



International Breast Cancer Study Group

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## Guidelines for Publications and Presentations of IBCSG Trials

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## **1. OVERVIEW**

The IBCSG welcomes cooperative participation in the conduct of clinical trials with the understanding that there will be rules to govern the development of manuscripts and designating authorship.

## **2. GOVERNING BODIES**

### **2.1. Foundation Board**

The ETOP IBCSG Partners Foundation Board is the governing body of the ETOP IBCSG Partners Foundation, which is a foundation under Swiss law. The Foundation Board is responsible for the strategy, finances, the management structure, overall supervision and the mission of the Group.

### **2.2. Executive Committee**

The Executive Committee is a subgroup of the Foundation Board that supervises the execution of the resolutions, initiates and implements the scientific activities together with the Scientific Committees, and supports and oversees the Director of the ETOP IBCSG Partners Foundation.

### **2.3. Scientific Committee (Breast)**

The primary role of the IBCSG Scientific Committee is to actively support and advise the Foundation Board on all scientific matters relating to the purpose and the activities of the Foundation. The Committee's principal tasks include the initiation, evaluation, planning and monitoring of clinical trials and translational research projects. For trials without a trial-specific steering committee, the Scientific Committee is responsible for trial oversight and review of all IBCSG manuscripts and presentations. (see 2.5).

### **2.4. Scientific Committee Co-Chairs (Breast)**

The primary role of the IBCSG Scientific Co-Chairs is to oversee the integrity of the scientific objectives of the clinical trials and translational research. Specific responsibilities related to the scientific publications and presentations are detailed below (see Sections 4 and 5).

### **2.5. Trial-Specific Steering Committee**

Some trials, usually Intergroup trials involving multiple cooperative groups are governed by a steering committee. When ETOP IBCSG Partners Foundation is the sponsor for an intergroup trial, the steering committee is advisory to the Foundation Board. These Guidelines are presumed to have been accepted by the trial-specific steering committee; a trial-specific publication and presentation policy would supersede these Guidelines.

### **2.6. Translational Research Working Group (TRWG)**

The TRWG is a self-governing group of scientists whose primary responsibility is to ensure that the IBCSG bio-specimen bank is used appropriately for scientifically-sound research proposals. IBCSG members as well as non-members comprise the TRWG. The TRWG is advisory to the Foundation Board and assesses the scientific value and the priority of tissue-based research projects and ensures the proper use of the material.

### **3. TYPES OF TRIALS**

#### **3.1. Intergroup Trial, with ETOP IBCSG Partners Foundation as the sponsor**

The trial steering committee assumes governance over this category of trials. In the event there is not a steering committee, the IBCSG Scientific Committee governs the trial. Both the steering committee and the IBCSG Scientific Committee are advisory to the ETOP IBCSG Partners Foundation Board. The guidelines in Appendix I apply to these types of trials.

Examples: BIG 1-98, SOFT, TEXT, CASA, SOLE, CALOR, PANACEA, POSITIVE, SNAP, etc.

#### **3.2. IBCSG Trial (sponsored by ETOP IBCSG Partners Foundation)**

An IBCSG trial is not an intergroup trial, although an agreement may enable some other groups to participate. The Guidelines in Appendix I also apply to these types of trials, the primary difference being the governing body, if there is no trial steering committee. The IBCSG Scientific Committee governs these trials (rather than a trial steering committee) and is advisory to the ETOP IBCSG Partners Foundation Board. The guidelines in Appendix I apply to these types of trials.

Examples: Trials I-IX; 10-15, 22, 23, TREND, METEORA-II, etc.

#### **3.3. Intergroup Trial, with IBCSG as Participating Group**

For intergroup trials in which IBCSG is a participating group, the coordinating group's guidelines are used rather than IBCSG. Generally, IBCSG assigns an IBCSG Study Chair, who may be part of the trial-specific steering committee, writing committee, etc. There are no guidelines for such trials in this document.

Examples: BIG 02-98, IES, HERA, ALTTO, MA.27, APHINITY, etc.

### **4. TYPES OF PUBLICATIONS**

#### **4.1. Clinical Trial Primary Results and Updates**

These papers present the first results of the primary objectives of the clinical trial or an update of the primary objectives after longer follow-up. The guidelines in Appendix I apply to these types of trials. In the event a trial or trials was prospectively designed with two or more primary research questions (e.g., 2 x 2 design, 2 or more primary analyses), or trials are prospectively designed to be combined, each publication is considered "primary results." If an update is appropriate, the Scientific Committee Co-Chairs and the trial steering committee will determine when, whether to combine trials, etc.

Examples: BIG 1-98 monotherapy, BIG 1-98 sequential therapy, Trial 13-93 tamoxifen, Trial 13-93 and 14-93 gap, 12-93 and 14-93 toremifene, SOFT and TEXT AI question (T+OFS vs. E+OFS), SOFT OFS question (T+OFS vs. T), 9-year update of CALOR, etc.

