1.1. **What is an annual 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. The Committee may request additional reports on the management of the Bank at any time.

It is important to note that 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.

1.2. **How do I write an annual report?**

The Health Research Authority (HRA) provides a template that must be populated, called the “Annual Report Form for Research Tissue Banks”. This can be found on the HRA website at the following address:


This form sets out the minimum content of the report and a template format, which may be adapted appropriately.

Importantly, this form does not have to be completed by the Research Tissue Bank curator themselves, as this responsibility can be delegated. However, the form should be signed by the tissue bank curator on the final page (declaration).

A help guide for how to complete this report is provided overleaf.
1.2.1. Help guide – writing an annual report

- **Section 1: Details of Tissue Bank Manager**

  In this section the name, address, telephone number and email address of the Research Tissue Bank Manager must be completed.
  - It should be noted that this individual may also be known interchangeably as the Chief Investigator “CI”, the Applicant, or Research Tissue Bank Curator.

- **Section 2: Details of the bank**

  | Title: | In this section, you must provide the full title of the bank, as taken from the IRAS application form. For example: The Human Developmental Biology Resource (HDBR) |
  | Establishment responsible for management of the bank: | Provide the name of the Institution responsible for the banks, for example: Newcastle University |
  | HTA licence number (where applicable): | If your research tissue bank stores relevant material under the Human Tissue Act (2004) you must provide the number of the licence. |
  | | • For Newcastle University, the Research Sector HTA licence number is Ref: 12534. |
  | | For banks not storing relevant material, please indicate this as “N/A” |
  | Designated Individual (where applicable): | If your research tissue bank stores relevant material under the Human Tissue Act (2004) you must provide the name of the Designated Individual named on this licence. |
  | | • For Newcastle University, the Designated Individual on the Research Sector HTA licence is Professor Andy Hall. |
  | | For banks not storing relevant material, please indicate this as “N/A” |
  | Main REC: | In this section, provide the name of the Research Ethics Committee that approved your bank – For example: Newcastle and North Tyneside 1 Research Ethics Committee |
  | REC reference number: | In this section, you must provide your REC reference number |
  | | For example for the HDBR bank this is: REC: 08/H0906/21 |

- **Section 3: Summary of activity for [period covered by report]**

  In this section the report asks for you to provide an overall summary of the bank’s activities during the year. In the section title, you must replace the text in brackets [period covered by report] with the dates for which the report applies.
For example, if your bank was approved in January 2013, and you are issuing your 2014 annual report insert [January 2013-January 2014]

The summary must then include the following information.

| Donor recruitment and sample collection | In your summary ensure you provide a summary of the number of donors that have been recruited in the reporting period, and the numbers and types of samples that have been collected. It is also useful to provide summary of the total number of samples which have now been collected by the bank.

For an example of how this could be documented, see below. Please note this is for information only, and reporting should be bank specific:

- Between the period [insert reporting period] the [insert tissue bank name] tissue bank received [insert number of donations] donations of [insert tissue types] for research. During this period [insert number of new donors] new individuals have registered prospectively as potential donors with another [insert number of potential donors] in process. There are now in excess of [insert number of registered donors] people registered with the bank as potential donors, with approximately [insert total sample numbers collected] stored in the bank.

| Release / use of samples | In your summary, provide an overview of how the samples that were collected were used. For example – were they used internally, or sent out externally for use by researchers at other institutions? If so, how was the release managed.

For an example of how this could be documented, see below. Please note this is for information only, and reporting should be bank specific:

- There have been [insert number of applications] applications for tissue during the period from [insert reporting period] and [insert sample numbers] samples have been issued. Of these applications [insert number] were from researchers outside the UK, [insert number] was from a commercial organisation, [insert number] were from other UK academic institutions, the remaining [insert number] were from within Newcastle University. All those external to Newcastle University have been subject to suitable Material Transfer Agreements.

As described in previous report, applications are formally approved by the tissue banks committee following circulation to the scientific group. The committee continues to meet at approximately [insert number] monthly intervals.

