1.1. What is a research tissue bank?

A Research Tissue Bank (RTB), also known as a Biobank, is:

"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."

Research Tissue Banks are not restricted to human tissue within the definition of “Relevant material” under the Human Tissue Act 2004, and may store non-relevant material such as DNA, plasma, cell lines, and/or clinical data.

However, research tissue banks storing relevant material must do so on Human Tissue Act licensed premises, under the oversight of the Designated Individual and Person Designate, in an approved storage location.

Every time a researcher wishes to use the material stored in a research tissue bank in a research project, they must obtain individual project-based Research Ethics Committee (REC) approval to do so.

However, to overcome the need to do this, organisations responsible for the management of research tissue banks anywhere in the UK may apply for ethical review of their arrangements for collection, storage, use and distribution of tissue (i.e. become a REC approved Research Tissue Bank). Applications for research tissue banks to obtain ethical approval is not a legal requirement, however it comes with a number of advantages.

1.2. What are the advantages of gaining ethical approval for a research tissue bank?

The main advantage of gaining ethical approval for a research tissue bank is that it facilitates programmes of research without the need for individual project-based ethical approval.

Applicants can apply prospectively for generic ethical approval for a range of research to be carried out by either:

- the establishment responsible for the bank
- and/or by other researchers to whom tissue is released by the bank...

provided the proposed research falls within the conditions of the ethical approval of the bank granted by the Ethics Committee.

Such approval may be given for a period of up to five years and will be renewable.
1.3. How do I apply to set-up a research tissue bank?

Applications should be made using the appropriate form in the Integrated Research Application System “IRAS” (https://www.myresearchproject.org.uk/). Detailed guidance for applicants is available within IRAS.

Applications may also be made to access a diagnostic archive for use in research. For information on accessing diagnostic archives, please refer to section 1.3.1.

The individual who applies to establish a research tissue bank and is responsible for the banks conduct may be called either:

- The “Applicant”
- The “Research Tissue Bank Curator”,
- The “Tissue Bank Manager” or,
- The “Chief Investigator”

The main purpose of the Research Tissue Bank Curator is to supervise the research effectively and be readily available to communicate with the Research Ethics Committee (REC) and other review bodies during the application process and where necessary during the conduct of the research. A role description for this individual can be found in the HTA Master File.

When submitting applications, applicants should be aware that:

- In order to gain ethical approval for a research tissue bank which will store relevant material under the Human Tissue Act, the application must be approved by the relevant Designated Individual and applicants must provide a copy of the institutions HTA licence, as a condition of the ethical approval, except where:
  - The RTB is established in Scotland.
  - The biological material to be stored for use in research is outside the definition of 'relevant material' under the Human Tissue Act, for example DNA, plasma or serum.

- Applications should be booked for ethical review through the National Research Ethics Service (NRES) Central Allocation System (0845 270 4400).

- NRES has designated particular Research Ethics Committees to review applications from research tissue banks. It is strongly recommended that any application for ethical review is sent to a flagged REC for research tissue banks. For more information, see the NRES website: http://www.nres.nhs.uk/applications/approval-requirements/ethical-review-requirements/research-tissue-banks-biobanks/

- Please note that the DI will require up to 10 working days to review any applications prior to authorisation.

- Approval is typically granted for a period of up to five years, and is renewable.

- The applicant must abide by the terms and conditions of ethical approval, as set out in section 1.
1.3.1. Accessing diagnostic archives

Tissue that is taken from the living for diagnosis and subsequently stored in a diagnostic archive can be a valuable research resource. There is therefore the potential to establish diagnostic archives as research tissue banks. However, as the material may not necessarily have been collected with consent for research, the Human Tissue Authority and National National Research Ethics Service (NRES) released a joint statement on the use of diagnostic archives in research. This statement can be found on the HTA website at the following address:

http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/positionstatementondiagnosticarchivesreleasingtissueforresearch.cfm

This statement indicates the HTA licensing requirements for diagnostic archives, ethical approval for accessing diagnostic archives for use in research, and consent requirements. A summary is provided below.

1.3.1.1. HUMAN TISSUE ACT - LICENSING:

- Purely diagnostic archives do not need to be stored on HTA-licensed premises. However, the Human Tissue Act 2004 (HT Act) clearly states that the storage of tissue for a ‘scheduled purpose’ (i.e. activity requiring consent) must be on licensed premises.

