



CCLG BIOLOGICAL STUDIES STEERING GROUP

APPLICATION REVIEW PROCESS

Applications will be reviewed four times a year. The closing dates for submissions will be 3 monthly:

15th February

15th May

15th August

15th November

The review process will commence immediately after each deadline.

The Biological Steering Group (BSSG) will identify:

For all applications:

- 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 Tumour Group Chair (all leukaemia projects will be reviewed prior by the ALL and/or AML Working Groups prior to further review)

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 (see attached) 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 BSSG,

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. The final decision on prioritisation will be made by the relevant tumour/leukaemia specific CCLG Working Groups.

Responses to applicants:

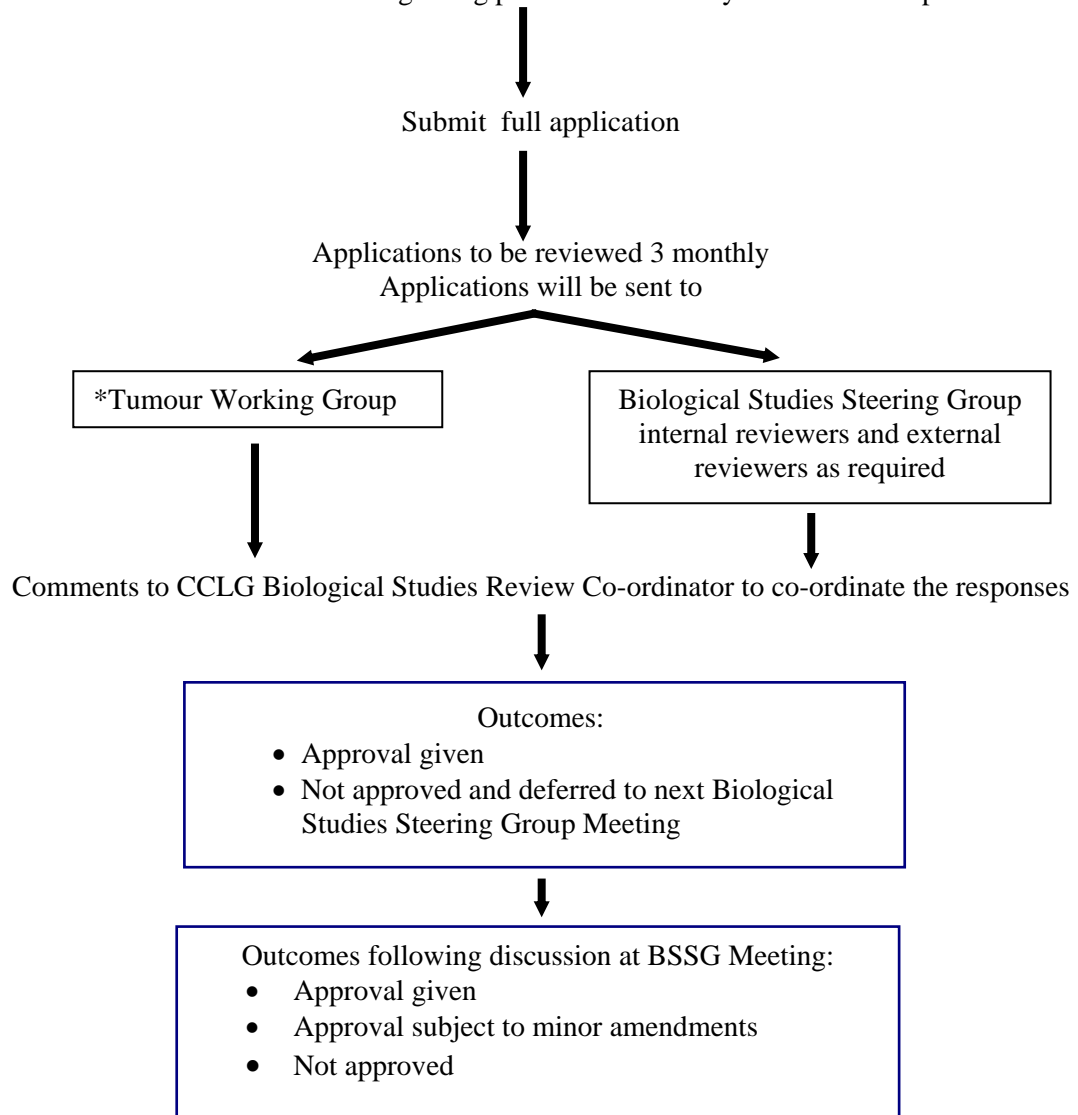
Response letters sent out to applicants by the BS Review Co-ordinator and copied to Division Head, relevant Working Group Chair, and members of BSSG, and Sue Thornton, CCLG Administrative Assistant for file. For applications for leukaemia samples a copy of the approval letter will be sent to the Chair of 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 Tumour Bank database or the Leukaemia Cell Bank regarding potential availability of suitable samples



*NOTE: leukaemia projects to be approved by ALL/AML working Group prior to scientific review by the Biological Studies Steering Group

GUIDANCE FOR REVIEWERS: CRITERIA FOR SCORING APPLICATIONS

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

Note for Biological Studies Steering Group Reviewers and Tumour Working Groups: 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 output of major importance

Feasibility of Study

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

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