



International Breast Cancer Study Group

IBCSG



ETOP·IBCSG
PARTNERS

Guidelines for Collaborative Research for ETOP IBCSG Partners Foundation Sponsored Clinical Trials (breast)

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For questions or comments contact the IBCSG Research Project Coordinator (stat_center@ibcsg.org).



ETOP IBCSG Partners Foundation

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1. Overview

The IBCSG welcomes collaborative research with participating investigators and other investigators with sound scientific proposals. This document presents guidelines for submitting a proposal and completing a research project.

A research project begins with a research question that may be answered through an analysis using the IBCSG clinical trial database. Research project proposals may be submitted at any time, but in general a research project may not be completed until the results of the primary objectives of the trial have been published. There may be exceptions, such as projects looking only at baseline variables, reporting on a safety observation, presentation of trial design and progress, etc.

1.1. Types of research projects

- 1.1.1. Research projects involving an analysis of collected clinical trial data performed by the IBCSG Statistical Center (StatC).
- 1.1.2. Clinical research projects involving a transfer of collected clinical trial data.
- 1.1.3. Statistical research projects generally involving the use of data collected for a clinical trial or relating to a clinical trial, in order to develop and/or illustrate application of statistical methods.
- 1.1.4. Research projects involving the reuse of IBCSG biospecimen bank data linked with collected clinical trial data, for example central pathology review data, genomic data.
- 1.1.5. Translational research working group-approved research projects, involving use of the IBCSG biospecimen bank (not covered in this document, see section 2.5).

2. Roles and responsibilities

2.1. IBCSG Research Project Coordinator and Scientific Committee Co-Chairs

The IBCSG Research Project Coordinator (RPCoord), in consultation with the IBCSG Scientific Committee Co-Chairs is responsible for reviewing, approving and prioritizing all IBCSG research projects. Specifically, they will assess feasibility, associated costs, timing, and the overall IBCSG scientific agenda. They will also periodically review the progress of projects. The Scientific Committee Co-Chairs are the ultimate authority on decisions regarding IBCSG-collaborative research projects.

2.2. Director of IBCSG Statistical and Data Management Center

The IBCSG Statistical and Data Management Center (SDMC) Director will also assess feasibility, associated costs, timing, and the overall IBCSG scientific agenda. In addition, the SDMC Director is responsible for approving all statistical research projects prior to submission to the IBCSG Scientific Committee Co-Chairs. The SDMC Director also advises the IBCSG Scientific Committee Co-Chairs and Steering Committees on all aspects of IBCSG collaborative research projects.

2.3. IBCSG Trial-Specific Steering Committee Chairs and Co-Chairs

Some trials, usually those involving multiple cooperative groups, are governed by a Steering Committee. When IBCSG is the coordinating group for a multi-group trial, the Steering Committee is also responsible for reviewing, approving and prioritizing research projects.

2.4. IBCSG Administration Director

If the proposal has received scientific approval, the Co-worker Administration at the IBCSG Coordinating Center (CC) will ensure that the required data sharing agreements for release of data for research purposes (see *Data Sharing Policy for IBCSG*) have been executed.

2.5. IBCSG Translational Research Working Group (TRWG)

The TRWG is an independent advisory group of scientists whose primary responsibility is to ensure that the IBCSG biospecimen bank is used appropriately for scientifically-sound research proposals. IBCSG members as well as non-members comprise the TRWG. The TRWG assesses the scientific value and the priority of biological specimen-based research projects and ensures the proper use of the material. These guidelines do not cover research projects that require TRWG approval, which can be found on the BioBank/Translational Research section of the IBCSG website (<https://www.ibcsg.org/en/patients-professionals/biobank>).

3. Research projects

Research projects use data previously collected for a clinical trial, substudy, and/or reuse of data arising from biospecimens, to address a specific hypothesis or other purpose. Table 1 details the procedural guidelines for the various types of projects using the clinical trial database for IBCSG trials.

* The IBCSG website (<https://www.ibcsg.org/en/patients-professionals/clinical-trials/open-trials>) has limited information publicly available and reports etc., available to members. If without member login credentials, for information on accessing content for a specific trial, email webmaster@ibcsg.org.