## 4.2. Clinical Trial Substudy Primary Results and Updates

Substudy publications present the (primary or updated) results of the primary objectives of a clinical trial substudy. The guidelines in Appendix I apply to these types of trials.

Examples: BIG 1-98 Cognitive Function, BIG 1-98 Bone, SOFT-EST, TEXT-Bone, POSITIVE POCS

## 4.3. Research Projects

Research project publications use data collected for a clinical trial, substudy, or other pre-planned sources to address a specific hypothesis or other purpose. The guidelines in Appendix II apply to these projects. Research projects fall into two categories:

**4.3.1.** The data analysis is performed at the **IBCSG Statistical Center**, where a report is prepared.

Examples: body mass index and treatment, prognostic value of tumor grade, patterns of recurrence, impact of body mass index, etc.

**4.3.2.** The IBCSG **provides data from the clinical trials database to another collaborating statistical group** to conduct the statistical analysis in collaboration with the IBCSG Statistical Center.

Examples: BIG 1-98 CTS5 validation, molecular profiling, etc.

## 4.4. TRWG-Approved Research Projects (Translational)

TRWG-approved project publications involve data obtained from the use of the IBCSG bio-specimen bank, usually in combination with clinical trial data. The TRWG review process is more rigorous than the general research projects described above, mainly because our bio-specimen resource is limited. The guidelines in Appendix III apply to these types of projects. TRWG-approved research projects fall into two categories:

**4.4.1.** The results of the translational assessment are collected at a laboratory and **submitted to the IBCSG Statistical Center**, where an analysis and a report are prepared.

Examples: BIG 1-98 CYP2D6, Trials VIII and IX p27/SKP2.

**4.4.2.** The results of the translational assessment are collected at a laboratory, and **the laboratory or other collaborating statistical group conducts the statistical analysis in collaboration with the IBCSG Statistical Center.**

Examples BIG 1-98 Genomic Grade Index, BIG 1-98 gene expression projects, VIII and IX p53.

#### **4.5. Statistical Research Projects**

Statistical research project publications generally use data collected for a clinical trial or related to a clinical trial, in order to develop and/or apply statistical methods. These projects are *not* intended to address a clinical question. The guidelines in Appendix IV apply to these types of projects. These projects also fall into two categories.

##### **4.5.1. Statistical projects conducted primarily at the IBCSG Statistical Center.**

Examples: STEPP papers, Q-TWiST, selective crossover for BIG 1-98, HERA, guarantee-time bias.

##### **4.5.2. Statistical projects conducted at other institutions upon receiving data from the IBCSG database.**

Examples: QL data for non-ignorable missingness, quality-adjusted survival.

### **5. CONDITIONS AND CLARIFICATIONS**

#### **5.1. Appendix of Participants**

**5.1.1.** For manuscripts of primary results and updates of IBCSG trials, Substudies, and QoL results, an appendix should be submitted (often published on-line only) with the paper that identifies relevant offices, participating groups and centers, and, at a minimum, the names of the principal investigators and/or contributing pathologists from each institution.

**5.1.2.** The IBCSG Scientific Committee Co-Chairs will determine whether the appendix is required.

**5.1.3.** The appendix may be limited to centers that have contributed a minimum number of patients, depending on overall accrual. The Scientific Committee Co-Chairs will determine the exact cut-off, if any, for a given trial.

**5.1.4.** The Publications Coordinator will provide the appendix, customized to the analysis cohort, with input from the IBCSG Trial Coordinator.

**5.1.5.** The participating center Principal Investigator or Participating Group representative is responsible for determining what names go in the appendix from his/her institution or Group, and for re-reviewing during author review.

#### **5.2. Investigator no longer participating in IBCSG or not available to complete the project**

**5.2.1.** In the event that the investigator who prepared the project proposal is no longer participating in the IBCSG, the Scientific Committee Co-Chairs will determine if the investigator should continue as the research project investigator.

**5.2.2.** In the event that the investigator who prepared the project proposal is no longer interested or available to complete the project, or does not complete it in a timely manner,

the Scientific Committee Co-Chairs will seek and assign a new research project investigator.

### 5.3. Responsibility for assigning authorship

**5.3.1.** The IBCSG Scientific Committee Co-Chairs have ultimate authority on authorship decisions for all abstracts and manuscripts using IBCSG clinical trial data, through the Publications Coordinator, unless otherwise specified by accepted trial-specific policies.

**5.3.2.** Research project investigators or Study Chairs **should not promise authorship** to collaborators without the written (e.g. email) agreement of the Publications Coordinator.

