Joint Research and Enterprise Services (JRES)	
Research Tissue Bank (Biobank) Policy	
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Author:	Georgia Bullock, Research Development and Governance Manager, JRES
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Policy Chronology		
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V1.0	1st July 2025	Original version

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PURPOSE AND SCOPE OF POLICY

A Research Tissue Bank (also known as a Biobank) can store different types of biological material to be used in future research projects.

When storing ‘relevant material’ as defined by the Human Tissue Authority (HTA), a storage licence from the HTA is required for the organisation storing the material. Both City St George’s (Tooting Campus) and St George's University Hospitals NHS Foundation Trust have a storage licence for research.

This policy outlines the ethical, governance and management requirements for the establishment of Research Tissue Banks (Biobanks) with City St. George's, University of London (CSG) or with St George's University Hospitals NHS Foundation Trust (SGHFT).

This policy applies to anyone employed by either CSG (Tooting Campus) or SGHFT wishing to establish a Research Tissue Bank.

DEFINITIONS

Research Tissue Bank (Biobank): a collection of human tissue or other biological material, which is stored for potential research use beyond the life of a specific project with ethical approval or for which ethical approval is pending.

Informed Consent: permission which has been given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question. Specific consent is given in relation to a defined project, treatment and/or use. Broad (generic) consent refers to consent given to allow the storage and use of tissue for an as yet unknown research project or as part of a Research Tissue Bank.

Relevant Material: 'relevant material' is defined by the Human Tissue Act 2004 (HT Act) as material other than gametes, which consists of, or includes, human cells. Relevant material does not include: (a) embryos outside the human body, or (b) hair and nail from the body of a living person. A full list of relevant material can be found on the HTA website.

Scheduled Purposes: there are 12 scheduled purposes described in Schedule 1 of the Human Tissue Act. The scheduled purpose which relates to research is 'Research in connection with disorders, or the functioning, of the human body'.

EXPECTATIONS FOR RESEARCH TISSUE BANKS

Samples

Researchers must determine what samples are to be collected and stored, including:

- The type(s) of samples, eg: blood, serum, urine.
- The quantity of samples it is anticipated will make up the Research Tissue Bank.
- The origin of the samples, ie: if they be obtained from direct recruitment or from a previously-approved research study.

Funding

Costs associated with a Research Tissue Bank may include sample transport, processing and storage as well as administrative costs for undertaking audits, completing reports and responding to requests for samples.

Funding to meet the costs of operating a Research Tissue Bank must be obtained either through internal financial support or from external grant awards.

The JRES Funding team can provide guidance and support in obtaining funding from grant applications.

Consent

Informed Consent is required for a Research Tissue Bank to store and provide relevant material for use in research. There are some exceptions to this:

- Storing and providing relevant material which is an 'existing holding', ie: material from the living or deceased that was already held for use for scheduled purposes when the Human Tissue Act came into force on 1 September 2006.
- Storing and providing relevant material where:
    - The material has been obtained from living donors and the donor cannot be identified by the researcher.
    - The material is released by a Research Tissue Bank with generic approval by a recognised Research Ethics Committee (REC) for research within the terms of the approval.
    - The material is to be used for a specific research project approved by a REC.
- Storing and providing 'imported' material (import into England, Wales or Northern Ireland from a place outside England, Wales and Northern Ireland). For imported material, there should be mechanisms in place to provide assurance that the tissue has been obtained in the source country with valid consent. The importer should have in place, policies and/or Standard Operating Procedures which clearly set out the evidence indicating how informed consent was obtained, including safeguarding the confidentiality of all information relating to consent. If a separate organisation is importing the material, a documented agreement should be in place demonstrating that there is a record of consent in a suitable format.
- Storing and providing relevant material which has been donated for research and more than 100 years have elapsed since the person's death.

Specific consent (to meet the requirements of a specific research study) and broad, generic consent (for the storage of the samples for future ethically-approved studies) can be obtained at the same time.

Where practicable, the consent of a research donor should be sought wherever possible and the views of the relatives of a deceased person must be respected.

Research Tissue Banks must hold all documentation to demonstrate consent such as:

- Documents from the research consent process, ie: Patient Information Sheets and Consent Forms.
- Any legal agreements with other parties which confirm that appropriate consent is in place (a copy of a blank participant information sheet and/or consent form could also be provided with the agreement). Signed consent forms should remain with the other party and be retained in line with its local policies.
- Appropriate disposal procedures with consideration of the wishes of the donor (living person).

Research Ethics Committee (REC) Approval

It is not a legal requirement to have ethical approval to establish a Research Tissue Bank but it is good practice to do so. It is recommended that generic REC approval for the Research Tissue Bank is obtained. Ethical approval for a tissue bank allows tissue and/or data from the Research Tissue Bank to be used in UK-based research studies without the need for separate ethical approval, providing it is fully anonymised and is used within the terms of the donor consent.

To obtain REC approval for a Research Tissue Bank, an application must be made via IRAS and submitted to a REC with the supporting documents (such as the protocol, Information Sheet(s), Consent Form(s) and a copy of the HTA Licence).

The JRES has templates for documents such as the protocol, PIS and Consent Form.
Policies, Standard Operating Procedures and Templates (sgul.ac.uk)

The JRES can review the IRAS form and associated documents prior to submission. The IRAS form will need to be authorised by the Designated Individual prior to submission.

The REC will review:

- The arrangements for the collection of new samples.
- The requirements to seek consent from new donors, further consent from previous donors, or consent from relatives where the donors are deceased.
- The terms of informed consent as set out in information sheets and consent forms.
- The justification for storage and use of tissue for research without specific consent where not legally required.
- The policy for provision of tissue to researchers, including arrangements for ensuring adequate scientific critique of projects and the conditions under which samples will be released.
- Any plans to provide donors with feedback of any clinically significant information obtained in research using their samples.

