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| C:\Users\nma47\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.Word\Freezers_+_people_4.jpg | ***What are Research Tissue Banks? (Biobanks)******NJRO-TISS-T-027*** | C:\Users\nma47\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.Word\Zoe_with_tube.jpg |

**AIM:**

This document has been written to help answer the following questions…

* + - * What is a research tissue bank?
			* What are the advantages of gaining Research Ethics Committee approval for a research tissue bank?
			* How do I apply to set up an NHS REC approved research tissue bank?
			* What are the conditions of ethical approval?
			* How do I conduct a research project under a REC approved research tissue banks ethics?
			* How do I close an NHS REC approved research tissue bank?

This document should be read alongside the [NJRO-TISS-WI-003](https://g14784.ideagenqpulse.com/QPulseDocumentService/Documents.svc/documents/active/attachment?number=NJRO-TISS-WI-003) “How to write a Research Tissue Bank annual report”. Full guidance on the conduct of human tissue research can be found [in NJRO-TISS-POL-001](https://g14784.ideagenqpulse.com/QPulseDocumentService/Documents.svc/documents/active/attachment?number=NJRO-TISS-POL-001) “Human Tissue in Research Manual - The collection, storage and use of human tissue in research at Newcastle University”. All documents can be found in the NJRO Q-Pulse document management system, accessed via the NJRO website (<https://newcastlejro.com/>). In addition, researchers should refer to the Health Research Authority website: <https://www.hra.nhs.uk/> (search under “Research Tissue Banks”.

* 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."*

**What does this mean?**

In lay terms, this simply means that a research tissue bank is a collection of human samples (such as blood, urine, tumour, biopsies) that are stored for use in future research projects. Any future project which intends to use the material will have to be approved by a research ethics committee and gain ethical approval.

**Where did the samples come from?**

Samples stored in research tissue banks may have been collected as part of another project, such as a clinical trial in the NHS, which has come to an end. Alternatively, they may have come from individuals who suffer from certain conditions (e.g. arthritis, cancer, skin complaints) who have kindly donated their tissue samples as part of their treatment to allow them to be used to study the disease. Healthy volunteers can also donate samples to a research tissue bank to aid research by comparing diseased and healthy tissue.

**Why are the samples being stored?**

Samples stored in research tissue banks act as valuable resources for medical research. Scientists can conduct tests on the material to study disease and help to develop new treatments.

**What samples are stored in research tissue banks?**

Research Tissue Banks can store a wide range of samples. This can include material which is classed as “relevant material” under the Human Tissue Act (2004), which is defined as

*“Material, other than gametes, which consists of, or includes human cells”*

RTBs can also store material which does not contain cells (and is not classed as relevant material), such as DNA, plasma, cell lines, which have been derived from human samples. They can also store clinical data.

Research tissue banks that store relevant material under the Human Tissue Act (2004) must do so on Human Tissue Authority licensed premises, under the oversight of the Designated Individual and Person Designated, in an approved storage location.

**How do researchers access the material stored in RTBs?**

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, The HTA and the HRA’s Research Ethics Service (HRA RES) have agreed a position whereby NHS Research Ethics Committees (RECs) can give generic ethical approval for a research tissue bank's arrangements for collection, storage and release of tissue, providing the tissue in the bank is stored on HTA-licensed premises. Such research tissue banks need to be licensed because at least some of the tissue being stored is not for specific projects holding REC approval.

Some research banks only hold material that is not considered ‘relevant material’ under the Human Tissue Act 2004. Examples of these would be banks that store only DNA or serum. In order to establish themselves as an NRES REC approved research tissue bank, these banks must also ensure they are held on licensed premises.

Applications for research tissue banks to obtain ethical approval is not a legal requirement, however it comes with a number of advantages, as set out below.

* 1. **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. This saves a researcher a significant amount of time and effort.

However, all research projects must fall within the scope of what has been preapproved by the ethics committee (i.e. research under a common pre-agreed theme) and comply with a number of terms and conditions of ethical approval – see section 1.5.

Ethical approval may also be extended to cover researchers working at other establishments.

Projects conducted under a RTBs ethical approval are typically small, involving relatively small numbers of donors, or sample numbers. For example to gather pilot data to gather evidence to support the creation of a new clinical trial. If larger scale projects are required, this may not be suitable to run under a tissue bank and full project specific approval may be required.