### 5.4. Policy for TRWG-approved project investigators and other collaborating investigator

#### 5.4.1. Situation

5.4.1.1. IBCSG trial patient data and tissue is shared with TRWG-approved investigator, e.g., for gene expression profiling.

5.4.1.2. The profiling is completed by the TRWG-approved investigator.

5.4.1.3. A collaborating investigator (not involved in the original TRWG-approved project) requests that the TRWG-approved investigator assess a gene signature using IBCSG data and gene expression results.

5.4.1.4. The collaborating investigator prepares a paper or abstract summarizing the results, possibly to be presented with the results from other datasets.

#### 5.4.2. Requirements for abstracts and manuscripts

Acknowledgement includes: We thank the ETOP IBCSG Partners Foundation for sharing data from the [IBCSG trial name or number] trial.

##### 5.4.2.1. Authorship

- TRWG-approved investigator(s).
- IBCSG statistician if appropriate contribution.
- Authorship should **not** include “for the IBCSG.”

#### 5.4.3. Review of abstract or manuscript

5.4.3.1. Submit to IBCSG Publications Coordinator **at least 5 working days** prior to journal submission. Publications Coordinator will determine if further review is necessary by the trial steering committee, or if none exists, the IBCSG Scientific Committee, and whether acknowledgement is adequate.

5.4.3.2. If statistical guidance is required, an early draft should be sent to the Publications Coordinator to establish statistical collaboration.

#### **5.4.4. Publication cost responsibility**

- 5.4.4.1. Any publication costs incurred for IBCSG clinical trial primary results and updates, substudy primary results and updates (Appendix I) will be the responsibility of ETOP IBCSG Partners Foundation.
- 5.4.4.2. Any publication costs incurred by research project investigators for approved projects will be the responsibility of the lead research project investigator. All other responsibilities of research project investigators are detailed in the appendices.

## **6. Appendices**

- I. Clinical trial primary results and updates, substudy primary results and updates
- II. Research projects
- III. TRWG-approved research projects
- IV. Statistical research projects
- V. Abstracts and Presentations

## Appendix I: Clinical Trial Primary Results and Updates, Substudy Primary Results and Updates

	<b>Clinical Trial Primary Results/Updates</b>	<b>Clinical Trial Substudy Primary Results/Updates</b>
<b>Description of Publication</b>	Manuscripts that present the primary or updated results of the primary objectives of the clinical trial. In the event a single trial is prospectively designed with two or more primary research questions (e.g., 2 x 2 design, 2 or more primary analyses), each is considered “primary results.”	Substudy manuscripts that present the results of the primary objectives of a clinical trial substudy, including primary results and subsequent results. Substudy results may be added to primary/updated results manuscript as deemed appropriate by the trial steering committee, or if none exists, the IBCSG Scientific Committee; or IBCSG Scientific Committee Co-Chairs.
<b>Timing of Publication</b>	When follow-up, number of events, or other criteria meet the protocol-defined timing, or when deemed appropriate by the trial steering committee, or if none exists, the IBCSG Scientific Committee; or IBCSG Scientific Committee Co-Chairs.	If the manuscript includes clinical trial patient outcome data, substudy results should only take place after the publication of the clinical trial first results. If the manuscript does not include clinical trial patient outcome data, it may be published prior to the first results (e.g., design of trial, methodology, etc).
<b>Authorship Guidelines</b>	<p>First author: trial study chair Second author: trial statistician NOTE: First and second author may be reversed to reflect the amount of effort or intellectual input (or co-first authors). Third, fourth, fifth authors: major contributors to the writing of the manuscript or conduct of the trial. May include (but is not limited to) trial co-chair(s), statistician, or participating center investigator. Sixth and higher: principal investigators (or designee) from the highest-accruing groups and/or centers; IBCSG staff who have contributed to the success of the trial; scientists who have made a major contribution to the preparation of the manuscript. The policy is one author at these centers/groups regardless of accrual, the site PI/group designee may forego authorship for a colleague (e.g., for updates); exceptions are decided by Scientific Committee Co-Chairs. Last author: the “senior” author is someone who has had a major impact on the success of the trial. NOTES: In the event that the trial has 2 or more co-chairs in lieu of a study chair, the co-chairs and trial statistician will determine authorship order in collaboration with the Publications Coordinator and Scientific Committee Co-Chairs; in this situation co-first and/or co-senior authors may be considered. For updated results, changes in PI and/or center compliance with submitting follow-up or other requested data should also be considered.</p>	<p>First author: substudy chair Second author: substudy statistician NOTE: First and second author may be reversed to reflect the amount of effort or intellectual input (or co-first authors). Third, fourth, fifth authors: major contributor to the writing of the manuscript or conduct of the substudy. May include (but is not limited to) co-chair(s), statistician, other scientists, or participating center investigator. Sixth and higher: principal investigators (or designee) from the highest-accruing groups and/or centers enrolling in the substudy; IBCSG staff who have contributed to the success of the substudy; scientists who have made a contribution to the preparation of the manuscript; “parent” clinical trial study chair. The policy is one author at these centers/groups regardless of accrual, the site PI/group designee may forego authorship for a colleague (e.g., for updates); exceptions are decided by Scientific Committee Co-Chairs. Last author: the “senior” author is someone who has had a major impact on the success of the substudy. NOTES: In the event that the trial has 2 or more co-chairs in lieu of a study chair, the co-chairs and trial statistician will determine authorship order in collaboration with the Publications Coordinator and Scientific Committee Co-Chairs; in this situation co-first and/or co-senior authors may be considered. For updated results, changes in PI and/or center compliance with submitting follow-up or other requested data should also be considered.</p>
<b>Selection of Authorship</b>	The trial steering committee chair(s) or, if none exists, the IBCSG Scientific Committee Co-Chairs, and Study Chair(s), in collaboration with the Publications Coordinator, will prepare an authorship list according to these guidelines.	
<b>Approval of Authorship</b>	The IBCSG Scientific Committee Co-Chairs, through the IBCSG Publications Coordinator, have ultimate authority on the authorship, unless otherwise specified in trial-specific policies. They will work within these guidelines, but also have the flexibility to consider factors specific to each manuscript.	

