

1 - Application Process

Sample feasibility check

Prior to submitting a VIVO Biobank Application Form, check the availability of the type and number of samples required for your study via email (enquiries@VIVOBiobank.org).

Please give as much detail as possible e.g. sex, age at diagnosis, cytogenetics etc. to enable the correct samples to be identified. This allows us to inform you what is available before you submit your application.

Application Form and supporting documents

The VIVO Biobank Application Form can be downloaded from the VIVO Biobank website (www.vivobiobank.org) or provided on request and completed electronically. Please note, there are no application deadlines.

Completed application forms must be submitted with the following documents:

- Curriculum Vitae(s)
- Grant Award Letter Confirming funding for the study, if available
- Grant Award or External Review Feedback, if available
- Documentation of regulatory approval for any animal experiments If applicable

Please note, it is not acceptable to complete the application form by referring to a pre-existing grant application attached to your application. All boxes on the application form must be completed.

It is essential that you complete the section on Patient and Public Involvement and Engagement. This is an important aspect of your application.

If you are an applicant from outside the UK, you must also provide evidence that your project has local governance and ethics approval in place before applying to access samples from the VIVO Biobank.

Completed application forms

A completed application form should include as much detail as possible on methodology, rationale, and plan of investigation.

Short summaries of any relevant prior publications / references (and associated figures) are welcome in the Scientific Background and Preliminary Data sections. Do not worry about including too much information, so long as it provides context it is welcome!

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Our application form also includes a section where you should outline any PPIE (Patient and Public Inclusion and Engagement) present within your study. This section requires a brief Lay Title and Summary (which may be included on our website to showcase supported projects), and two questions requesting details of PPI input to the project and evidence of public engagement. This section is an important part of the application and will be considered by the reviewers.

Once the application is completed, please send it along with all supporting documents to enquiries@VIVOBiobank.org. Upon receipt of a VIVO Biobank Application Form, it is initially screened for completeness and relevant supporting documents. Any obvious problems or omissions with the application are notified to the applicant as soon as possible.

2 - Review Process

Internal Review

All applications are reviewed on submission, by at least five Sample and Data Access Committee (SDAC) reviewers, made up of researchers, clinical practitioners, and PPIE representatives. If further information is required questions will be passed on through the Research Coordinator from the SDAC to the applicant, and in exceptional circumstances the applicant may be asked to attend one of the regular SDAC meetings to answer more technical questions.

There are three categories of review which will be determined by the SDAC team:

- A Fully funded with external review and requesting existing samples
- B Requesting existing samples but with no peer review supplied
- C Prospective collections, rolling projects, requests from commercial organisations, complex requests.

Applications categorised as A or B will undergo fast-track review.

Category C applications and any other applications where queries are raised will be reviewed by the next bi-monthly meeting of the committee.

Responsibility for final scientific approval for all applications resides with the SDAC.

External review (for funded applications)

If your study has been approved for funding by a national/international grant funding body or organisation and has been reviewed by an external panel of experts then this feedback will

be considered alongside your application by the SDAC. This will expedite the outcome and will likely require less additional questioning from the SDAC.

If funding for the project is part of a programme grant, this will not be considered as having been eternally reviewed, unless the reviews are submitted which specifically relate to the project detailed in the application.

Please note, applications which are not currently funded or funded by soft monies, or local charitable funds, and have not been reviewed by external experts, will be at the next regular SDAC meeting. You will be informed if your application falls into this category.

3 – Approval Process Outcome

After completion of the application review process, you will be notified of the outcome which can be one of the following categories:

- Approved
- Provisional Approval subject to satisfactory response to SDAC questions/comments
- Not Approved

VIVO Biobank projects (designated YY VIVO XX) will run for an initial period of 5 years, subject to appropriate funding being in place. After this initial 5-year period, a submission for extension must be submitted to the SDAC for approval. If approved, the study will continue for a further 5-year period (again subject to appropriate funding) before it ceases. At this point a new VIVO application will need to be submitted and a new VIVO Biobank Project reference issued.

