



Breast Cancer Surveillance Consortium (BCSC) Collaborative Writing Guidelines

The BCSC collaborative writing guidelines should be used for manuscripts that (1) arise from the use of pooled BCSC data from one or more consortium sites and (2) use the SCC to conduct analyses. These guidelines are designed to promote more up-front work before analyses start to increase efficiency and improve manuscript development.

Our guidelines outlined below are designed to enhance:

- Communication
- Organization
- Timeliness
- Process
- Planning

The BCSC requires a **working proposal** and **title** that are updated every 6-12 months to reflect the main study hypotheses and objective of the analyses. The **working proposal** is a current version of the approved proposal with any updates to items such as inclusion/exclusion criteria or writing group.

Manuscript proposal development and approval

1. Lead author develops initial idea for a paper and submits a brief concept proposal to the BCSC Steering Committee through a Steering Committee member. (Papers related to grant aims that have already been approved by the BCSC Steering Committee do not require a concept proposal form.)
2. The BCSC Steering Committee reviews the concept proposal to identify potential overlap with other projects and proposals and, if needed, suggest BCSC investigators to facilitate development of the full proposal.
3. Within 6 months of concept proposal approval and after obtaining approval from coauthors identified to date, the lead author submits the BCSC proposal form to the BCSC Steering Committee through a Steering Committee member.
4. BCSC registry leads may circulate the proposal to individuals with relevant expertise from their site to identify persons interested in participating on the small or large writing groups. See Table 1 for a summary of the responsibilities of small and large writing group members. The lead author will make final decisions on co-authorship with consultation from the Steering Committee in order to balance scientific contributions with writing group size and efficiency.
5. BCSC Steering Committee reviews the proposal.
6. If necessary, lead author revises the working proposal and communicates any changes resulting from Steering Committee review to all contributing authors.
7. The small and large writing groups should be identified and reported to the SCC within 1 month of approval of the proposal. The ideal size of the small writing group is 3-4 people, including the SCC analyst and lead author.
8. Investigators not on the Steering Committee will be assigned a BCSC Steering Committee member to serve as facilitator to the BCSC.
9. Each manuscript produced from a grant needs an approved manuscript proposal.

Between approval of the full proposal and start of SCC analysis

1. The BCSC facilitator or SCC notifies the lead author that the analysis will begin in the next 6 months. The SCC identifies the analyst (if not done already). Designated members of the SCC



must be involved in all data analyses, except where de-identified or limited datasets are provided directly to an investigator.

2. The lead author organizes a kick-off meeting of the large writing group with the SCC to review the approved proposal. The SCC programmer and analyst should be invited to this meeting so that they are aware of the scientific background of the proposal and general analytic plan. Before the large group meeting, the lead author (or designee) should update the literature review so that the approved proposal addresses the current state of scientific knowledge. The lead author works with the small writing group to revise the working proposal to reflect any changes based on new information and will send the revised working proposal to the SCC (KPWA.scc@kp.org).
3. The SCC meets to review the revised working proposal with specific attention to the study population, proposed definitions and analytic plan.
4. The large writing group reviews: 1) the main purpose of the analysis, 2) inclusion/exclusion criteria including years of data being used, 3) definitions (with details if not standard BCSC definitions), and 4) draft (mock) manuscript tables. The writing group may request preliminary data analyses by the SCC to finalize inclusion/exclusion criteria.
5. The SCC analyst and lead author (with or without the small writing group) meet following the large writing group and SCC meetings to finalize the detailed analytic plan and a timeline for analysis, presentation and publication.

Culling the data

1. The SCC analyst analyzes the data and sends provisionally completed tables to the lead author. The lead author sends the data tables to the small writing group for review within 1-2 weeks.
2. The small writing group works closely with the lead author and SCC analyst to conduct rigorous review of data tables generated using planned methods, definitions, relevant coding and analyses, and revises approach as necessary.
3. The lead author organizes a conference call with the large writing group before the manuscript is drafted. The large writing group should review and agree to the objectives, methods, data tables, main points, and target journal.
4. Major revisions not included in the originally approved proposal require Steering Committee approval. See the [Guide to Working with BCSC Data](#) for details.

