



# GUIDELINES FOR APPLICATIONS TO THE CCLG TUMOUR AND LEUKAEMIA BANKS

## Instructions for Applicants

### 1. **Fixed dates for submission of applications**

Applications to the Biological Studies Steering Group (BSSG) are reviewed 3 monthly. The closing dates for submissions each year will be:

15<sup>th</sup> February

15<sup>th</sup> May

15<sup>th</sup> August

15<sup>th</sup> November

The review process will commence immediately after each deadline.

### 2. **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 Tumour 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 BSSG Review Co-ordinator. 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 Administrative Assistant, [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 (send to: Sue Thornton, CCLG Administrative Assistant, CCLG Data Centre, Leicester).

*\*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.*

### **3. Review process**

- **Internal review**

All applications will be reviewed by at least 2 members of the BSSG and by the relevant CCLG Working Group.

Applications for samples from the Childhood Leukaemia Cell Bank will be reviewed by the CCLG ALL and/or AML Working Groups for approval prior to proceeding to further independent scientific review. Only if granted approval by the CCLG ALL and/or AML Working Group will the application proceed to scientific review by the BSSG.

If an application already has approval from a relevant Tumour Working Group, a letter of approval should accompany the application (this will prevent the application going to the Tumour Group a second time!).

- **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 or do not require financial support:**

If your 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.

#### 4. **Approval Process**

All applicants will receive a response to their application within 12 weeks of the closing date for submissions. 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 are approved which compete for the same samples, prioritisation will be guided by the reviewers' scores (see below) and the Tumour Specific Working Group.

#### 5. **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 Multi Centre Research Ethics Committee (MREC) approval. Projects approved by the BSSG are automatically granted MREC approval under the auspices of the CCLG Childhood Tumour and Leukaemia Banks protocol, provided the project fulfils the criteria detailed in appendix 1. Your letter of approval from BSSG will verify whether this includes MREC approval for your project. **Any project not fulfilling these criteria will require separate approval by a MREC**. Applications for separate MREC approval may be made through the CCLG Biological Studies Co-ordinator ([Gavin.Whyman@le.ac.uk](mailto:Gavin.Whyman@le.ac.uk)). No samples can be released without confirmation of the appropriate research ethics approval.

#### 6. **Release of Samples**

For release of samples from the Childhood Leukaemia Cell Bank, please refer to the Cell Bank Guidelines ([www.cellbank.org.uk](http://www.cellbank.org.uk)).

For release of samples from the CCLG Tumour Bank:

- After the project has BSSG and MREC approval to the researcher should confirm their tissue requirements with the Biological Studies Co-ordinator ([Gavin.Whyman@le.ac.uk](mailto:Gavin.Whyman@le.ac.uk)).
- 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 Biological Studies Co-ordinator will issue a request to centres to release the material. Should the tissue be unsuitable, the CCLG Tumour 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.

#### **7. 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 tumour banking centre for storage, again the researcher is to pay all transport costs.

#### **8. 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 the CCLG Tumour and Leukaemia Banks.

## **9. Publications**

All manuscripts and abstracts resulting from analysis of CCLG biological specimens should be sent to the Chair, CCLG of the Biological Studies Steering Group and, where appropriate, the relevant Tumour Working Group Chair.

Manuscripts and abstracts involving leukaemia material must be sent simultaneously to the Chairs of the Division of Leukaemia and Lymphoma and the Childhood Leukaemia Cell Bank Steering Committee,

For biological studies on clinical trial cohorts of patients from the CCLG, requiring active input from these respective bodies for analysis of clinical correlates, the wording "*on behalf of the Childhood Cancer and Leukaemia Group (CCLG)*" or "*on behalf of the CCLG Division of Leukaemia and Lymphoma*" 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 Childhood Tumour and Leukaemia Banks for access to specimens. The Childhood Tumour and Leukaemia Banks are funded by Cancer Research UK and the Leukaemia Research Fund."*

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 Leukaemia Research Fund Childhood Leukaemia Cell Bank, in accordance with the requirements of the Childhood Cancer and Leukaemia Group (CCLG) and the Cell Bank Steering Committee".*