Table 1. Collaborative Research Procedures for Using the Clinical Trials Database for IBCSG Trials

	<i>Types of research projects</i>			
	1.1.1. Research projects involving an analysis of collected clinical trial data, performed by the IBCSG StatC	1.1.2. Research projects involving an analysis of collected clinical trial data involving data transfer	1.1.3. Statistical research projects of collected clinical trial data involving data transfer	1.1.4. Research projects involving reuse of biospecimen bank data with collected clinical trial data
Research proposal preparation	<ol style="list-style-type: none"> Formulate relevant research question(s). Review the most recent related Biostatisticians' Report, papers, presentations, etc., available on the Clinical Trials section of the IBCSG website* Review previous work by others relating to the project. Prepare a 1–3-page proposal including the following items: <ul style="list-style-type: none"> <i>Name, address, phone, and e-mail address of the investigator</i> <i>Project title</i> <i>Research question(s)</i> <i>Brief research plan including background and objectives, project design, description of the analytic cohort</i> <i>Description of suggested tables and figures</i> <i>Proposed timeline</i> <i>Availability of funding</i> Email the proposal to the IBCSG RPCoord (stat_center@ibcsg.org) who is also available to advise the investigator on the preparation of the proposal. 	<p>Follow steps 1 through 5 in column 1.1.1; the exception is <i>Description of suggested tables and figures</i>: provide: (a) a general description of data items needed; and (b) proposal for data transfer, which must specify the specific data items / variables to be transferred.</p>	<p>Follow steps 1 through 5 in column 1.1.1; the exception is <i>Description of suggested tables and figures</i>: provide: (a) description of the statistical method being tested or illustrated including why IBCSG data are appropriate; (b) general description of data items needed; and (c) proposal for data transfer, which must specify the specific data items/variables to be transferred.</p>	<p>Follow steps 1 through 5 for research project type 1.1.1 or 1.1.2, depending on whether the analysis is performed at IBCSG StatC or involves data transfer.</p>
Research proposal approval	<ol style="list-style-type: none"> The RPCoord will submit the proposal for review by the SDMC Director and IBCSG Scientific Committee Co-Chairs to determine feasibility, associated costs, timing, and priority. 	<ol style="list-style-type: none"> Follow steps 1 through 3 in column 1.1.1. 	<ol style="list-style-type: none"> Follow steps 1 through 3 in column 1.1.1. 	<ol style="list-style-type: none"> Follow steps 1 through 3 in column 1.1.1. The investigator who originally generated the data from biospecimens will also be

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	<p>2. The project proposal, along with the assessment from the SDMC Director and Scientific Committee Co-Chairs, will go to the relevant Steering Committee Chair (if there is one) for review and approval.</p> <ul style="list-style-type: none"> • Trial Steering Committees may have their own policies and procedures for reviewing, approving, and prioritizing research projects. <p>3. The RPCoord will inform the investigator regarding whether the project has been accepted and other details. <i>If accepted, a research project number will be assigned.</i></p>			contacted during the review process.
Statistician assignment and determination of data transfer details, if applicable	<p>1. The SDMC Director will assign a Research Project Statistician who will directly collaborate with the investigator on the following steps:</p> <ul style="list-style-type: none"> • Finalizing the proposal. • Preparing a statistical analysis plan. • Preparing a research project report. • Preparing the manuscript. 	<p>1. The SDMC Director will assign a research project statistician, who will directly collaborate with the investigator on the following steps:</p> <ul style="list-style-type: none"> • Finalizing the proposal, especially definition of the analytical cohort and items to be transferred. • Determining the details of the secure transfer, including where to send the data and eventually confirming receipt of data. • Preparing a statistical analysis plan and submit it to the Research Project Statistician for approval. 	<p>1. The SDMC Director will assign a research project statistician, who will work with the investigator on the following:</p> <ul style="list-style-type: none"> • Clarifying definition of the analytical cohort and items to be transferred. • Determining the details of the secure data transfer, including where to send the data and eventually confirming receipt of data. If treatment assignment information is critical to the statistical question being addressed, provisions must be made for review and approval by the SDMC Director prior to any presentation or publication. 	<p>1. Follow steps for research project type 1.1.1 or 1.1.2, depending on whether the analysis is performed at IBCSG StatC or involves data transfer.</p>
Agreements, funding and data transfer, if applicable	<p>1. Funding: Funding for the project must be in place before proceeding; this will be handled by the Head Finances at the CC.</p>	<p>1. The RPCoord will coordinate with the Co-worker Administration at the CC who puts into place the required</p>	<p>1. Follow step 1 in column 1.1.2.</p>	<p>1. Follow column 1.1.1 or 1.1.2, depending on whether the research project involves data transfer.</p>

