *The Human Tissue Act 2004* (HT Act). It should be read in conjunction with the University's 'Policy on compliance with the Human Tissue Act in Research', and the Human Tissue Authority's *(HTA) Codes of Practice*.

A research tissue bank (RTB) is a collection of human tissue or biological materials, which are stored for potential research use, either beyond the scope of a specific research project with ethical approval or for which ethical approval is pending.

Organisations responsible for the management of RTBs anywhere in the UK can apply for NHS REC review of their arrangements for the collection, storage, use of human tissue or relevant biological materials and associated data. UoL requires that all RTB applications be submitted to an NHS REC for ethical review to ensure the appropriate governance of the samples.

NHS REC-approved RTBs are particularly useful for storing and governing the future use of tissue for research where ethically approved project-specific research studies are expiring. If a RTB is NHS REC-approved, then tissue held can be used for new research without the need to apply for further ethical approval (there are certain conditions required to be followed which can be found at the HRAs website) and the material can be used at sites that do not have a HTA Research Licence.

The advantages of an NHS REC-approved RTB is that it allows tissue to be released to research projects without further REC approval, providing the research falls within the remit of the conditions agreed in the RTB ethical approval.

Where "generic ethical approval" applies, the storage and use of the released material by the end user will not require a HTA licence, nor will the researcher require their own ethical approval. Research that falls outside the scope of the RTB ethical application will require its own project-specific REC approval or a substantial amendment can be submitted to the REC to include the new work (see section 4.5).

Once the research project has finished, the researcher will need to transfer the remaining tissue back to the RTB or dispose of the material.

The activities of an NHS REC-approved RTB are conducted under the governance of the UoL HTA Research Licence 12384, and must be reported under the Licence.

2.0 Scope

This document is to provide guidance for Chief/Principal Investigators (CIs/PIs) and Researchers on how to apply for an NHS REC-approved RTB, the internal processes involved, and any requirements to be aware of before applying for your RTB NHS REC approval.

Definitions:

ARC	Academic Review Committee
CI	Chief Investigator
DI	Designated Individual
HoD	Head of Department
HoS	Head of School

HRA	Health Research Authority
HTA	Human Tissue Authority
IRAS	Integrated Research Application System
PI	Principal Investigator
REC	Research Ethics Committee
RGO	Research Governance Office
RTB	Research Tissue Bank
SOP	Standard Operating Procedure
UoL	University of Leicester

3.0 Procedure

When applying for an NHS REC-approved RTB, the application must be submitted to the RGO for review via the Research Management System Infonetica. This can then be allocated to the HTA Monitor and one other reviewer who will confirm approval to submit. The HRA does not require sponsorship for RTBs, but it is UoL policy to take formal responsibility for them as they are required to be reported under the governance of the HTA Research Licence 12384, and therefore we do require RGO Office-approval for RTBs to ensure their oversight and compliance with HTA legislation.

Submission to a REC requires application using the Integrated Research Application System (IRAS).

Where NHS REC approval is being sought, the application to a REC that specialises in RTB applications (Flagged RECs) is required. These RECs are designed for review RTBs as they have the relevant professional, academic and ethical expertise among the committee membership.

3.1 Application Documentation Requirements

To apply for the NHS REC review of a RTB, you will first need to submit a business case approval outlined in appendix 2 to gain departmental approval / support of establishing a new RTB. Please refer to section 4.2 below, if applicable. Documentary evidence of approval will be required to be submitted on Infonetica.

Once departmental approval is obtained, submission for approvals can be obtained via Infonetica. Please ensure the RTB option in the Integrated Research Application System (IRAS) is selected to generate the appropriate application form for RTB ethical approval. Further guidance can be found at the *HRAs website*.

An RTB IRAS application form along with the following documents will be required for your application, all of which can be:

1. IRAS application for the RTB.
2. Protocol for the management of the RTB.
3. Short CV of the RTB manager.
4. Copies of donor information sheets / consent forms (if new consent will be sought from new donors) (If applicable).
5. Advertisement of the RTB (if applicable).

6. Electronic copy of the HTA licence (if already obtained, and if the RTB is in England, Wales, and NI). This can be provided by the HTA Monitor.
7. Approval documentation from College Business Group (if applicable).

Favourable ethical option of the RTB is valid for 5 years in the first instance, and therefore needs renewing every 5 years.

3.2 Internal Application Process

RTBs require a tissue bank manager (at a minimum) and storage facilities to ensure the appropriate running of the RTB. Where running a RTB requires “core” support, the establishment of a RTB should be discussed and supported by the Head of School or Department (HoS/HoD) and the appropriate Operations Manager informed of the intent.

If support is approved by the HoS/HoD then a business case would be required and submitted for review by the College Business Group to demonstrate how these needs can be met within current resources or what additional support is being requested and outlining the benefits of the activity. Please refer to appendix 2; CBG guidance form. Only once this approval has been granted can submission via the RGO for regulatory approvals commence.

The required documentation should be submitted to the UoL RGO using the Universities Research Management System.

Applications missing any of the required documentation will be returned to the CI/PI, pending submission of the whole suite of documentation for review.

Upon validation, the application will be shared with the relevant individuals to conduct the review. Applications will be reviewed within a three-week period. Comments will be returned to the applicant for guidance on amendments where necessary. Once comments have been addressed/points clarified, they can be resubmitted to the RGO office for final checks.