	<b>Clinical Trial Primary Results/Updates</b>	<b>Clinical Trial Substudy Primary Results/Updates</b>
<b>Authors</b>	All authors must comply within the guidelines of the International Committee of Medical Journal Editors (ICMJE) ( <a href="http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html">http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html</a> ). All those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors. <i>The ICMJE recommends that authorship be based on the following 4 criteria: (1) Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND (2) Drafting the work or revising it critically for important intellectual content; AND (3) Final approval of the version to be published; AND (4) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. In addition to being accountable for the parts of the work he or she has done, an author should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-authors.</i> In order to confirm authorship, all authors must respond to author review emails that pertain to the manuscript under review and submit forms as required in timely manner.	
<b>Writing Committee</b>	The trial steering committee chair(s) or, if none exists, the IBCSG Scientific Committee Co-Chairs, in collaboration with the Publications Coordinator, will establish a writing committee including but not limited to the study/substudy chairs, co-chairs and trial statistician; this committee may also include primary contributors to the study design, implementation, conduct or analysis (e.g., pathologist, medical reviewer, QL specialist, biologist, etc). In addition, they should assign a corresponding author. A timeline must be developed, and approved by writing committee, taking into consideration contractual obligations, with expectation of manuscript within approximately 6 months of study report; if not adhered then the Scientific Co-Chairs may make changes to the committee.	
<b>Writing Committee Responsibilities; Journal Selection</b>	The writing committee, led by the study/substudy chair(s), has primary responsibility for drafting the manuscript based on the statistical report(s). The writing committee can also suggest the target journal. The trial steering committee chair(s) and the IBCSG Scientific Committee Co-Chairs, must approve the journal.	
<b>Recognizing collaborative groups and participating centers</b>	The authorship should be followed by “for ETOP IBCSG Partners Foundation and the [study name] collaborative group” or similar wording. An appendix should be submitted with the manuscript that identifies relevant offices, participating groups and centers, and, at a minimum, the names of the principal investigators from each institution. See Section 5.1 of this document for details.	
<b>Recognizing funding sources</b>	The Publications Coordinator will provide appropriate language for funding sources.	
<b>Acknowledgement</b>	The Publications Coordinator will provide appropriate language for an acknowledgement.	
<b>Data sharing policy</b>	The Data Sharing Policy for IBCSG trials may be accessed on the IBCSG website.	
<b>Data transfer and processing agreements</b>	For any data transfer, Data Transfer and Data Processing Agreements must be in place between the parties. These agreements originate at the Coordinating Center.	
<b>Review and approval of the draft manuscript</b>	The first author must submit a manuscript draft to the Publications Coordinator <b>before submission to a journal</b> . The Publications Coordinator will obtain the approval of all authors followed by the trial steering committee, or if none exists, the IBCSG Scientific Committee, and pharmaceutical company, if involved. Manuscripts of studies using pathology and/or quality of life resources must also be reviewed by the respective IBCSG representatives of these fields. <b>The review process (author review and committee review) takes a minimum of 3 weeks and must also take into consideration any contractual agreements for review time.</b>	
<b>Manuscript Submission</b>	No manuscript should be submitted until there is approval from all authors, the trial steering committee (or if none exists, the IBCSG Scientific Committee), the IBCSG Scientific Committee Co-Chairs, and company involved. In general, the corresponding author should work closely with the Publications Coordinator on the final preparation for submission, ensuring journal guidelines are met, submitting the manuscript to the journal, following up after reviews are received, resubmission, and acceptance. The Publications Coordinator is responsible for keeping the writing committee informed of manuscript status.	
<b>Publication Circulation</b>	Upon publication, the Publications Coordinator will send the journal article to the authors and add it to the IBCSG publications list. The Publications Coordinator will send the publication to the Data Management Center for distribution to principal investigators and other appropriate recipients, and the webmaster for posting on the IBCSG website.	