* 1. **What ethically approved research tissue banks do we have in Newcastle?**

A list of all NRES REC approved research tissue banks currently held by Newcastle University is provided in the Human Tissue Master File ([NJRO-TISS-T-015](https://g14784.ideagenqpulse.com/QPulseDocumentService/Documents.svc/documents/active/attachment?number=NJRO-TISS-T-015)). This document is stored in the Newcastle Joint Research Office (NJRO) Q-Pulse document management system.

* 1. **How do I apply to set-up a research tissue bank?**

In an attempt to promote a singular, harmonised approach to tissue banking and enhance governance, the implementation of new research tissue banks at Newcastle University should be minimised wherever possible.

Any researchers wishing to gain ethical approval for a new research tissue bank collecting and storing relevant material under the Human Tissue Act (2004) must first obtain permission from the Designated Individual on the licence (Dr Chris Morris, c.m.morris@ncl.ac.uk, Newcastle University and Dr Max Robinson, max.robinson@nhs.net, for Newcastle Hospitals).

Where approval is granted, there are two main steps when establishing a new ethically approved research tissue bank:

* Gaining Research Ethics Committee approval from a recognised NHS Research Ethics Committee (REC)
* Obtaining permission from the relevant NHS Trust(s) where the collection of samples takes place

These steps are set out in section 1.4.1. and 1.4.2.

* + 1. **Gaining Research Ethics Committee Approval**

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| Applications should be made using the appropriate form in the Integrated Research Application System “[IRAS](http://www.nres.nhs.uk/applications/integrated-research-application-system/)” (<https://www.myresearchproject.org.uk/>). Detailed guidance for applicants is available within IRAS. Once granted, 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. Applications may also be made to access a diagnostic archive for use in research. For information on accessing diagnostic archives, please refer to Appendix 1. |  |

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

* The “Chief Investigator” (CI).
* The “Applicant”
* The “Research Tissue Bank Curator”
* The “Tissue Bank Manager”

For the purposes of this document, this individual will be referred to as the Chief Investigator. The main purpose of the CI 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.

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| **When submitting applications, applicants should be aware that:** |

* In order to gain ethical approval for a research tissue bank, the application must be stored on HTA licensed premises and be approved by the relevant Designated Individual. 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).
* The Health Research Authority (HRA) has designated particular Research Ethics Committees to review applications from research tissue banks. It is strongly recommended that any application for ethical review be sent to a flagged REC for research tissue banks.  For more information, see the NRES website: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-tissue-banks-and-research-databases/>
* Please note that the DI will require at least 1 month 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 1.5.

Where the application relates to accessing diagnostic archives, please refer to Appendix 1.

* + 1. **NHS Management Review**

Under the Research Governance Framework, there is no requirement for NHS permission for research for the establishment of research tissue banks in the NHS.  Applications to NHS Research and Development (R&D) offices through IRAS are not required as all NHS organisations are expected to have included management review in the process of establishing the tissue bank and, where applicable, applying for licensing of a tissue bank.

For researchers wishing to access patients in Newcastle upon Tyne Hospitals NHS Foundation Trust, either when setting up a new NHS REC approved research tissue bank, or when conducting a new project under the banks ethical approval, the R&D department must be contacted to gain the relevant approvals/permissions (nuth.genericqueries@nhs.net).

* 1. **What are the conditions of ethical 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 Chief Investigators have a responsibility to ensure that they are aware of these conditions, and comply with all requirements. These conditions include the following requirements. For a full list of requirements, researchers must refer to their own specific conditions of approval:

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| * **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 banks access policy, which must be formally documented.  | C:\Users\nma47\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.Word\Access committee panel 2.png |
| 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.  |
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| * **STORAGE UNDER A HUMAN TISSUE ACT LICENCE**

Subject to conditions, the bank’s ethical approval extends to specific projects receiving non-identifiable tissue from the bank. The tissue does not then need to be stored on HTA-licensed premises for the duration of the project; nor does it need project specific ethical approval. If the research is not carried out in accordance with these requirements, specific project approval by a recognised REC will be required or, alternatively, the samples will need to be stored under a HTA licence.* **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 that 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.For further information on how to write an annual report, please refer to [NJRO-TISS-WI-003](https://g14784.ideagenqpulse.com/QPulseDocumentService/Documents.svc/documents/active/attachment?number=NJRO-TISS-WI-003) “How to write a Research Tissue Bank annual report”.  |

* **COMMUNICATION**

Research Tissue Bank Chief Investigators 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.
* **Register on the UKCRC Tissue Directory**

The **UK Ethics Committee Authority (UKECA)** have now made registration in the [UKCRC Tissue Directory](https://directory.biobankinguk.org/) a condition of the Research Ethics Committee (REC) favourable opinion for research tissue banks (RTB).