The Research Tissue Bank should be registered on an appropriate directory such as the one operated by the UKCRC and this is **mandatory** for ethically-approved Tissue Banks.

TDCC - UKCRC Tissue Directory and Coordination Centre (biobankinguk.org)

Once received, a copy of the REC Favourable Opinion Letter should be provided to the JRES and to the Designated Individual.

Any 'Conditions of Approval' issued with, or listed in, the Letter must be adhered to.

Amendments

Any significant change(s) to the arrangements for the management of the Tissue Bank as described in the original application must be notified to the REC as a substantial amendment. A favourable opinion must be obtained before the changes are implemented.

The changes that constitute a substantial amendment can be found here: Research Tissue Banks Conditions of REC Favourable Opinion - Health Research Authority

Non-substantial amendments do not have to be notified to the REC.

Substantial amendments are notified using the Notice of Substantial Amendment form in IRAS, created from the Amendment tab associated with the Research Tissue Bank form. Guidance on this can be found here: IRAS Help - Maintaining your approvals - Amendments

Research Tissue Bank Management Committee

The Research Tissue Bank must be governed by a Management/Steering Committee whose constitution, remit and meeting frequency should be set out in a written document, such as a Terms of Reference.

The Committee should ensure that there is adherence to the relevant legislation, including Data Protection legislation and the Human Tissue Act, and ensure that the terms of any REC approval is adhered to.

It will be responsible for the collection, storage and security of the samples/tissue and for maintenance of the Tissue Bank.

It will agree and manage the request procedure for samples, including any costs for this and how these charges will be implemented and managed.

It will be responsible for both the receipt and transfer of samples, ensuring that the appropriate consent is in place and that Material Transfer Agreements (MTAs) are implemented as required. For example, an MTA will be required between SGHFT and CSG where tissue/samples are transferred from SGHFT to CSG.

It will uphold the rights of the donors and manage any complaints.

It will ensure adherence to the standard policy for the disposal of specimens/tissue.

Provision of Samples/Tissue to Others

It is not essential that samples are made available to other groups but this has to be justified when applying for ethical approval for a Research Tissue Bank.

The Research Tissue Bank management should include information about each collection, including policies for access to tissue in each collection and distribution to external researchers. The Biobank Management Committee should review all requests according to an agreed process.

If samples may be released to a commercial entity, this needs to be made clear to donors in the Patient Information Sheet and Consent Form.

Where samples have been donated with broad consent, the Research Tissue Bank must be satisfied that the use of the samples complies with the terms of donor consent. Samples and any associated clinical information must be non-identifiable to the researcher at the point of release. If the researcher wishes to use identifiable clinical information on the samples they have received, they must apply for project-specific REC approval.

A Material Transfer Agreement (MTA) must be in place with the researcher to ensure the storage, use and disposal (or return) of the human tissue samples in accordance with the terms of the Research Tissue Bank's ethical approval.

On completion of the research, the researcher must choose the most appropriate option in agreement with the Research Tissue Bank management as part of the MTA:

- Transfer the human tissue back to the Research Tissue Bank.
- Transfer the human tissue to an alternative HTA-licensed establishment.
- Apply for their own HTA licence (unless the further storage can be covered by an existing local licence).
- Apply for specific project approval from a REC.
- Dispose of the human tissue according to local policies and SOPs.

Compliance with HTA Requirements

- Relevant material must be stored in premises with an HTA licence, unless they are being used as part of an NHS REC approved study.
- Samples must be traceable and be tracked using an appropriate tracking system.
- Samples must be linked to evidence that appropriate consent is in place.
- Samples must be stored in secure, well-maintained facilities.
- Contingency plans should be in place should the storage facility fail. This should be recorded in a risk assessment for the Research Tissue Bank, in accordance with HTA guidance. Frozen samples will need to have adequate back-up systems in case of freezer/power failure.
- Evidence that the correct temperature has been maintained for all samples will be required.
- The Designated Individual for the relevant HTA licence is responsible for ensuring that the conditions of the Act are observed and the Human Tissue Authority can conduct audits to monitor this.

Compliance with Governance Requirements

- Departmental authorisation from the relevant Care Group Lead should be obtained by the JRES and management permission from the NHS care organisation must be issued by the JRES.
- Collections must be registered with the CSG/SGHFT Human Tissue Act Designated Individual (DI), in accordance with local procedure.
- The confidentiality of the donor's personal details must be ensured at all times.
- All electronic data should be stored on computers that are password-protected with restricted access.
- Adequate and accurate documentation and record keeping must be maintained and must be available for audits/inspections.
- An audit trail for all samples, including any that have been withdrawn, must be available.
- Standard Operating Procedures (SOPs) and/or Policies for the Tissue Bank's processes should be in place.
- Tissue Bank staff must adhere to local policies and SOPs relating to the collection, processing, storage, shipment and disposal of human tissue within their organisation.
- Tissue Bank staff should complete training on the Human Tissue Act and Good Clinical Practice (GCP).
- All protocol non-compliances or breaches of policy must be reported to the relevant DI to facilitate ongoing reporting to the HTA/REC as required.

REFERENCES AND FURTHER INFORMATION

City St George's: Human Tissue Act (sgul.ac.uk)

IRAS: Integrated Research Application System (myresearchproject.org.uk)

Research | Human Tissue Authority (hta.gov.uk)

Eight things you should consider before setting up a biobank | Blog | Human Tissue Authority (hta.gov.uk)

Research tissue banks and research databases - Health Research Authority (hra.nhs.uk)

Research Tissue Banks Conditions of REC Favourable Opinion - Health Research Authority

Joint research and enterprise services (sgul.ac.uk)