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The definitive version of all University of Leicester (UoL) Human Tissue Authority (HTA) Standard Operating Procedures (SOPs) appear online, not in printed form, to ensure that the up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the Research Governance Ethics and Integrity (REGI) Website.

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Development and Approval Record for this Document

Role	Name	Job title	Signature	Date
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Reviewer	All members of the College of Life Sciences Human Tissue Governance Committee	College of Life Sciences Human Tissue Governance Committee	N/A	N/A
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Background

A research tissue bank (RTB) is a collection of human tissue or biological materials, which are stored for potential research, 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 the ethical review of their arrangements for the collection, storage, use of human tissue or relevant biological materials and associated data.

RTBs are particularly useful for storing and then the future use of tissue for research where ethically approval project specific research studies are expiring. If a RTB is ethically approved, then tissue held can be generally used for new research without need to apply for further ethical approval, (there are caveats to this) and can be used at sites that do not have a HTA research licence.

Purpose and Scope

This document is to provide guidance for Chief/ Principle Investigators (CIs/PIs) and Researchers on how to apply for a RTB, the internal processes involved, and any requirements to be aware of before applying for your ethical approval of the RTB.

Definitions:

ARC	Academic Review Committee
CI	Chief Investigator
DI	Designated Individual
HRA	Health Research Authority
HTA	Human Tissue Authority
IRAS	Integrated Research Application System
MTA	Material Transfer Agreement – A contract that governs the transfer of tangible research materials between two organisations, when the recipient intends to use it for his or own research purposes.
PI	Principle Investigator
REC	Research Ethics Committee
REGI	Research Governance Ethics and Integrity
RTB	Research Tissue Bank
SOP	Standard Operating Procedure
UoL	University of Leicester

Roles and Responsibilities

It is the CI/PI's responsibility to ensure all of the required documentation for the approval of the RTB are submitted to sponsor for sponsor review process and to provide oversight of the governance of the remaining material.

It is the DI, HTA Monitoring Officer, and a representative from the Sponsor that will conduct the review of the RTB application to ensure all of the applicable documentation have been submitted, in addition to ensuring that the RTB is registered appropriately under the UoL HTA research licence.

Procedure to follow

The Heath Research Authority (HRA) have made a series of changes to facilitate the ethical review of research involving human tissue. One of these changes is a REC approval process for licensed RTB. There has been the establishment of 'flagged' RECs which specialise in RTB applications. It is important that if establishing an RTB that you apply to one of the 'flagged' RECs to ensure the appropriate approvals are sought.

The advantages of an RTB with ethical approval 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 this "generic ethical approval" applies, the storage of the material of 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 (as an example DNA analysis might require further ethical approvals).

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

The UoL requires that all RTB applications be submitted to an NHS REC for ethical review to ensure the appropriate governance of the samples.

Application Documentation Requirements

To apply for the ethical review for a RTB, you will need to select the relevant option on the Integrated Research Application System (IRAS) to generate the appropriate application form. Further guidance can be found at the *HRAs website*.

A Research Sponsorship application form along with the following documents will be required for your application:

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).

Favourable ethical option of the RTB is valid for 5 years, in the first instance after that time it is possible to renew the ethical approval of the RTB for another 5 years.

Internal Application Process

Upon a completed *Sponsor application form (HTA-A1002 Appendix 1)*, along with the appropriate RTB documentation. The application will be validated to ensure all of the documentation required for the RTB has been submitted.

Any applications missing any of the required documentation will be returned back to the CI/PI, until the whole suite of documentation have been submitted to be reviewed.

Upon validation, the application will be shared with the relevant individuals to conduct the review. Applications will be reviewed within a three week period. Any comments will be returned to the applicant for the comments to be addressed. Once comments have been addressed/points clarified, they can be resubmitted to sponsor for final checks.

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

RTB Committee

Each RTB will be required to form an RTB management and academic review committee (ARC) to ensure the effective governance and oversight in how that material will be used. This will vary depending on the size and scope of the RTB. For a small focussed RTB the minimum requirement would be an academic lead, RTB manager, and a representative from the sponsor (ideally, the HTA Monitoring Officer). Input from the PI who originally collected any project-specific tissue should also be included as appropriate.

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

As an example, research projects that will apply to utilise RTB material will require the committee oversight to ensure that the material being used for the research project fall within the remit of the RTBs ethical approval, in addition, to ensuring any future research is in the terms of the original consent that they've were obtained.

We would recommend that applications for tissue to be provided from a RTB, include evidence of peer review for the proposed project, for example, grant funding, separate ethical approval, or peer review (local or national/international) from other investigators.

RTB Renewal

RTBs are approved for 5 years by ethics committees, and at the end the 5 year approval, you are able to renew this. You must ensure you apply for the renewal at a minimum of 3-6 months before the current approval expires for your RTB.

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

Failure to use the resource to support research that is of public benefit.

Failure to comply with the terms and conditions of the approval.

Substantial Amendments

In the life time of the RTB you may be required to submit a substantial amendment for the RTB. 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 license, change in RTB manager etc.)

RTB Closure

There are various circumstances that might lead to the RTB requiring to be closed.

If an RTB does require closure the REC and HTA require at least 2 months' notice before the closure of the RTB.

The REC should be informed of what arrangements are 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 ethical approval of those samples in not transferable.

The HRA does not require sponsorship for RTBs, 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, and therefore we do require formal sponsorship for RTBs to ensure their oversight and compliance with the University's HTA research licence.

Project Specific Studies

If you have a project-specific study coming to a close, and since the conception of the original research study, further scientific questions have been raised that you would like to be investigate, then the most applicable solution to address this is to: i) transfer your samples to an already established RTB, or ii) get approvals to establish a new RTB providing the samples from the original study have the consent clause for the samples to be used for future research. The RTB application should be sought 3-6 months before the project specific ethical approval expires.

This table is used to track the development and approval of the document and any changes made on revised / reviewed versions.

Review Record

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