Drafting the manuscript

1. The lead author circulates an **outline** of the manuscript for review by the large writing group that outlines the main points for the introduction, results, and discussion. These should be agreed upon based on the main points of the manuscript and the target audience.
2. The lead author should work closely with the small writing group during the drafting of the manuscript.
3. The lead author circulates drafts of the manuscript to coauthors. The *purpose of each draft and issues appropriate for comment/editing* should be clearly outlined in each request from the lead author for review of a draft. Each draft should be dated in the body of the text or title of the manuscript file.
4. Coauthors have 2 weeks to review the manuscript. If a coauthor cannot complete the review in the 2 week period, there must be communication to the lead author with a date that comments will be returned. Coauthors should send manuscript comments to all other coauthors for review.

Guidelines for completing major milestones (* see diagram at end of document)

Milestone	Estimated time
Time for first-author to create and submit full proposal (following approved concept proposal)	6 months
Time for first-author to identify small and large writing groups (following approved full proposal)	1 month
Time for SCC to schedule kick-off meeting once small and large working groups identified	1 month
Time for analyst to develop data specifications from kick-off meeting	2 weeks
Time for programmer to create project dataset after receiving specifications	1 month
Time for analyst to finish first set of analyses once dataset created	2 months
Time for first-author and small writing group to review tables	1-2 weeks
Time for analyst to update analyses based on feedback	2-4 week: easy analysis, 1-2 months: complex
Time for first-author to develop final paper tables and summarize results once analyses complete	1-2 months
Time for first-author to write first draft of paper once final tables approved by large writing group	2-3 months
Time for co-authors to comment on outlines and drafts	2 weeks
Time for first-author to incorporate author comments on drafts	1 month
Number of full drafts circulated to large writing group before submission	typically 2 versions
Time for steering committee to review and approve final manuscript	1-2 weeks
If NCI scientist is a co-author, time for NCI to review and approve final manuscript	2 weeks
Time for first-author to respond to reviewers' comments and revise manuscript	2 weeks (sooner, if required by journal)
Time for co-authors to review revised manuscript and comments	2 weeks (sooner, if required by journal)

Finalizing draft and submission

1. The lead author declares when the final draft is ready, and coauthors have 2 weeks to review and approve the final manuscript.
2. The final manuscript must be reviewed and approved by the BCSC Steering Committee prior to journal submission. This review process is usually completed within 1-2 weeks. Before



submitting for Steering Committee review, the lead author must verify the following by submitting the BCSC manuscript approval checklist:

- a. The manuscript does not show site-level data,
 - b. The manuscript acknowledges the BCSC, includes the contract number, includes other relevant grant numbers (e.g., AIM, FAVOR, BCSC-GO, U01 grant numbers), and acknowledges cancer registry data, as appropriate (see suggested manuscript acknowledgments)
 - c. The manuscript acknowledges the contributions of BCSC investigators and participants in an acknowledgment section, if allowed by the journal. Contributions of the BCSC as a whole may also be recognized by including BCSC in the title or adding "... for the Breast Cancer Surveillance Consortium" at the end of the list of named authors (see suggested manuscript acknowledgments)
 - d. Information on protections to women, radiologists, and facilities are included as appropriate (see standard paragraph on confidentiality).
 - e. All authors have read and approved the final version of the paper.
3. If the author group includes an NCI scientist, clearance from NCI must be obtained before manuscript submission for peer-review. This review process is usually completed within 2 weeks.
 4. The lead author submits the manuscript for publication and sends the submitted version to all coauthors and the SCC (KPWA.scc@kp.org).
 - a. When submitting your manuscript, please consider using "BCSC" as a key word to enable searching for BCSC manuscripts on PubMed.
 5. The lead author informs all coauthors and the SCC (or KPWA.scc@kp.org) when the manuscript has been rejected, received a revise and resubmit, or accepted. In this correspondence the lead author will send the most recent version of the paper so the SCC can enter this information into the publications database and post the manuscript on the password-protected SCC private website.

