1 – Application Process

Check sample availability
Prior to submitting a CCLG Biological Study Application Form, check the availability of the type and number of samples required for your study, via email (tissuebank@cclg.org.uk) or contact the Tissue Bank Manager.

Biological Study Application Form and supporting documents
The Biological Study Application Form can be downloaded from the CCLG Tissue Bank website (www.cclgtissuebank.org.uk) and completed electronically.

Completed application forms must be submitted with the following documents:

- Curriculum Vitae(s)
- Grant Award Letter - Confirming funding for the study, if applicable.
- Supporting letters from collaborators - If applicable
- Documentation of regulatory approval for any animal experiments - If applicable
- Other supporting documents - i.e. grant funding application, external peer-review comments, etc.

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.

If you are an applicant from outside the UK, you must also complete a Biological Study Application Form and provide evidence that your project has local governance and ethics approval in place before applying to access samples from the CCLG Tissue Bank.

Completed application forms
Email the completed application and all supporting documents to tissuebank@cclg.org.uk or post to:

Christine Davidson (BSSG Administrator)
Children's Cancer and Leukaemia Group
Third Floor, Century House
24 De Montfort Street
Leicester LE1 7GB

Upon receipt of a Biological Study 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.

All applications are then checked for feasibility by the Tissue Bank team, then formally reviewed by the CCLG Biological Studies Steering Group (BSSG). The Scientific Review Coordinator co-ordinates the review process.
2 – Review Process

Internal review

All biological study applications are reviewed by at least three BSSG members and one or more independent expert reviewers and/or members of the relevant CCLG Special Interest Group, if the BSSG considers that more expert advice is required (unless the application has already been favourably scientifically reviewed by a recognised funding body or organisation). Responsibility for final scientific approval for all applications resides with the BSSG.

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, your application will not be sent for further independent external review provided the following conditions are fulfilled:

i. A grant award letter is submitted with the application.
ii. The completed biological study application form submitted does not differ from the application reviewed by the funding body, unless amendments were in response to advice from the external reviewers (amendments should be made clear in the application).
iii. If funding for the project is part of a programme grant, this will not be considered as having been externally 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 has not been reviewed by external experts, will be sent by the BSSG to at least two independent experts for review.

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

• Approved subject to satisfactory response to comments from BSSG
  Applicants must respond to comments within 8 weeks, failure to do so will result in the application being automatically withdrawn.

• Not approved

If more than one application is approved which competes for the same samples, prioritisation will be guided by the reviewers’ scores and comments. Final scientific approval resides with the BSSG.

4 – Research Ethics Committee (REC) approval

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

• 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 Tissue Bank or legacy sample collections stored for research and deposited in the Tissue Bank 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 BSSG Chair after consultation with the BSSG.

No samples or datasets will be released without confirmation of appropriate REC approval.

If your project does not fulfil all of the above criteria, then you will need to obtain separate Health Research Authority (HRA) REC approval, in order to access samples from the Tissue Bank.

5 – Sample release

Process for releasing samples from the Bank is as follows:

- Once you have been granted BSSG approval for the study, as required confirm sample required, review anonymised clinical pathology/cytogenetics or molecular genetics reports and view the Digital Imaging Hub (DIH) database to determine suitable paraffin embedded tissue samples (if application).
- 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 Tissue Bank team will issue a request to the Central Bank (Newcastle Biobank Resource) 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.
- Samples will be dispatched from the Central Bank within 25 working days of receiving the request.
- 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 the study any left-over samples or derivates (i.e. extracted DNA/RNA, etc) if correctly stored, should be returned to the Central Bank for storage and use in future studies. If sample quality has been compromised, dispose of these in accordance with the Human Tissue Act 2004, Codes of Practice. Paraffin embedded tissue blocks should be returned to the original centres or alternatively to the Central Bank where the blocks will be returned to the original centres or retained for use in future research.

7 – Annual Progress and End of Study reports

Annual progress reports for all studies must be completed and provided to the BSSG 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.

Report templates are available from the CCLG Website (www.cclgtissuebank.org.uk)
8 – Publication policy

All researchers who access samples from the CCLG Tissue Bank 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 all biological studies where CCLG samples are used, the CCLG Tissue Bank should be acknowledged in publication as follows:

“We thank the CCLG Tissue Bank, The CCLG centres and the ECMC Paediatric Network for the collection and provision of tissue samples, and especially thank the patients and families who have voluntarily donated them. The CCLG Tissue Bank is funded by Cancer Research UK and CCLG. Project number XXXX BS YY.”

XXXX BS YY is the BSSG project code assigned to the project upon approval. For information XXXX is the year the project was approved and YY is the sequential identifying number of this project assigned by the BSSG committee. This project number should be included in every publication, poster and presentation.
9 – Application Process Summary

1. **Search for suitable samples**
   Check if suitable samples are available for your study by contacting the Tissue Bank team at tissuebank@cclg.org.uk

2. **Complete your application form**
   Download the Biological Study Application Form (www.cclgtissuebank.org.uk) and complete electronically. Make sure you refer to the ‘Guidance for Applicants’

3. **Submit**
   Email the completed Biological Study Application Form and all relevant supporting documentation to tissuebank@cclg.org.uk

4. **Check and feasibility review**
   Your application will be checked for missing documents and information and will undergo a feasibility review by the Tissue Bank team.

5. **Biological Studies Steering Group review**
   Your application will then be reviewed by BSSG member or if required, by one or more independent expert reviewer(s).

6. **Decision**
   The Scientific Review Coordinator will let you know the outcome of your application within six weeks of submission.

7. **Material Transfer Agreement signed**
   If your application has been successful, a Material Transfer Agreement will be drafted and sent out for signing.

8. **Samples released**
   Once the Material Transfer Agreement has been signed, samples and associated data will be released to the researcher.

   Annual Reports are filed on a yearly basis throughout the life of the project. An End of Study Report is filed upon completion of the project.