

# GUIDELINES FOR APPLICATIONS TO THE CCLG TISSUE BANK

## Instructions for Applicants

(v2.0, November 2010)

### 1. Application process

- **Sample availability:**

Prior to submission of an application, applicants must establish whether the type and number of samples required for their study are potentially available. This information is available on-line:

For information regarding samples from the CCLG Tissue Bank see [www.tissue-bank.org.uk](http://www.tissue-bank.org.uk)

For information regarding samples from the Childhood Leukaemia Cell Bank see [www.cellbank.org.uk](http://www.cellbank.org.uk)

NB: It is not guaranteed that samples identified on the on-line databases will be available for release to approved projects.

- **Application Documents**

The review process for all applications is co-ordinated by the Biological Studies Steering Group (BSSG) Review Co-ordinator and will commence as soon as the application is received. All applications are initially screened for completeness and appropriateness of the submission. Any obvious problems or omissions from the application will be notified as soon as possible.

All applications must include:

1. BSSG Application Form\*
2. Curriculum vitae
3. Letter of approval from grant awarding body (if applicable)
4. Supporting letters from collaborators (if relevant)
5. Any other supporting documents\*

The forms can be downloaded from [www.cclg.org.uk/public/biological\\_studies/index.html](http://www.cclg.org.uk/public/biological_studies/index.html).

Documents 1 and 2 MUST be submitted electronically to Sue Thornton, CCLG Administrator, ([st22@leicester.ac.uk](mailto:st22@leicester.ac.uk)). It is preferred that all documents are sent electronically, however, documents 3 to 5 can be submitted as hard copies if electronic versions are unavailable.

\*Please note that it is NOT acceptable to complete the BSSG application form by referring to a pre-existing grant application attached to your application. All boxes on the application form must be completed within the spaces provided.

## 2. Review process

- **Internal review**

All applications will be reviewed by at least 2 members of the BSSG. Where appropriate, applications will also be reviewed by the Chair of the relevant NCRI Children's Cancer and Leukaemia Clinical Studies Group (CCL CSG) or the CCLG Interest Group.

If an application already has approval from the relevant NCRI CCL CSG or the CCLG Interest Group, a letter of approval should accompany the application.

- **External review**

**Funded applications:**

If your study has been approved for funding by a national grant awarding body and has been reviewed by an external panel of experts, your application will not be sent for further external review provided the following conditions are satisfied:

- i. The letter of award is submitted with the application and should include any conditions placed on the award, for example any amendments to the project.
- ii. The project submitted does not differ from the project reviewed by the fund awarding body, unless the amendments were in response to advice from the external reviewers (these amendments should be made clear in the application).
- iii. If the funding for the project is part of a programme grant, this will not be considered as having been externally reviewed, unless reviews are submitted which specifically relate to the project in the application.

**Applications which are not currently funded or funded on soft monies or local charitable funds do not require financial support:**

If a study falls into one of these categories and therefore has not been reviewed by an external panel of experts, it will be sent to at least 2 independent experts for review.

Applicants are invited to suggest expert reviewers for their application but it should be noted that alternative reviewers may be used.

## 3. Approval Process

All applicants will receive a response to their application as soon as possible following completion of the review process. The responses will be in one of three categories:

- Approved
- Approval subject to satisfactory responses to comments from Biological Studies Steering Group. (Applicants must respond to comments within 8 weeks. Failure to do so will result in the application being automatically withdrawn.)
- Not Approved

If projects which compete for the same samples are approved, prioritisation will be guided by the reviewers' scores (see below).

#### **4. Ethics Committee Approval**

For the CCLG to provide you with the tumour material you require and also the relevant clinico-pathological data, your project must have Research Ethics Committee (REC) approval. Projects approved by the BSSG are automatically granted REC approval under the auspices of the CCLG Tissue Bank protocol, provided the project fulfils the criteria detailed in Appendix 1. The letter of approval from BSSG will verify whether this includes MREC approval for the project. Any project not fulfilling these criteria will require separate approval by a REC. Applications for separate REC approval may be made through the CCLG Tissue Bank Manager, Gita Mistry ([ym60@le.ac.uk](mailto:ym60@le.ac.uk)). No samples can be released without confirmation of the appropriate research ethics approval.

#### **5. Release of Samples**

For release of samples from the Childhood Leukaemia Cell Bank, please refer to the Cell Bank Guidelines.

For release of samples from the CCLG Tissue Bank:

- After the project has been approved by the BSSG, the researcher should confirm their tissue requirements with the Tissue Bank Manager.
- Once tissue has been identified, anonymised pathology reports, where available, are sent to the researcher to confirm that the tissue is suitable. It is the responsibility of the researcher(s) to confirm the identity and suitability of the tissue received.
- If the tissue is suitable, the Tissue Bank Manager will issue a request to centres to release the material. Should the tissue be unsuitable, the CCLG Tissue Bank will be searched for alternatives, which will be released if available.
- When the material is available for dispatch, centres will contact the researcher to arrange the shipment of the tissue. Note, that the researcher is responsible for all shipping costs.
- When Formalin Fixed Paraffin Embedded tissue is requested, some centres will not release the entire block. In these situations they will cut unstained sections to be shipped to the researcher.