Manuscript revisions after submission

1. To facilitate manuscript revisions, the lead author should select one or two of the most active writing participants to help respond to reviewers' comments and revise the manuscript within 2 weeks after notification that revisions are required (or sooner, if required by the journal).
2. The revised manuscript and comments to reviewers should be circulated to the full author group for comment and any response should be made within 2 weeks, so that total turn around time is one month (unless the journal requires a faster response). If reanalysis of data makes this timeline impossible to meet, the lead author should develop a timeline and share it with the final author group.

The lead author will:

1. Determine the first, second, and senior authors at the outset as these are key roles in the manuscript development. The first, second, and senior authors are all members of the small writing group. In addition, the lead author will delineate roles and responsibilities of each co-author (at a face-to-face meeting or by e-mail) in the development, editing or revising of the manuscript, following the agreed upon timetable. It is possible final authorship order may change depending on contributions.
2. Identify an appropriate mechanism to share drafts and communicate effectively (e.g., e-mail, wiki, Google docs) and use it consistently.



3. Provide reasonable deadlines for each review/revision (standard is 2 weeks for review) and promote an understanding among collaborators that these will be adhered to unless scheduling issues are discussed with lead author before the deadline.
4. Determine final authorship order based on the relative contributions of each coauthor and communicate any changes to the SCC via e-mail (KPWA.scc@kp.org) or update directly on the SCC website. Authorship order can be changed at any point during the writing process based on the relative contributions of the coauthors. Discussion with the senior author is an appropriate way to resolve concerns about order.
5. Monitor controversy among coauthors and effectively communicate the rationale for making or not making manuscript revisions to all coauthors before subsequent related reviews. When possible, conflicts between coauthors will be resolved by the writing group. When this is not possible, the BCSC Steering Committee may be asked to recommend a resolution. The Steering Committee will provide an advisory vote on the recommendation. Steering Committee members involved in the conflict will abstain from voting. The lead author will make final decisions. If a coauthor cannot agree with the final decision, then that individual can withdraw authorship, recognizing that the paper will go forward.
6. Submit publication to PubMed Central. NIH requires that any publications that arose from an NIH award be submitted to PubMed Central. NIH provides sample language that can be used in a copyright agreement between the author or institution and the publisher: *“Journal acknowledges that Author retains the right to provide a copy of the final peer-reviewed manuscript to the NIH upon acceptance for Journal publication, for public archiving in PubMed Central as soon as possible but no later than 12 months after publication by Journal.”* More information on how to abide by this policy can be found at: <http://www.nihms.nih.gov/help/> and <http://publicaccess.nih.gov/>

Note that if deadlines are not consistently met and work is not progressing, the lead author or Steering Committee may request changes in membership of the contributing author list, including a change in the lead author. The initial timetable and requests for reasonable extensions of the deadlines must be considered before any authorship change.

Authorship and Acknowledgments

Many people contribute to manuscript development in different ways. Authorship credit should be based on *ALL THREE* of the following as outlined by the International Committee of Medical Journal Editors (Uniform Requirements for Manuscripts Submitted to Biomedical Journals, updated 2009, <http://www.icmje.org>):

1. Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
2. Drafting the article or revising it critically for important intellectual content; and
3. Final approval of the version to be published.

Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship; these activities may be acknowledged.