	<b>Clinical Trial Primary Results/Updates</b>	<b>Clinical Trial Substudy Primary Results/Updates</b>
<b>Order of Publications (First results)</b>	No participating group or center should publish its own patient data on the trial results prior to the Group's publication of the main trial results.	No participating group or center should publish its own patient data on the substudy results prior to the Group's publication of the main substudy results.

## Appendix II: Research Projects

	<b>Research Projects IBCSG Statistical Center Analysis</b>	<b>Research Projects Not IBCSG Statistical Center Analysis</b>
<b>Description of Publication</b>	Research project manuscripts use data collected for a clinical trial, substudy, or other source to address a specific hypothesis, update the clinical trial results, or other purpose.	Research project manuscripts use data collected for a clinical trial, substudy, or other source to address a specific hypothesis, update the clinical trial results, or other purpose. A statistician outside the IBCSG Statistical Center has been identified in proposal as conducting the analysis.
<b>Role of IBCSG Statistical Center</b>		An IBCSG Statistical Center staff member must collaborate. The collaboration should include, but is not limited to, project design, selection of the analytical cohort, preparation of data from the IBCSG database for transfer, analysis plans, review of reports, abstracts, presentations, and publications.
<b>Timing of Publication</b>	If the manuscript includes clinical trial patient outcome data, research project results should only take place after the publication of the clinical trial first results. If the manuscript does not include clinical trial patient outcome data, it may be published prior to the first results (e.g., design of trial, methodology, etc).	
<b>Authorship Guidelines</b>	<p>First author: research project investigator            Second author: research project statistician            NOTE: First and second author may be reversed to reflect the amount of effort or intellectual input (or co-first authors).            Third, fourth, fifth authors: major contributors to the writing of the manuscript. May include (but is not limited to) trial chair and/or co-chair(s), statistician, other scientists, or participating center investigator.            Sixth and higher: principal investigators (or designee) from the highest-accruing groups and/or centers; IBCSG staff who have contributed to the success of the trial; scientists who have made a major contribution to the preparation of the manuscript.            Authorship should include, if feasible, the study chair of the trial the research project is based on.            Last author: the “senior” author is someone who has had a major impact on the success of the trial or research project; may be co-senior authors.</p>	<p>The research project investigator that receives IBCSG data is responsible for proposing the authorship.            Authorship should include, if feasible, the study chair of the trial the research project is based on, relevant IBCSG co-investigators, investigators from high-accruing centers or groups, and others described on the left.</p>
<b>Selection of Authorship</b>	The research project investigator, in collaboration with the Publications Coordinator, will prepare an authorship list according to these guidelines.	
<b>Approval of Authorship</b>	The IBCSG Scientific Committee Co-Chairs, through the Publications Coordinator, have ultimate authority on the authorship, unless otherwise specified in trial-specific policies. They will work within these guidelines, but also have the flexibility to consider factors specific to each manuscript.	The IBCSG Scientific Committee Co-Chairs, through the Publications Coordinator, must approve the authorship prior to submission; unless otherwise specified in trial-specific policies.
<b>Authors</b>	Same as Appendix I.	The research project investigator is responsible for ensuring all authors meet authorship guidelines.
<b>Writing Committee</b>	The research project investigator and statistician should collaborate on the contents of the manuscript. Additional people can be added as appropriate.	The research project investigator is responsible for writing the first draft of the manuscript.