#### **6. Use of Samples and handling surplus material**

The released tissue can only be used for the CCLG studies to which it is specifically assigned. Surplus material must be stored by the researcher ready for release to another study. Where this is not possible, the tissue should be returned to the original tissue banking centre for storage, again the researcher is to pay all transport costs.

#### **7. Annual Reports**

Investigators must provide an annual report on the study to the CCLG BSSG and for Leukaemia and Leukaemia related studies to the Leukaemia Cell Bank Steering Committee. A more comprehensive final report should also be provided to both on completion of the study. Failure to submit annual reports will disqualify the investigator from further access to samples from the CCLG Tissue Bank and Leukaemia Cell Bank.

#### **8. Publications**

All manuscripts and abstracts resulting from analysis of CCLG biological specimens should be sent to the Chair of the CCLG Biological Studies Steering Group. Manuscripts and abstracts involving leukaemia material must be sent simultaneously to the Chairs of CCLG Biological

Studies Steering Group and the Childhood Leukaemia Cell Bank Steering Committee, and the wording "on behalf of the Children's Cancer and Leukaemia Group (CCLG)" must be placed at the end of the list of authors.

For biological studies requiring lesser input from the CCLG, or where the tissue samples form only part of a greater collection, then the CCLG should be included in the acknowledgements as follows:

"We thank the CCLG Tissue Bank and the Leukaemia Cell Bank for access to specimens. The Banks are funded by Cancer Research UK and Leukaemia and Lymphoma Research."

For Biological Studies using samples from the Childhood Leukaemia Cell Bank only, all publications should include the following acknowledgement:

"Primary childhood leukaemia samples used in this study were provided by the Childhood Leukaemia Cell Bank, in accordance with the requirements of the Children's Cancer and Leukaemia Group (CCLG) and the Cell Bank Steering Committee".

## Appendix 1

Extract from the CCLG Tissue Bank protocol:

Samples from the CCLG Tissue Bank and the Leukaemia Cell Bank will be made available to researchers if granted scientific approval by the CCLG Biological Studies Steering Group. Research proposals submitted to the CCLG Biological Studies Steering Group will undergo the following approval process:

All proposals will be reviewed for their scientific merit, feasibility and clinical relevance. Proposals will be reviewed by a scientific panel comprising at least 2 members of the CCLG Biological Studies Steering Group, by at least 2 independent expert reviewers and, where appropriate, the Chair of the relevant NCRI Clinical Study Subgroup or the CCLG Interest Group. Responsibility for final scientific approval rests with the CCLG Biological Studies Steering Group.

Projects approved by the CCLG Biological Studies Steering Group which fulfil all the following criteria, as required by Trent MREC, will not require further submission to a research ethics committee:

- The research is restricted to research on the prevention, detection, diagnosis, treatment and patho-physiology of children's cancer
- The proposal has been granted scientific approval by the CCLG Biological Studies Steering Group
- The research will only use samples registered in the CCLG Tissue Bank and the Leukaemia Cell Bank for storage and use for research purposes
- No patient identifiable information is to be released to researchers
- The research does not have direct impact on individual patient care nor is there feedback of results to individual patients

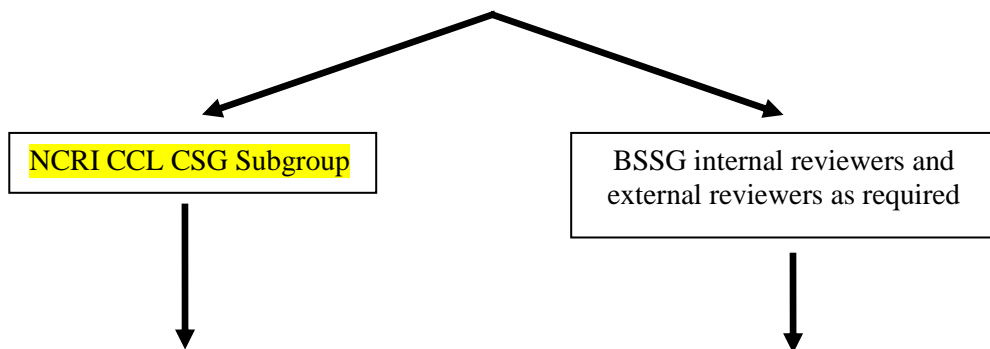
If any of the above criteria are not met, the project will be submitted to Trent REC for approval before samples can be released from the CCLG Tissue Bank or the Leukaemia Cell Bank. If a project has approval from another REC, this will be confirmed by submission of a copy of the COREC/NRES Application and letter of approval to the CCLG Biological Studies Steering Group.

## PROCEDURE FOR REVIEW OF A CCLG BIOLOGICAL STUDY APPLICATION

Individual wishing to carry out a biological study should first consult the Tissue Bank or the Leukaemia Cell Bank databases regarding potential availability of suitable samples

↓  
Researcher submits full application to CCLG Administrator

↓  
All applications sent to Scientific Co-ordinator  
(Leukaemia applications sent to the Leukaemia Cell Bank Manager)



Comments to CCLG Biological Studies Scientific Co-ordinator to co-ordinate the responses