JAMA "Authorship Responsibility, Criteria and Contributions" statement requires that:

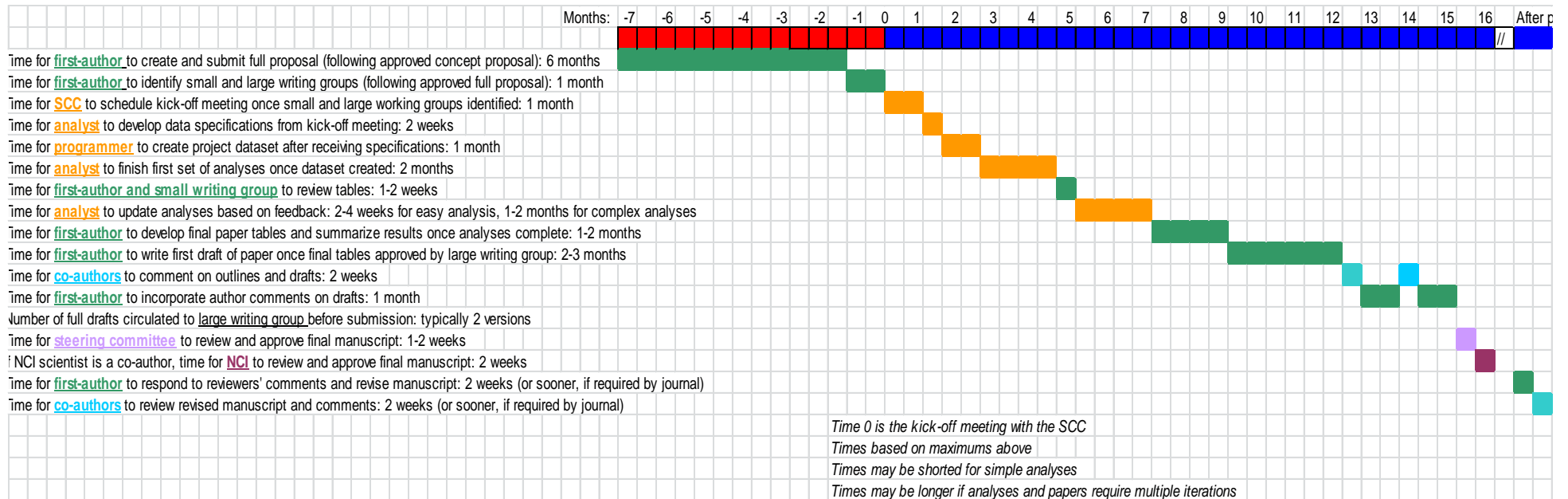
- The manuscript represents valid work and that neither this manuscript nor one with substantially similar content under similar authorship has been published or is being considered for publication elsewhere.

- If requested by the editors, authors will provide data or will cooperate fully in obtaining and providing data on which the manuscript is based for examination by the editors or their assignees. Exceptions may be made for some BCSC submissions.
- For papers with more than one author, the corresponding author (lead) is to serve as the primary correspondent with the editorial office, to review the edited typescript and proof, and to make decisions regarding the release of information in the manuscript to the media, federal agencies, or both.