	<b>Research Projects IBCSG Statistical Center Analysis</b>	<b>Research Projects Not IBCSG Statistical Center Analysis</b>
<b>Writing Committee Responsibilities; Journal Selection</b>	The writing committee, led by the research project investigator has primary responsibility for preparing the manuscript, based on the statistical report(s). The writing committee can also suggest the target journal. The trial steering committee chair(s) and the IBCSG Scientific Committee Co-Chairs must approve the journal.	The research project investigator should suggest the target journal. The trial steering committee chair(s) and the IBCSG Scientific Committee Co-Chairs must approve the journal.
<b>Recognizing collaborative groups and participating centers</b>	Whenever feasible, the authorship should be followed with “for the International Breast Cancer Study Group and the [study name] collaborative group.” or similar wording. At a minimum, the IBCSG must be acknowledged in the manuscript, which would have to be approved by the Publications Coordinator.	The ETOP IBCSG Partners Foundation must be acknowledged in the manuscript. The acknowledgement must be approved by the Publications Coordinator.
<b>Recognizing funding sources</b>	The Publications Coordinator will provide appropriate language for funding sources.	
<b>Acknowledgement</b>	The Publications Coordinator will provide appropriate language for an acknowledgement.	
<b>Data sharing policy</b>	See Appendix I.	
<b>Data transfer and processing Agreements</b>	See Appendix I.	
<b>Review and approval of the draft manuscript</b>	The research project investigator must submit a manuscript draft to the Publications Coordinator <b>after obtaining approval from all authors</b> . The Publications Coordinator will obtain the approval of the trial steering committee, or if none exists, the IBCSG Scientific Committee, and company, if involved. Manuscripts of studies using pathology and/or quality of life resources must also be reviewed by the respective IBCSG representatives of these fields. <b>The review process (author review and committee review) takes a minimum of 3 weeks.</b>	
<b>Manuscript Submission</b>	No manuscript should be submitted until there is approval from all authors, the trial steering committee (or if none exists, the IBCSG Scientific Committee) and the IBCSG Scientific Committee Co-Chairs. In general, the corresponding author should work closely with the Publications Coordinator on the final preparation for submission, ensuring journal guidelines are met, submitting the manuscript to the journal, following up after reviews are received, resubmission, and acceptance. The corresponding author is responsible for manuscript submission and keeping the writing committee informed of manuscript status.	
<b>Publication Circulation</b>	Upon publication of the journal article, the Publications Coordinator will ensure that the article is sent around to the authors and added to the IBCSG publications list. The publication will be forwarded to the Data Management Center for distribution to principal investigators and other appropriate recipients, and the webmaster for posting on the IBCSG website.	

### Appendix III: TRWG-Approved Research Projects

	TRWG-Approved Research Projects--IBCSG Statistical Center Analysis	TRWG-Approved Research Projects--Not IBCSG Statistical Center Analysis
<b>Description of Publication</b>	TRWG-approved project manuscripts are those using data obtained from the use of the IBCSG Bio-specimen Bank, usually in combination with clinical trial data. The IBCSG Statistical Center has been identified in the approved project as conducting the analysis of the project.	TRWG-approved project manuscripts are those using data obtained from the use of the IBCSG Bio-specimen Bank, usually in combination with clinical trial data. A statistician outside the IBCSG Statistical Center has been identified in the approved project as conducting the analysis.
<b>Role of IBCSG Statistical Center</b>		An IBCSG Statistical Center staff member must collaborate. The collaboration should include, but is not limited to, project design, selection of the analytical cohort, preparation of data from the IBCSG database for transfer, analysis plans, review of reports, abstracts, presentations, and publications.
<b>Timing of Publication</b>	If the manuscript includes clinical trial patient outcome data, research project results should only take place after the publication of the clinical trial first results. If the manuscript does not include clinical trial patient outcome data, it may be published prior to the first results (e.g., design of trial, methodology, etc).	
<b>Authorship Guidelines</b>	<p>First author: research project investigator            Second author: research project statistician            Third, fourth, fifth authors: major contributor to the writing of the manuscript. May include (but is not limited to) trial co-chair, statistician, other scientists, or participating center investigator.            Sixth and higher: principal investigators (or designee) from the highest-accruing groups and/or centers; IBCSG staff who have contributed to the success of the trial; scientists who have made a major contribution to the preparation of the manuscript.</p> <p>Authorship should include, if feasible, the study chair of the trial the research project is based on.</p> <p>Last author: the “senior” author is someone who has had a major impact on the success of the project; may be co-senior authors.</p>	<p>The research project investigator that receives IBCSG data and/or material is responsible for proposing the authorship.</p> <p>Authorship should include, if feasible, the study chair of the trial the research project is based on, relevant IBCSG co-investigators, investigators from high-accruing centers or groups, and others described on the left.</p> <p>The collaborating IBCSG statistician should be included as an author.</p>
<b>Selection of Authorship</b>	The research project investigator, in collaboration with the Publications Coordinator, should prepare an authorship list according to these guidelines. <b>Authorship should not be ‘promised’</b> by anyone other than the Publications Coordinator.	
<b>Approval of Authorship</b>	The IBCSG Scientific Committee Co-Chairs, through the Publications Coordinator, have ultimate authority on the authorship. The project investigator must submit the authorship list to the Publications Coordinator prior to circulating a manuscript with authorship listed.	
<b>Authors</b>	Same as Appendix I.	
<b>Writing Committee</b>	The research project investigator and statistician should collaborate on the contents of the manuscript. Additional people can be added as appropriate.	The research project investigator is responsible for writing the first draft of the manuscript.
<b>Writing Committee Responsibilities; Journal Selection</b>	The writing committee, led by the research project investigator, has primary responsibility for preparing the manuscript, based on the statistical report(s). The writing committee can also suggest the target journal. The trial steering committee chair(s) and the IBCSG Scientific Committee Co-Chairs must approve the journal.	
<b>Recognizing collaborative groups</b>	Whenever feasible, the authorship should be followed with “for ETOP IBCSG Partners Foundation and the [study name] collaborative group.” or similar wording. At a minimum the	The ETOP IBCSG Partners Foundation must be acknowledged in the manuscript. The acknowledgement must be approved by the Publications Coordinator.