Attached is a list of all the applications detailing investigators and institutions requesting tissue and projects to be undertaken (see appendix 1).
| Collaborations with other banks /programmes | In your summary, provide information on any new collaborations that have been established in the last year. Where new Service Level Agreements/collaboration agreements have been implemented, these should be referred to. For example:  
The [insert tissue bank name] continues to collaborate with the [insert institution or network name]. New collaborative agreements have now been set up with [insert institution or network name] to [insert brief summary of basis of collaboration]. These collaborations have been formally documented in [insert details of SLA, collaboration agreement etc] |
| Donor engagement and publicity | In your summary, provide a summary of any activities that have been conducted by the bank in the last year to engage the public, or donors. For example, any new material that has been created (fliers, websites) any public lectures, charity involvement, conferences or communications that have been run to publicise the bank. |
| Any significant developments in the bank’s scope, operation or governance. | In this section, provide any updates on changes to the bank since the last report, including dates that these were approved. For example, if the bank has submitted any substantial amendments, been renewed, faced any changes to governance/operation. Any serious adverse events, breaches of conditions of approval, bank closure should also be summarised here. |

- **Section 4: Amendments**

In this section you must provide details of any substantial amendments that have been submitted for the bank in the reporting period.

Substantial amendments should be notified to the Committee and ethical approval sought before implementing the amendment. A substantial amendment generally means any significant change to the arrangements for the management of the Bank as described in the application to the Committee and supporting documentation.

The NRES Notice of Amendment form should be used to seek approval. The form is available at [http://www.nres.nhs.uk/applicants/after-ethicalreview/amendments/#Noticesofsubstantialamendment](http://www.nres.nhs.uk/applicants/after-ethicalreview/amendments/#Noticesofsubstantialamendment).

The following changes should always be notified as substantial amendments:

- Any significant change to the policy for use of the tissue in research, including changes to the types of research to be undertaken or supported by the Bank.
- Any significant change to the types of biological material to be collected and stored, or the circumstances of collection.
• Any significant change to informed consent arrangements, including new/modified information sheets and consent forms.
• A change to the conditions of generic approval.
• Any other significant change to the governance of the RTB.

If a substantial amendment has been submitted in the reporting period, select “Yes” on the form, and give the date and amendment number for each amendment made.

**Section 5 – Application for release of samples**

The form then asks you to append a listing of all applications made to the bank for release of samples during the reporting period, *together with a lay summary* (maximum 200 words) of the purpose of each of the approved project.

This must include any releases authorised following a further project-specific application to a REC, as well as those authorised under generic approval.

A table is provided in the form and the Research Tissue Bank Curator asked to populate these fields. This includes:

<table>
<thead>
<tr>
<th>Reference (optional)</th>
<th>If the RTB has issued an internal reference number to the project, this should be included.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title of project</td>
<td>Insert the full title of the project</td>
</tr>
<tr>
<td>Name of Chief Investigator</td>
<td>Insert the name of the Chief Investigator responsible for the project</td>
</tr>
<tr>
<td>Institution (name/address)</td>
<td>Insert the name and address of the Institution which applied for the release of samples</td>
</tr>
<tr>
<td>Samples/data requested</td>
<td>Insert a summary of the samples and data requested (e.g. number, tissue type, clinical data requested)</td>
</tr>
<tr>
<td>Outcome (e.g. approved, rejected, pending)</td>
<td>Insert the outcome of the application. N.B. For all approved projects, a lay summary is required (maximum 200 words) to summarise the project.</td>
</tr>
<tr>
<td>Additional comments (optional)</td>
<td>Insert any additional comments that have not been captured elsewhere. For example, any releases authorised following a further project-specific application to a REC rather than under the authorised generic approval.</td>
</tr>
</tbody>
</table>

**Section 6 – Declaration**

The tissue bank manager must then physically sign the report, including the date of submission.
1.3. Submitting annual reports

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.

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 (andy.hall@ncl.ac.uk).

Annual reports are reviewed each March by the Access and Governance Committee.

1.4. 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