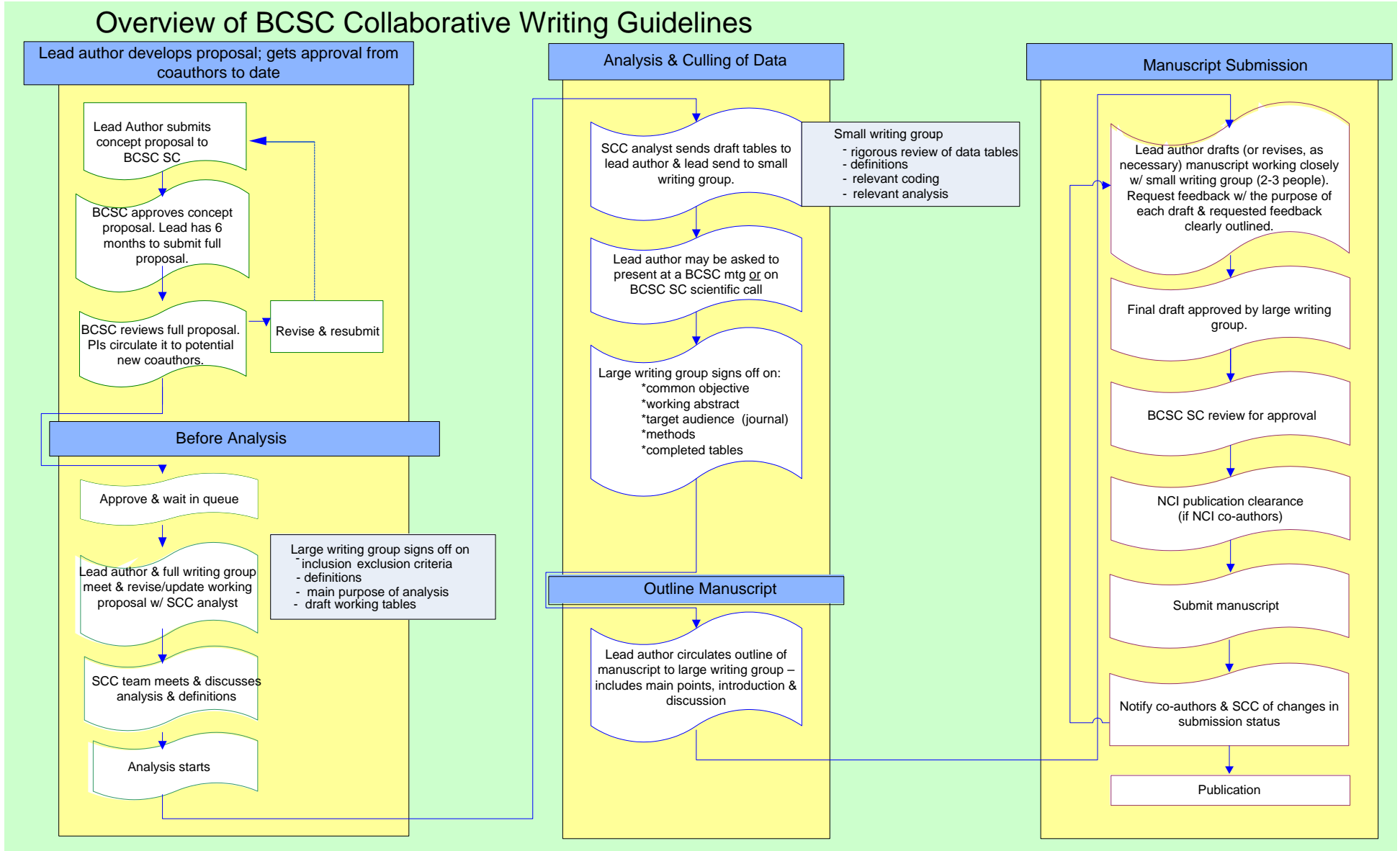
Table 1. Summary of roles and responsibilities of writing groups and Steering Committee

	Small writing group	Large writing group	Steering Committee
Develop proposal and submit to BCSC Research Resource or P01 Steering Committee. Involve authors identified to date.	X	X	
Approve initial proposal.	X	X	X
Contribute to and approve working proposal before analysis begins. Pay specific attention to inclusion/exclusion criteria, definitions, main purpose of the analysis and mock manuscript tables.	X	X	
Conduct rigorous review of table shells using planned methods, definitions, analyses, and relevant coding. Revise as necessary.	X		
Help to prepare presentation to the BCSC Steering Committee. Approve presentation. (Required for P01 manuscripts, may be requested for BCSC Research Resource manuscripts.)	X		
Review final manuscript tables before drafting manuscript.	X	X	
Contribute to manuscript outline. Help to identify main points of manuscript and highlight unique contributions to the literature. Help to identify target journal.	X	X	
Review interim drafts of manuscript with lead author. Large writing group may also be involved.	X		
Review final draft before submitting to BCSC Steering Committee.	X	X	
Take responsibility for accuracy and content of entire manuscript.	X	X	
Approve manuscript before journal submission.	X	X	X
Respond to peer review.	X	X	

Guidelines for completing major milestones - Timeline



Overview of BCSC Collaborative Writing Guidelines



SC = Steering Committee; SCC = Statistical Coordinating Center; MS = Manuscript