- Where a diagnostic archive functions as a resource for researchers as it invites applications for the release of samples, and/or in any way advertises the archive as a research resource, it is functioning as a research tissue bank and must therefore be encompassed within the HTA’s licensing framework.

- This legal requirement stands, even where tissue released from the archive will only ever be used as part of a specific project approved by a NHS research ethics committee (REC).
  - Where the archive is on premises already licensed by the HTA for storage, providing the Designated Individual (DI) is willing to take responsibility for the governance of the archive, the licence can be extended in anticipation of the archive operating as a research tissue bank.
  - Where the archive is on premises not licensed by the HTA for storage, a new licence application will need to be submitted prior to the archive operating as a research tissue bank.

- Applying for a licence:
  - It is only possible to apply for a licence with the approval of your employing authority.
  - If you require a new licence you need to complete a new research compliance report application via the HTA website at /db/documents/2006-06-28_Designed_Research_Compliance_Report_on_the_website_amended.pdf
  - If the archive is on a site that can be linked to existing HTA-licensed premises you can apply for a satellite licence at /db/documents/2006-07-03_Satellite_Establishment_Information_on_website_v0_200806030415.doc
  - If you require an HTA licence e.g. a post mortem licence, to be extended to cover a diagnostic archive that is not yet functioning as a research tissue bank, you need to email enquiries@hta.gov.uk quoting the existing HTA licence number and provide a brief narrative about where on the premises the archive is held (attaching a site map if possible) and how the DI is going to ensure the archive functions within the establishment’s existing governance and quality system.
Applicants should allow three months from submission of a new application to the grant of a licence and one month following the submission of a satellite application or a licence extension request. The statement notes that:

“If you are inviting applications for the release of samples, and or in any way advertising an archive as a research resource and it is not on HTA-licensed premises, you must stop doing so immediately and contact the HTA at the enquiries email address above. You must not re-commence releasing tissue until you have been granted an extension to an existing HTA licence or a new HTA licence. If you are aware of any other establishment that this applies to, please contact the HTA”.

1.3.1.2. ETHICAL APPROVAL

Applications for ethical review may be made by diagnostic archives planning to operate as research tissue banks. Generic ethical approval will be subject to licensing by the HTA in the same way as for other approved banks.

If the archive does not gain generic research tissue bank approval the tissue can only be released:

1. To another HTA-licensed establishment, or
2. For use in a specific project with ethical approval by a REC; therefore negating the need for it to be stored under the authority of an HTA storage licence.

1.3.1.3. CONSENT

Whenever identifiable tissue is released for research from a diagnostic archive, it must only be released in accordance with the donor's consent; unless it was stored prior to implementation of the HTA Act on 1 September 2006, in which case consent is not required, as it is regarded as an "existing holding".

Tissue that has not been consented for research (other than existing holdings) can only be released if:

- it was taken 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
- where the material is released by a research tissue bank with generic ethical approval from a REC for research within the terms of the approval
OR
- it is to be used for a specific research project approved by a REC.
There may be occasions when a clinician involved in research has access to a secure database that would permit identification of a sample and the identity of the patient whose material is being used. Providing the research material is not identifiable to the researcher (e.g. coded by a laboratory accession number) and the researcher does not seek to link the tissue to the patient, the sample will still be regarded as non-identifiable and the research will be permissible without consent if it is given ethical approval by a REC.

1.4. Conditions of approval for a research tissue bank:

Once a Research Ethics committee has granted ethical approval for the Research Tissue Bank, a document entitled “Conditions of Ethical Approval” will be provided to the Applicant. This document confirms the duration of the ethical approval, and the terms and conditions of the approval granted. All Research Tissue Bank Curators have a responsibility to ensure that they are aware of these conditions, and comply with all requirements. These conditions include the following requirements:

- **ESTABLISH AN ACCESS COMMITTEE AND ACCESS POLICY:**

  An access committee should be established to review any applications to use the research tissue bank, in accordance with the bank’s access policy, which must be formally documented.

  The access policy must contain details on the procedures for processing applications to use the bank, the conditions of access and any governance requirements. Researchers may be requested to acknowledge the biobank as the source of samples used in their research. The National Cancer Research Institute (NCRI) has produced a useful template to aid the development of an access policy which is applicable across all disease types (http://www.ncri.org.uk/initiatives/biobanking)

- **RECORD KEEPING**

  The Bank should maintain a record of all research projects to which tissue has been supplied. The record should contain at least the full title of the project, a summary of its purpose, the name of the Chief Investigator, the sponsor, the location of the research, the date on which the project was approved by the Bank, details of the tissue released and any relevant reference numbers. The conditions of generic approval for projects receiving tissue will be set out in the conditions of ethical approval, including the requirement to have supply agreements in place for projects receiving tissue. The Committee may request access to these records at any time.