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	2. Agreement: Acknowledgment of collaborative research guidelines and Pubs & Present Guidelines	agreements prior to data transfer, and addresses finances, IP, etc.		
Research project progression expectations	<p>1. The investigator prepares a manuscript draft based on the report. Generally the investigator is responsible for preparing the introduction and discussion, and the statistician is responsible for preparing the methods (with some exceptions) and results (including tables and figures) The investigator, along with the statistician, discusses and prepares amended or supplementary reports as needed.</p> <p>2. The collaborating investigator should keep the IBCSG Research Project Statistician informed as the project progresses (at least annually until publication or a decision to abandon the project).</p> <p>3. A project status update is required annually until the completion of the project. The RPCoord may request the update if needed.</p>	<p>1. Follow steps 1 through 3 in column 1.1.1. In step 2, Collaborating investigator’s progress updates to the IBCSG research project statistician should include receipt of reports created by the collaborating investigator’s statistician.</p>	1. Follow steps in column 1.1.2.	1. Follow column 1.1.1 or 1.1.2 depending on whether the research project involves data transfer.
Research project publication / presentation preparation and submission	<p>1. All manuscripts, abstracts and presentations prepared must conform to the “Guidelines for Publications and Presentations for IBCSG trials”</p> <p>2. The IBCSG Publications Coordinator must receive the manuscript (or abstract or presentation) prior to distribution for review among authors (before submission to a journal or congress).</p> <p>3. The Publications Coordinator will ensure that the authorship, acknowledgement, appendix of participants, funding sources, etc. as appropriate appear correctly and according to the “Guidelines for Publications and Presentations of IBCSG trials.”</p> <ul style="list-style-type: none"> The Publications Coordinator will also ensure that any manuscript, abstract, or 	1. Follow steps in column 1.1.1.	<p>1. Follow step 1 in column 1.1.1.</p> <p>2. The Publication Coordinator should receive the manuscript prior to submission.</p> <p>4. The Publications Coordinator will ensure that the authorship, acknowledgement, etc appear correctly and according to the “Guidelines for Publications and Presentations of IBCSG trials.”</p> <p>5. The Publication Coordinator should receive an electronic copy of the published manuscript.</p>	1. Follow steps in column 1.1.1.

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	<p>presentation is reviewed and approved by the Scientific Committee Co-Chairs and/or, Steering Committee.</p> <p>4. The investigator should keep Publications Coordinator updated about manuscript status, including opportunity to review proofs with regard to items about in step 3.</p> <p>5. The Publication Coordinator should receive a final electronic copy of the (e)-published manuscript (w/supplements).</p>			
Research project archiving	<p>1. The Research Project Statistician will ensure that reports, supplements, and manuscript drafts are archived.</p>	<p>1. The RPCoord will archive the securely transferred dataset and documentation, reports and supplements and manuscript drafts from collaborators.</p> <p>2. The RPCoord will acknowledge receipt of the items in step 1 above.</p>	N/a	N/a

**N/a = not applicable*

4. References

- Data Sharing Policy for IBCSG Trials Dec 2022
- Guidelines for Publications and Presentations of IBCSG Trials 2.2 Dec 2022
- IBCSG Statistical Center SOPs: Research Projects (02-03); Data Sharing (03-05); Statistical Analysis Plan for IBCSG Clinical Trials (02-01)