4 – Research Ethics Committee (REC) Approval

If you are a UK based researcher and your project has been approved by the SDAC then it will not require further submission to a REC, if the project fulfils all the following criteria:

- The research is restricted to the prevention, detection, diagnosis, treatment and pathophysiology of cancers of children, teenagers and young adults.
- The application has been reviewed and granted scientific approval by the SDAC.
- The research will only use samples for which written consent has been obtained from
 patients and/or parents/guardians for storage and use of these samples for research
 purposes, existing holdings registered with the VIVO Biobank (formerly CCLG Tissue
 Bank or CellBank) or legacy sample collections stored for research and deposited in
 the VIVO Biobank with REC approval.
- No patient identifiable information will be released to researchers.



• The research does not influence individual patient healthcare. If research results in the incidental finding of a result with possible clinical significance the best course of action will be passed to the healthcare professional team in charge of the patient's care, by the SDAC Chair after consultation with the SDAC.

If your project does not fulfil all the above criteria, then you will need to obtain separate Health Research Authority (HRA) REC approval, in order to access samples and /or data from the VIVO Biobank.

5 - Sample Release

Once you have been granted SDAC approval for your study a Material Transfer Agreement (MTA) will be issued to you to sign off along with all relevant parties and/or collaborators.

- Upon receipt of the fully signed MTA, the Biobank team will issue a request to the Central Bank (Newcastle Biobank / UK Biocentre depending on sample type) and/or to centres to release the samples requested.
- Samples will be dispatched by the Central Bank Team and/or by pathology staff in centres, who will contact you directly to arrange the transport of samples.
- The researcher is responsible for the costs of delivery and packaging and will be invoiced prior to samples being dispatched.
- Paraffin embedded tissue generally resides within centres. If paraffin embedded tissue
 is requested, centres may not release the whole block. In this case, unstained sections
 on slides and/or curls in tubes may be requested for release (please note the
 researcher is responsible for the cost of cutting sections and curls, slides and transport
 costs).

6 - Remaining Samples

At the end of each research project, investigators are required to log any samples and sample derivatives surplus to their requirements. They should also include details of any FFPE blocks. This information is to be sent to the Sample and Data Access Committee who will decide if it should be made available for future research projects or if it should be destroyed. Further studies would require a separate submission to SDAC.

In cases where the tissue in question is very rare or the remnants are of high quality then the SDAC may approve additional testing beyond the scope of the original application (subject to an approved amendment), or for the sample to be sent back to the Central Biobank for potential use by other researchers.



7 – Annual Progress and End of Study reports

Annual progress reports for all studies must be completed and provided to the VIVO Biobank on a yearly basis. Failure to submit annual progress reports will disqualify a researcher from further access to samples from the Bank. Upon completion of the study an End of Study report must be completed.

8 – Publication Policy

All researchers who access samples from the VIVO Biobank are expected to publish their results in peer-reviewed scientific/medical journals, including negative results, if possible. Details of publications, posters and presentations arising from approved studies must be listed in annual and end of study reports.

For studies where VIVO samples are used, the VIVO Biobank should be acknowledged in publication as follows:

"Samples and data used in this study were provided by VIVO Biobank, supported by Cancer Research UK & Blood Cancer UK (Grant no. CRCPSC-Dec21\100003). Samples were released under VIVO project number YY VIVO XX."

This VIVO project number should be included in every publication, poster, and presentation.

VIVO

VIVO Biobank Applicant Guidelines V1.1

9 - Application Process Summary

1 Search for Suitable Samples

Check if suitable samples are available for your study by contacting the VIVO Biobank team at enquiries@VIVOBiobank.org

2 Complete your Application Form

Complete the VIVO Application Form electronically, referring to the 'VIVO Biobank Applicant Guidelines' document and liaising with your VIVO Biobank contact if you have any questions

3 Submit

Submit your application form and supporting evidence to either enquiries@VIVOBiobank.org or your VIVO Biobank contact

4 SDAC Review

Your application will be reviewed by the SDAC and you will be contacted if there are any questions/comments that require clarification

5 Decision

Your VIVO Biobank contact will let you know the outcome of your application within three weeks of submission (unless otherwise specified)

6 Material Transfer Agreement

If your application is successful, a Material Transfer Agreement will be drafted and sent to you and your legal representative for signing

7 Sample Release

Once the MTA is in place, samples will be picked out and a courier will be organised between the sending and receiving site

8 Annual Report / End of Study Report

Annual Reports are filed on a yearly basis throughout the life of the project. These should contain details of the analysis methods used. An End of Study Report is filed upon completion of the project which must include details of any remaining samples or derivatives