Breast Cancer Surveillance Consortium (BCSC)
Collaborative Writing Guidelines

The BCSC collaborative writing guidelines should be used for manuscripts that arise from the use of pooled BCSC data and use the SCC to conduct analyses. **The guidelines are designed to enhance communication, organization, timeliness, process, and planning**.

For questions or to obtain forms, please contact the SCC at KPWA.scc@kp.org.

The BCSC requires a ***working proposal*** and ***title*** that are updated annually (if needed) to reflect the main study hypotheses and objective. The **working proposal** is a current version of the approved proposal with any updates to items such as inclusion/exclusion criteria or the writing group.

Manuscript proposal development and approval

1. Lead author develops initial idea for a paper and submits a brief concept proposal (available from the SCC at KPWA.scc@kp.org) 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, if needed, suggest BCSC investigators to help develop 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 full manuscript 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 to balance scientific contributions with writing group size and efficiency.
5. BCSC Steering Committee reviews the full manuscript proposal.
6. If necessary, lead author revises the proposal and communicates any changes resulting from Steering Committee review to all writing group members.
7. The small and large writing groups should be identified and reported to the SCC within 1 month of approval of the proposal. (See authorship guidelines on pp 4-5.) 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 full 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 SCC members 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 to be aware of the scientific background and general analytic plan. Before the large writing group meeting, the lead author (or designee) should update the literature review so that the 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) if needed.
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 the main purpose of the analysis; inclusion/exclusion criteria including years of data; definitions (with details if not standard BCSC definitions; and draft (mock) manuscript tables. The writing group may request preliminary SCC data analysis to finalize inclusion/exclusion criteria.
5. The SCC analyst and lead author (with or without the small writing group) meet after the large writing group and SCC meetings to finalize the detailed analytic plan and a timeline for analysis, presentation, and publication.

Data analysis

1. The SCC analyst analyzes the data and sends provisional 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 rigorously review the data tables. The methods, definitions, coding, and analyses are revised as needed.
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 on the Working with the BCSC page on the BCSC website 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 works closely with the small writing group while drafting 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 review request. 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 weeks, the coauthor must communicate to the lead author a date that comments will be returned. Coauthors should send manuscript comments to all other coauthors for review.

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 before journal submission. This review is usually completed within 1-2 weeks. When submitting a manuscript for Steering Committee review, the lead author must verify the following by submitting the BCSC **manuscript approval checklist** (available from the SCC at KPWA.scc@kp.org):
    a. The manuscript does not show site-level data,
    b. The manuscript acknowledges the BCSC by including relevant grant numbers, and acknowledges cancer registry and vital status data as appropriate (see suggested acknowledgments, available from KPWA.scc@kp.org)

   c. The manuscript acknowledges the contributions of BCSC investigators and participants in an acknowledgment section, if allowed by the journal (see suggested acknowledgments, available from KPWA.scc@kp.org).
   d. Information on protections to women, radiologists, and facilities are included as appropriate (see confidentiality statement, available from KPWA.scc@kp.org).
   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 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 the coauthors and SCC (or KPWA.scc@kp.org) about the results of manuscript review. In this correspondence the lead author sends the most recent version of the paper so the SCC can update the BCSC publications database and track the manuscript.

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 turnaround time is one month (unless the journal requires a faster response). If re-analysis of data makes this timeline impossible to meet, the lead author should develop a timeline and share it with the final author group.

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 via the SCC. Involve authors identified to date.	X	X	
Approve initial proposal.	X	X	X
Contribute to and approve working proposal before analysis begins. Pay attention to the main purpose of the analysis, inclusion/exclusion criteria, definitions, and mock tables.	X	X	
Conduct rigorous review of tables using planned methods, definitions, analyses, and coding. Revise as necessary.	X		
Review final manuscript tables before drafting manuscript.	X	X	
Contribute to manuscript outline. Help to identify main points of manuscript and highlight contributions to the literature. Help to identify target journal.	X	X	
Review interim drafts of manuscript. 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	

The lead author will:

1. Determine the first, second, and senior authors at the outset as these are key roles in manuscript development. The first, second, and senior authors are all members of the small writing group. The lead author will also delineate roles and responsibilities of each co-author in the development, editing, or revising of the manuscript following the agreed upon timetable. Final authorship order may change depending on contributions.
2. Identify an appropriate mechanism to share drafts and communicate effectively (e.g., e-mail, Google docs) and use it consistently.
3. Provide reasonable deadlines for each review/revision (standard is 2 weeks for review) and promote understanding among collaborators that the timeline 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). Authorship order can be changed during the writing process based on the relative contributions of 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 reviews. When possible, conflicts will be resolved by the writing group. When this is not possible, the Steering Committee may be asked to recommend a resolution, and 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, that individual can withdraw authorship, recognizing that the paper will go forward.
6. Submit publication to PubMed Central. NIH requires that publications that arise 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 this policy is 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 writing group, 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

People contribute to manuscript development in different ways. Authorship credit should be based on *ALL THREE* of the following criteria outlined by the International Committee of Medical Journal Editors (Uniform Requirements for Manuscripts Submitted to Biomedical Journals, 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.

