

REVIEWING APPLICATIONS TO THE CCLG TISSUE BANK

Guidelines for Reviewers

(v.2.0, November 2010)

For all applications the Biological Studies Steering Group (BSSG) will identify:

- 2 internal reviewers with relevant expertise relating to the application (Biological Studies Steering Group members review should specifically consider the feasibility of the study)
- Pathologist review (if required)
- Relevant CCLG Tumour Interest Group Chair or NCRI Children's Cancer and Leukaemia Clinical Studies Group (CCL CSG) Chair.

For applications where no previous external review process is documented:

- At least 2 external reviewers

All reviewers will be sent the applications and the response forms electronically. Reviewers will be asked to confirm receipt of the request and their ability to undertake the review within the defined time period.

All reviewers will be required to submit their responses electronically within 6 weeks of receiving the request to review. A reminder will be sent to the reviewers after 4 weeks. A minimum of 2 external reviews will be accepted. In the event of major problems arising in obtaining timely external reviews, the applicants will be immediately notified that there may be a delay in the review process.

The reviewers will be asked to score the applications (1-4). Guidelines on scoring will be sent with each application. The responses will be collated and summarised by the Scientific Coordinator, including collation of the scores allocated. The applications will be assigned to one of two categories:

Approved: an approved study will fulfil the following criteria:

- Score an average of 3 or above in all 3 categories (science, clinical relevance and feasibility)
- No major concerns have been raised by any of the reviewers

Not approved: a study will not be approved if:

- The study scores an average of less than 3 in any of the categories (science, clinical relevance and feasibility)
- A major concern regarding the study is raised by any of the reviewers

All studies in the not approved category will be tabled for discussion at the following BSSG Meeting or telephone conference. The discussion at the BSSG Meeting will be lead by the designated internal reviewers. A decision on the response to the applicants will be made at that meeting.

Prioritisation

In the event of competing studies, prioritisation of the studies will be discussed at the BSSG and will be guided by the average score from each of the review categories, and the total score.