## Appendix 1

### Abstract from the Childhood Tumour and Leukaemia Banks Protocol:

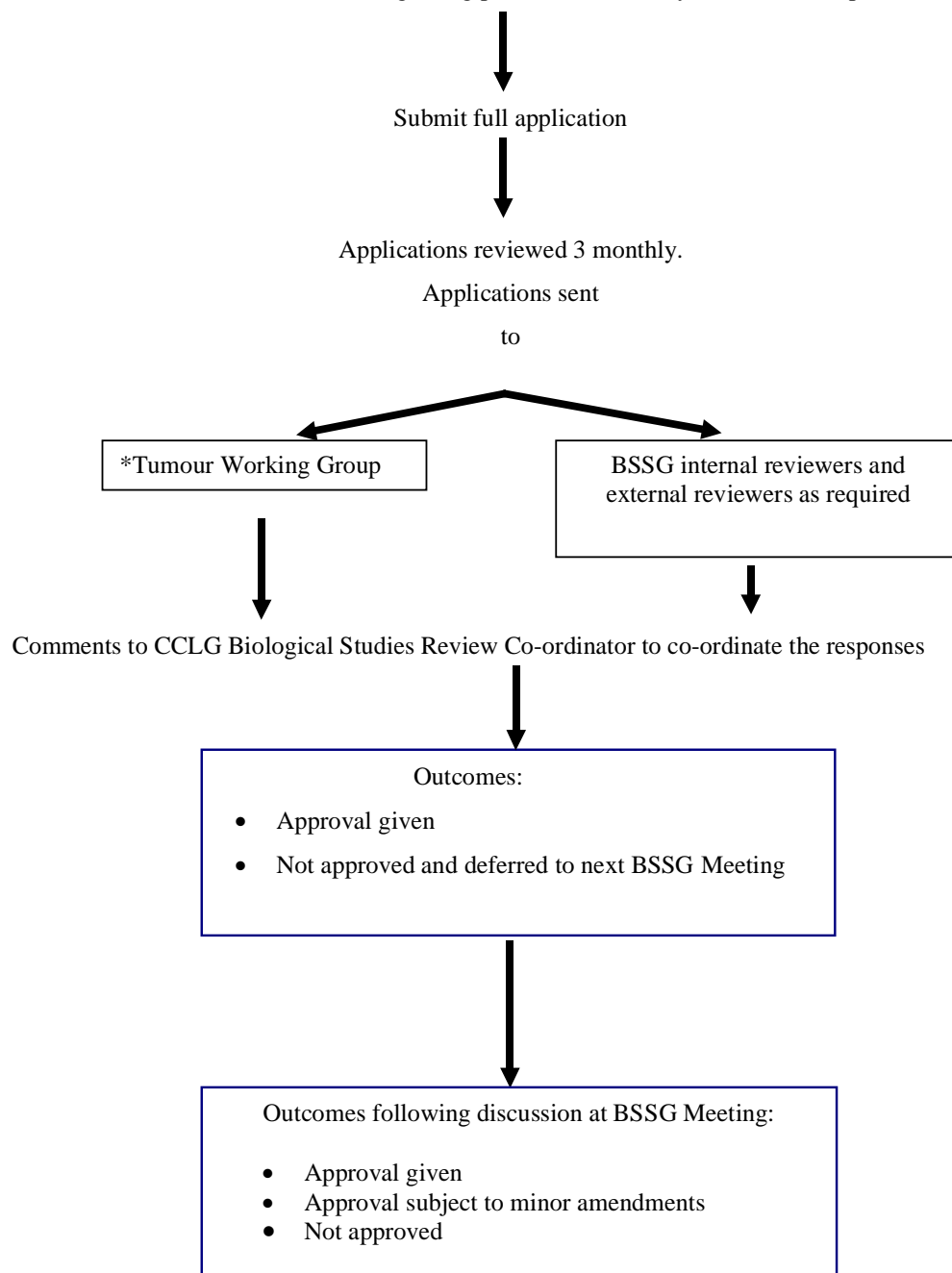
Samples from the Childhood Tumour and Leukaemia Banks will be made available to researchers if granted scientific approval by the CCLG Biological Studies Steering Group. Research proposals submitted to the CCLG Biological Studies Steering Group will undergo the following approval process:

- 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 the Chair of the relevant CCLG Tumour Working 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 Childhood Tumour and Leukaemia Banks for storage and use for research purposes
  - The Chief Investigator for the research proposal is based in the UK
  - There is no transfer of tissue outside the UK
  - 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 MREC for approval before samples can be released from the CCLG Tumour Bank or the Leukaemia Cell Bank. If a project has MREC approval from another REC, this will be confirmed by submission of a copy of the COREC 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 Tumour Bank or the Leukaemia Cell Bank databases regarding potential availability of suitable samples



\*NOTE: leukaemia projects to be approved by ALL/AML working Group prior to scientific review by the BSSG