Once the checks have been conducted, the applicant will be given the approval to submit their application to the HRA/REC.

3.3 RTB Committee

Each RTB will be required to form an RTB management and academic review committee (ARC) to ensure effective governance and oversight. This will vary depending on the size and scope of the RTB. For small focussed RTBs the minimum requirement would be an academic lead, RTB manager, and a representative from the RGO office (ideally, the HTA Monitor). Input from the CI/PI who originally collected any project-specific samples should also be included as appropriate.

The RTB committee will promote and facilitate ethical tissue banking, ensure policies and procedures are followed, and provide guidance to researchers on the appropriate use of the donated tissue and biological samples.

For example, research projects that apply to utilise RTB material will require the committee’s oversight to ensure that the proposed use of the material falls within the

remit of the RTBs ethical approval, in addition to ensuring this is within the terms of the original consent that was obtained.

We recommend that applications made for tissue to be provided from a UoL-governed RTB, include;

1. Evidence of peer review for the proposed project, e.g., grant funding peer review, or peer review (local or national/international) from other investigators.
2. Copies of the IRAS application form and approval document letter if separate ethical approval is applicable to the project.
3. Valid, in date Human Tissue Training and RTB training from the applicants (Please refer to HTA training and RTB training sections)

3.4 RTB Renewal

NHS REC-approved RTBs are approved for 5 years. Renewal requires a new IRAS application before the current approval expires. You must ensure you apply for the renewal at a minimum of -6 months before the current approval expires.

HRA Ethics service staff will issue a reminder to the RTB manager when the application is due for renewal, to help ensure there is no gap in the ethical approval for the RTB.

Any renewal documents should take into consideration any development in legislation, policy and guidance in the interim from the RTBs initial application. Renewal documents should incorporate any amendments that were approved since the original approval.

Renewal documentation should be reviewed at the next available full REC committee meeting, and should be to the attention of the REC that approved the original application.

The REC has the power to decide not to renew the approval where it has serious concerns regarding the following:

1. Failure to use the resource to support research that is of public benefit.
2. Failure to comply with the terms and conditions of the approval.

3.5 Substantial Amendments

In the lifetime of the RTB you may be required to submit a substantial amendment B. These are the following circumstances where a substantial amendment maybe required:

- Any change in policy for the use of the materials, including changes to the types of research to be undertake or supported from the RTB.
- Changes to types of tissue to be collected or stored.
- Any significant change to informed consent arrangements, including new/ modified information sheets and patient facing documentation.
- Any change to the conditions of generic approval.
- Any other significant change to the governance of the RTB (e.g., Change in the DI of the HTA licence, change in RTB manager)

3.6 RTB Closure

If a RTB needs to be closed, the REC and HTA require at least 2 months' notice before the proposed closure date.

The REC should be informed of the arrangements to be made for the disposal of the tissue or whether the material is to be transferred to another RTB. If the tissue is transferred to another already established RTB, the original RTB ethical approval of those samples is not transferable.

3.7 HTA Training

It is mandatory for personnel involved in studies using human samples of any kind to undertake the HRA's training on "Research Involving Human Tissue" on the NIHR platform, even where an individual is not actively involved in processing the samples. This e-learning module provides an overview of human tissue regulation in the UK, best practice and practical tips for compliance.

The RTB manager should ensure that individuals applying to access material from their RTB have valid in date HTA training. UoL mandate the HRA's training module that has been relocated to the NHIR learning platform.

3.8 RTB Training

It is a requirement that all staff involved with a RTB undertake the NIHR Learn eLearning Module Research Tissue Banks – an introduction.

The module has been designed to help research and development staff, tissue bank managers, DIs and other staff to be aware of the structure of RTBs and the regulations and ethics behind them. Copies of any training certificates should be made available in the individuals personalised training records and a copy given to the RTB manager.

4.0 Responsibilities

Responsibility	Undertaken by	Activity
Chief Investigator / Principal Investigator (CI/PIs)	Chief Investigator / Principal Investigator (CI/PIs) or delegate / designated RTB manager	Application submission to RGO via Research Management System. Ensure all appropriate documentation is sent to RGO for review outlined in 3.1. Ensuring internal application process is followed as in 3.2. Any substantial amendments. RTB training on NIHR Learn
Head of Department / Head of School (HoD/HoS)	Head of Department / Head of School (HoD/HoS)	Review and support of business case where core staff support is required to facilitate the running of an RTB.

Responsibility	Undertaken by	Activity
Research Governance Office (RGO)	RGO member / HTA Monitor	Review of documentation is undertaken. Ensuring application is flagged to DI for their oversight and approval
Designated Individual (DI)	Designated Individual (DI)	Review of RTB IRAS and documentation. Signatory of IRAS RTB application.

5.0 Development and approval record for this document

This table is used to track the development and approval of the document.

Author	Job title	Reviewed by	Approved by	Date approved
Amanda Sutcliffe	HTA Monitor	UoL Human Tissue Governance Committee (HTGC)	Professor Peter Bradding 	28/11/2024

6.0 Review Record

This table is used to track the changes made on revised/reviewed versions.

Date	Issue number	Reviewed by	Description of changes (If any)
November 2024	v2.0	A. Sutcliffe	• Administrative changes. • Addition of application to Research Management System. • Appendix 2 added. Guidance for College Business case. • Addition of internal application process before establishing a RTB under the UoL umbrella. • Update to RTB training