

## **International Breast Cancer Study Group (IBCSG) Biological Protocols Working Group Policies and Procedures**

### **Introduction**

The Biological Protocols Working Group (BPWG) was established to ensure that projects using the IBCSG tissue resources address fundamental and relevant biological questions. To manage this valuable and limited resource it is essential that correct procedures are established to manage the resource and to critically assess projects that are proposed from both within and outside IBCSG to use the resource. The process must ensure that we only support the best science in the best place.

### **Biological Protocols Working Group (BPWG)**

The BPWG is a subcommittee of the IBCSG Scientific Committee, and is advisory to the IBCSG Executive Committee. It is composed of a Chairman and 10-15 members from among IBCSG investigators and non-IBCSG investigators. The membership contacts will be kept current by the IBCSG Translational Research Coordinator.

All members of the BPWG will have fixed terms of three years renewable through approval of the Executive Committee. Additional members can be proposed by the Chair, especially for intergroup trials.

NOTE: In the case of collaborative trials for which IBCSG is the Coordinating Group, the Trial Steering Committee as well as the IBCSG Executive Committee may be involved in selecting members and establishing whether the appointment is for a fixed term or ad hoc.

### **Tissue Bank**

The term "Tissue Bank" refers to all biological samples whether blood or tissue, frozen and formalin-fixed, paraffin-embedded, slides, TMAs, etc., wherever stored, that relate to IBCSG Trials. The IBCSG Tissue Bank can only be used after a project has been approved by the BPWG and the IBCSG Executive Committee.

### **Role of the Biological Protocols Working Group**

1. To advise the Executive Committee on the best use and priority of the tissue bank.
2. To advise on the appropriate biological questions and necessary tissue collection for proposed new trials and retrospective studies.
3. To act as the primary reviewing body for all project applications to use the tissue bank.

4. To advise the Executive Committee on the use of the tissue bank for applications that have been approved through other entity's review mechanisms. (e.g. NCI/NIH, National Charities, and Research Centers.)
5. To play a major role in seeking outside funding sources, such as through grant applications, to secure future funding of the tissue collection and research projects that use the tissue bank.
6. To monitor and report the progress of projects to the Executive Committee.
7. To advise the Executive Committee on ethical issues relating to the use of human tissue.

### **Submission of proposals and feasibility review**

A rigorous peer review process and the review of annual progress reports will ensure the proper scientific integrity of the projects.

All applications should be written in accordance with the format in Appendix 1, with inclusions identifying clearly the tissue resources needed and the funding available to cover the cost of providing this material, the amount of tissue required, material transfer, and details on data management and statistical considerations. The IBCSG Statistical Center has primary responsibility for the data analysis of all approved projects. Because the IBCSG trials are definitive randomized, controlled phase III trials, the specimen collections developed from these trials strongly lend themselves to correlative studies seeking to test and validate hypotheses. Given the highly annotated nature of these specimens, including the carefully collected patient outcome and other clinical data with which they are associated, the BPWG will give priority to validation studies of pre-existing hypotheses supported by data from previously performed pre-clinical and/or preliminary clinical studies. Preliminary data, including assay validation, are required.

Applicants must submit the proposal in electronic format, either Microsoft Word or PDF, to the IBCSG Translational Research Coordinator (Rosita Kammler) ([Rosita.Kammler@ibcsg.org](mailto:Rosita.Kammler@ibcsg.org)).

Proposals will first be sent for a feasibility review to determine the feasibility of the project in terms of the project goals, amount of tissue requested, statistical plan, and costs associated with central resources. The BPWG Chairman, BPWG Statistician, Senior IBCSG Pathologist, IBCSG Translational Research Coordinator, and IBCSG Executive Committee will conduct the feasibility review.

If the project is considered feasible, the BPWG Chairman will assign three referees, at least one of whom is a member of the BPWG and at least one of whom is an expert outside of the BPWG. One of the BPWG referees will serve as Primary Referee. Referees are not given the names of others being consulted on the same application.

### **BPWG assessment of applications**

The Primary Referee will present a summary of the proposal and the referees' opinions to the IBCSG Translational Research Coordinator ([Rosita.Kammler@ibcsg.org](mailto:Rosita.Kammler@ibcsg.org)). She will provide the summary to the members of the BPWG (either via email or at a BPWG

meeting). Members will decide by consensus which banding: alpha, beta or gamma is appropriate. Members then score alpha-banded applications (on a three point continuous scale) and these scores are subsequently averaged. On the basis of these average scores applications are allocated to the following categories:

**ALPHA:**       **High** - at forefront internationally, substantial impact to field.

**Medium** - Internationally competitive; significant contribution to field.

**Low** - Valuable contribution to field.

**BETA:**        Would add to understanding, and is worthy of support in principle, but which is considered to be of less priority and significance than alpha-rated work.

**GAMMA:**     Reject; flawed in scientific or technical approach, or repetitive of other work.

**RESUBMIT:**  Has potential but needs revision following feedback.

Note: The cutoff for access to the tissue resource is on ALPHA rating, but will also take into account availability of material and priorities for the use of the resource.

### **Ethics Committee Review**

The IBCSG Coordinating Center will submit a summary of the proposal to the IBCSG Ethical Committee. The Ethical Committee must approve all projects.

### **Results of Decision**

The BPWG Chairman and IBCSG Translational Research Coordinator will provide the applicant, the referees, the BPWG and the IBCSG Executive Committee with a report of the decisions taken with regard to the project they submitted or reviewed.

### **Receiving the Material**

Approved applicants must sign the IBCSG "Use of Tissue Agreement."

### **Reporting Progress and Results**

Applicants receiving tissue must submit a report annually to the Director of Scientific Administration on the progress of the project. Papers and presentations must be in compliance with the "IBCSG Publications and Presentation Guidelines."