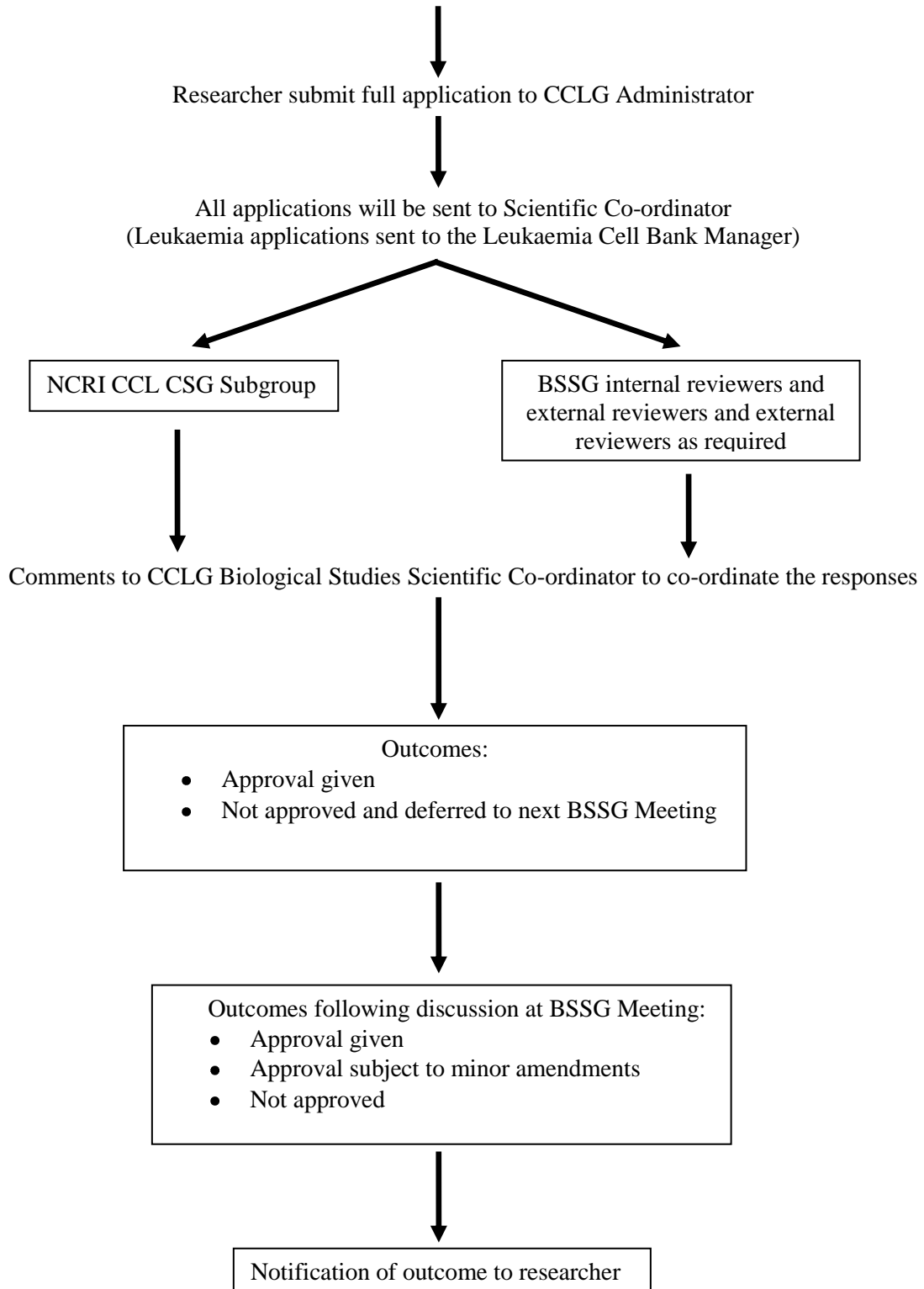
Responses to applicants

Response letters sent out to applicants by the Biological Studies Scientific Co-ordinator immediately following approval by the BSSG. For applications for leukaemia samples a copy of the approval letter will be sent to the Childhood Leukaemia Cell Bank Steering Committee. There will be 3 categories of response:

- 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

PROCEDURE FOR REVIEW OF A CCLG BIOLOGICAL STUDY APPLICATION

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



GUIDANCE FOR REVIEWERS: CRITERIA FOR SCORING APPLICATIONS

Please assign a score for the application in each of the categories.

Note for Biological Studies Committee Reviewers and Tumour Interest Groups or NCRI CCL CSG Subgroups: please score for feasibility of study and clinical relevance. Only score for scientific excellence if you are confident that you have relevant expertise in the subject of the application. Reviewers are reminded that projects that score <3 in any category are unlikely to be approved.

SCIENTIFIC EXCELLENCE

Score	1	2	3	4
	Unoriginal, scientifically flawed, would not add any new knowledge to the field	Scientifically valid but not novel	Scientifically valid, Original, innovative,	Scientifically excellent, Original, innovative, Likely to lead to data of major importance

FEASIBILITY OF STUDY

Score	1	2	3	4
	Samples requested would not be available or would not be available in the timescale requested, No justification for the number of samples requested Insufficient evidence that the group could undertake the work, For example no preliminary data	Samples available or would be available in the timescale requested, Valid justification for the number of samples requested. No pilot data to demonstrate technology established	Samples available or would be available in the timescale requested. Valid justification for the number of samples requested Good pilot data for the study demonstrating technology established.	Samples available or would be available in the timescale requested. Good pilot data for the study demonstrating technology established. Valid justification for the number of samples requested. Clearly deliverable goals in the time scale Evidence of maximum use of samples either within the project or through collaboration with other groups.

CLINICAL RELEVANCE OF STUDY

Score	1	2	3	4
	Project could be undertaken <u>without</u> the use of clinical samples	Project could not be undertaken without the use of clinical samples but clinical relevance not very clear	Project could not be undertaken without the use of clinical samples. Relevant to current clinical management	Project could not be undertaken without the use of clinical samples High clinical relevance With potential for important impact on clinical management in the future