The Research Ethics Committee favour collection of tissue for future research use by research tissue banks, however, there is an expectation that this tissue is made visible to the research community. The UKECA are keen to maximise the re-use of samples and so will now expect Research Tissue Banks to register their collections on the UKCRC Tissue Directory. Registration will also be a condition of the five-year renewal of the ethical opinion. The benefits of making these tissue collections visible are that researchers from outside local networks will be able to find samples they may need and therefore reducing duplicate collections.

To register a research tissue bank on the directory, researchers must first create an account at the following link: <https://directory.biobankinguk.org/Register/Biobank>. For further information, please see the UKCRC website: <https://www.biobankinguk.org/directory-registration-favorable-terms/>

* 1. **How do I conduct a research project under a REC approved research tissue banks ethics?**

Researchers may wish to use a research tissue banks ethical approval to

* Access and use existing material already stored in the tissue bank
* Prospectively collect new material to establish a collection for future use in research projects.

Researchers must contact the research tissue banks Access Committee, stating what they wish to do, providing details on the samples required. The Access Committee will then review this request, in line with their access policy, to ensure that the proposal fits within the scope of the banks approval, and that there are sufficient samples available to meet the request. If there are multiple requests for the same samples, then the committee must prioritise requests based on scientific rationale to ensure the best use of the samples.

Where the project involves the prospective collection of new material from Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH) patients, projects must also be submitted for NHS review, via nuth.genericqueries@nhs.net.

* 1. **Closing an NHS REC approved Research Tissue Bank**

To close an NHS REC approved Research Tissue Bank, the Chief Investigator must submit a “Declaration of End of Study” form to the Research Ethics Committee that approved their bank. This form can be found on the HRA website at the following link.  <https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/>

If material from the bank is to be retained (e.g. under an research HTA licence, or transferred for use under an NHS REC approved project, this should be stated under section 5 of the form, providing reference details for the related licence number, or REC approval number.

End of Study Forms must be sent to the REC that approved the bank, copying in the NJRO R&D team (NuTH.genericqueries@nhs.net) and QA Team (humantissueresearch@ncl.ac.uk) to enable the bank to be marked as closed in the Newcastle Hospitals REDA system.

## Appendix 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.

Purely diagnostic archives do not need to be stored on HTA-licensed premises as no licensable activity would be taking place. However, the Human Tissue Act 2004 clearly provides that the storage of tissue for a ‘scheduled purpose' must be on licensed premises. The HTA’s position is that if a diagnostic archive releases tissue for research occasionally upon request, its status as a diagnostic archive is clear. However, if there is an expectation that tissue will be released on a regular basis, then it ceases to be a purely diagnostic archive, particularly where there are developed governance/decision-making structures and procedures for applying for tissue.

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 RTB. It 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 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 RTB.
* **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 RTB.

If you require a new licence, you need to complete an application via the HTA website (<https://www.hta.gov.uk/licence-application-guidance>).

If the archive is on a site that can be linked to existing HTA-licensed premises, you can apply for a satellite licence via the HTA website (<https://www.hta.gov.uk/policies/satellite-premises#Satellite Sites Application Forms>).

If you require an existing HTA licence e.g. a post mortem licence, to be extended to cover a diagnostic archive that is not yet functioning as a RTB, you need to email Licensing.Enquiries@hta.gov.uk quoting the HTA licensing 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.

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 a new HTA licence or sought an extension to an existing HTA licence. If you are aware of any other establishment that this applies to, please contact the HTA.

Further information on the consent requirements when accessing samples in a diagnostic archive are provided overleaf.

## Consent for accessing samples in diagnostic archives

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 1September 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.