	<b>TRWG-Approved Research Projects--IBCSG Statistical Center Analysis</b>	<b>TRWG-Approved Research Projects--Not IBCSG Statistical Center Analysis</b>
<b>and participating centers</b>	IBCSG must be acknowledged in the manuscript, which would have to be approved by the Publications Coordinator.	
<b>Recognizing funding sources</b>	The Publications Coordinator will provide appropriate language for funding sources for ETOP IBCSG Partners Foundation.	
<b>Acknowledgement</b>	The Publications Coordinator will provide appropriate language for an acknowledgement.	
<b>Data sharing policy</b>	See Appendix I.	
<b>Data transfer and processing agreements</b>	See Appendix I.	
<b>Review and approval of the draft manuscript</b>	The first author must submit a manuscript draft to the Publications Coordinator <b>after obtaining approval from all authors</b> . The Publications Coordinator will obtain the approval of the trial steering committee, or if none exists, the IBCSG Scientific Committee. Manuscripts of studies using pathology resources must also be reviewed by the respective IBCSG representatives of these fields. <b>The review process (author review and committee review) takes a minimum of 3 weeks.</b>	
<b>Manuscript Submission</b>	No manuscript should be submitted until there is approval from the trial steering committee (or if none exists, the IBCSG Scientific Committee) and the IBCSG Scientific Committee Co-Chairs. In general, the corresponding author should work closely with the Publications Coordinator on the final preparation for submission, ensuring journal guidelines are met, submitting the manuscript to the journal, following up after reviews are received, resubmission, and acceptance. The corresponding author is responsible for manuscript submission and for keeping the writing committee informed of manuscript status.	No manuscript should be submitted until there is approval from the trial steering committee (or if none exists, the IBCSG Scientific Committee) and the IBCSG Scientific Committee Co-Chairs. The research project investigator is responsible for submitting the manuscript and keeping the authors and the Publications Coordinator informed of its progress.
<b>Publication Circulation</b>	Upon publication of the journal article the Publications Coordinator will ensure that the article is sent around to the authors and added to the IBCSG publications list. The publication will be forwarded to the Data Management Center for distribution to principal investigators and other appropriate recipients, and the webmaster for posting on the IBCSG website.	

## Appendix IV: Statistical Research Projects

	Statistical Research Projects IBCSG Statistical Center	Statistical Research Projects Not IBCSG Statistical Center
<b>Description of Publication</b>	Research project manuscripts use data collected for a clinical trial, substudy, or other source to address a statistical, trial design, analysis, or interpretation issue.	
<b>Role of IBCSG Statistical Center</b>	An IBCSG statistician is the research project investigator.	A non-IBCSG statistician is the research project investigator. An IBCSG Statistical Center staff member must collaborate in, project design, selection of the analytical cohort, preparation of data from the IBCSG database for transfer, analysis plans, review of reports, abstracts, presentations, and publications
<b>Timing of Publication</b>	If the manuscript includes clinical trial patient outcome data, research project results should only take place after the publication of the clinical trial first results. If the manuscript does not include clinical trial patient outcome data, it may be published prior to the first results (e.g., design of trial, methodology, etc).	
<b>Authorship Guidelines</b>	Authorship is determined by the research project investigator.	
<b>Selection of Authorship</b>	The research project investigator, in collaboration with the Publications Coordinator, should prepare an authorship list according to these guidelines.	
<b>Authors</b>	The research project investigator is responsible for ensuring all authors meet authorship guidelines.	
<b>Writing Committee</b>	The research project investigator is responsible for writing the first draft of the manuscript.	
<b>Acknowledgement</b>	The ETOP IBCSG Partners Foundation must be acknowledged in the manuscript. The acknowledgement must be approved by the Publications Coordinator.	
<b>Recognizing funding sources</b>	The Publications Coordinator will provide appropriate language for IBCSG-related funding sources.	
<b>Data sharing policy</b>	See Appendix I.	
<b>Data transfer and processing agreements</b>	See Appendix I.	
<b>Reviewing the draft manuscript</b>	The research project investigator must submit a manuscript draft to the Publications Coordinator <b>after obtaining approval from all authors</b> . The Publications Coordinator will obtain the approval of the trial steering committee (or if none exists, the IBCSG Scientific Committee) and/or Director of the IBCSG Statistical and Data Management Center if needed. Manuscripts of studies using pathology and/or quality of life resources may also be reviewed by the respective IBCSG representatives of these fields.	
<b>Manuscript Submission</b>	No manuscript should be submitted until there is approval from the trial steering committee (or if none exists, the IBCSG Scientific Committee) and the IBCSG Scientific Committee Co-Chairs. The research project investigator is responsible for submitting the manuscript and keeping the authors and the Publications Coordinator informed of its progress.	
<b>Publication Circulation</b>	Upon publication of the journal article, the Publications Coordinator will ensure that the article is sent around to the authors and added to the IBCSG publications list. The publication will be forwarded to the Data Management Center for distribution to principal investigators and other appropriate recipients, and the webmaster for posting on the IBCSG website.	