- **SUBMIT AN ANNUAL PROGRESS REPORT**

  A progress report should be submitted to the Research Ethics Committee which gave the favorable opinion for the research tissue bank 12 months after the date on which the favorable opinion was given i.e. on the anniversary of approval of the bank. Annual progress reports should then be submitted on the anniversary of approval thereafter until the end of the study/closure of the bank.
listing all projects for which tissue has been released in the previous year. If the biobank approval is renewed, and the month of renewal does not match the original month of approval, then the new report due date becomes the month of the renewal.

The Committee may request additional reports on the management of the Bank at any time.


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<th>Requirements of annual progress report:</th>
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<td>- The report must give a comprehensive summary of the annual activity of the bank, including the full title of each project, including projects that are pending or rejected, the name of the Chief Investigator, the sponsor, the location of the research and the date of approval by the Bank.</td>
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<td>- It should be noted that in empowering the Access Committee to make ethical judgements on the suitability of each applicant to use the bank in lieu of individual project approval by a REC, the Curator must provide the Ethics Committee with sufficient information to summarise each research project, and justify the ongoing activity of the bank.</td>
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<td>- Reports should be submitted in typescript and be signed by the research tissue bank curator. A paper copy should be sent to the REC within 30 days of the end of the reporting period.</td>
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<td>- For banks storing relevant material under the Human Tissue Act, a copy of the annual report should also be submitted to the Designated Individual for the HTA research licence (<a href="mailto:andy.hall@ncl.ac.uk">andy.hall@ncl.ac.uk</a>). Annual reports are reviewed each March by the Access and Governance Committee.</td>
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<td>- For banks which have extended their ethical approval by an additional 5 years, and are assigned a new approval date, the date that the annual report is due remains the original date of approval of the bank.</td>
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- **COMMUNICATION**

Research Tissue Bank Curators have a responsibility to communicate with the Research Ethics Committee that approved the bank to inform them of any:

- substantial amendments
- serious adverse events
- changes (e.g. to contact details of applicant)
- breaches of approval.

- Any plans to close the bank must also be notified to the Committee as early as possible and at least two months before closure. The Committee should be informed what arrangements are to be made for disposal of the tissue or transfer to another research tissue bank.
1.5. Renewing Ethical Approval for Research Tissue Banks

Approval is given for a period of 5 years, which may be renewed on consideration of a new application by the Committee, taking account of developments in legislation, policy and guidance in the interim. New applications should include relevant changes of policy or practice made by the Bank since the original approval together with any proposed new developments.

1.6. Research Tissue Banks at Newcastle University:

A list of the research tissue banks with current approval at Newcastle University is provided in the HTA Master File and in the HTA Virtual Research Environment. For further information on these tissue banks, please refer to: www.ncl.ac.uk/nbb/collections. All research tissue banks stored under the Newcastle University HTA licence should be advertised on the Newcastle Biomedicine Biobank website, including a copy of the Access Policy.

1.7. Further advice and resources:

The National Research Ethics Service (NRES) website: http://www.nres.nhs.uk/applications/approval-requirements/ethical-review-requirements/research-tissue-banks-biobanks/


The Human Tissue Authority website for information on storing human tissues for research: www.hta.gov.uk

The Newcastle Biomedicine Biobank website: www.ncl.ac.uk/nbb or the Newcastle Joint Research Office website: www.newcastlejro.org.uk

For advice on submitting IRAS application, please refer to: https://www.myresearchproject.org.uk/Help/Contact.aspx

For advice on R&D approvals, please use the R&D inbox: trust.R&D@nuth.nhs.uk

For advice on the Newcastle University research Human Tissue Act (2004) licence, please contact:

- Mhairi Anderson, Quality Assurance & Development Manager: Mhairi.anderson@ncl.ac.uk
- Professor Andy Hall, Designated Individual: andy.hall@ncl.ac.uk

Or refer to the human tissue pages of the Newcastle Joint Research Office website: http://www.newcastlejro.org.uk/research-governance/research-involving-human-tissue