## Appendix V: Abstracts and Presentations

	<b>IBCSG Trials or IBCSG Coordinating Group Collaborative Trials</b>
<b>Abstracts</b>	No trial results, substudy results or research project abstracts should be submitted to scientific meetings before a publication is planned.
	Abstract authorship should follow the guidelines in Sections I-IV, recognizing that abstracts generally have fewer authors than publications, and the number of authors is governed by the rules of the conference. Abstracts for trial results, substudies or research projects must be submitted to the IBCSG Scientific Committee Co-Chairs must approve authorship. Publications Coordinator ensures review and approval following the guidelines in Sections I-IV.
	Abstracts using IBCSG data sent to individuals or groups outside the ETOP IBCSG Partners Foundation must be sent to the IBCSG Publications Coordinator before being submitted to a conference. The Publications Coordinator will obtain the approval of the IBCSG Scientific Committee Co-Chairs, and they will determine if full trial steering committee (or if none exists, the IBCSG Scientific Committee) approval is required. Adequate time must be provided.
<b>Scientific meetings</b>	Submission of abstracts to scientific meetings is encouraged, in accordance with all guidelines in this document.
<b>Local presentations</b>	Local presentations are encouraged, but they should identify the trials as ETOP IBCSG Partners Foundation-sponsored trials rather than those of a local or regional group.
<b>Approval of abstracts</b>	The “final draft” version of the abstract must be reviewed and approved by the trial steering committee (or if none exists, the IBCSG Scientific Committee). Adequate time to review, reply, and make revisions will be strictly enforced. The abstract must be sent to the Publications Coordinator at least <b>two weeks prior to the expected date of submission, longer may be required considering contractual agreements</b> . The Publications Coordinator will circulate the abstract and inform the first author/writing committee of all suggestions. The first author should consider all input, consult with co-authors, and decide on the final content of the abstract. The abstract should be forwarded to the Publications Coordinator after submission, and the first author should keep the Publications Coordinator informed of acceptance decisions.
<b>Approval of presentations</b>	The “final draft” version of the poster or slide presentation must be reviewed and approved by the trial steering committee (or if none exists, the IBCSG Scientific Committee). A statistical project poster must be approved by the Director of the IBCSG Statistical and Data Management Center. Adequate time to review, reply, and make revisions will be strictly enforced. The presentation must be sent to the Publications Coordinator at least <b>two weeks prior to the expected date of submission or presentation, longer may be required considering contractual agreements</b> . The Publications Coordinator will circulate the document and inform the first author/writing committee of all suggestions. The first author should consider all input, consult with co-authors, and decide on the final content of the presentation. The final version should be forwarded to the Publications Coordinator.
<b>Use of IBCSG logos</b>	Permission to use the IBCSG or ETOP IBCSG Partners Foundation logo must be obtained from the Publications Coordinator. Logos may only be used upon review and approval of the presentation, as stated above. Adequate time for review (see above) is required. High resolution, properly-scaled versions of the logos should be used and can be obtained from the IBCSG Publications Coordinator.
<b>Presentation format for oral presentation Logos</b>	When used in presentations, the IBCSG or ETOP IBCSG Partners Foundation logo should be placed on each a slide (unless stylistically unfeasible). If the trial involved is a BIG trial, the BIG logo should be placed in the lower right side. Logos from participating groups may appear on the front slide or acknowledgment/“thank you” slide. Trial and substudy results should include the logo(s) on all slides; projects are not required to do so. Acknowledgment/thank you slide must be discussed with Publications Coordinator.
<b>Presentation format for poster presentation Logos</b>	When used in a poster the IBCSG or ETOP IBCSG Partners Foundation logo should be placed at the top of the poster (unless stylistically unfeasible). If the trial involved is a BIG trial, the BIG logo should be included. Acknowledgment/thank you section must be discussed with Publications Coordinator.

<b>Keeping IBCSG informed</b>	<b>Final abstracts and presentations should be emailed to the IBCSG Publications Coordinator.</b> These will be announced in the IBCSG Circular Letter and may be posted on the IBCSG website (in accordance with conference embargo policies).
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