On BCSC papers, the SCC analyst is a coauthor and is usually in the small writing group. An SCC programmer who makes scientific contributions to the paper (such as intellectual contributions to

study definitions or analysis plans) should be included as a coauthor. Programming work involving substantial time and effort is not in itself sufficient for authorship.

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

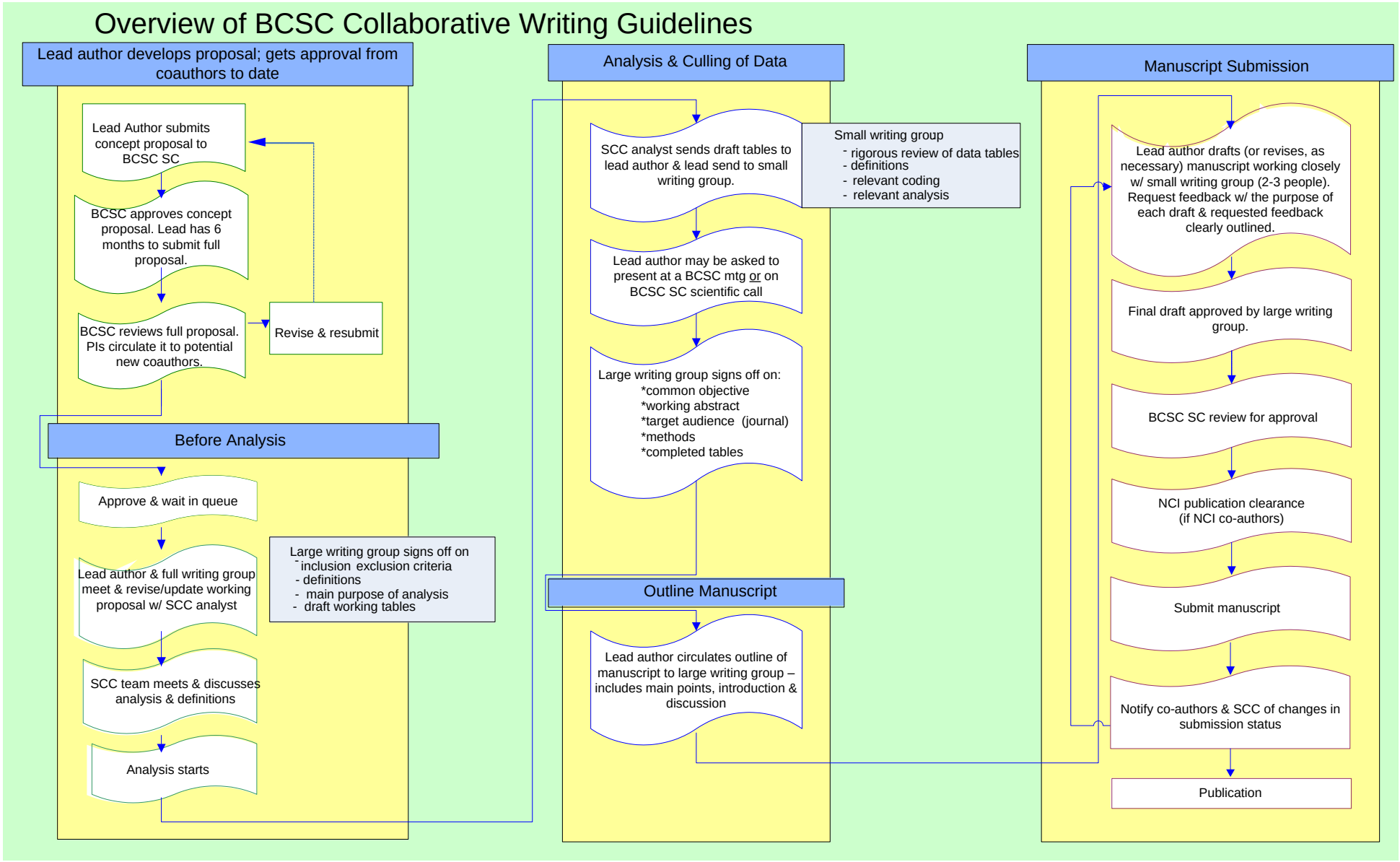
- The manuscript represents valid work and that neither this manuscript nor one with substantially similar content under similar authorship has been published or is being considered for publication elsewhere.
- If requested by the editors, authors will provide data or cooperate fully in obtaining and 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) serves as the primary correspondent with the editorial office to review the edited typescript and proof and to make decisions regarding the release of manuscript information to the media and/or federal agencies.

Guidelines for completing milestones: Timeline

The target timeline for completing milestones is summarized in the table. Starting with the kick-off call, when work on the approved proposal starts, the time to manuscript submission to a journal is about 13-19 months, depending on complexity and the number of drafts reviewed.

Milestone	Estimated time after previous step completed
Concept proposal approved	-
First author develops and submits full proposal	6 months
First author identifies small and large writing groups	1 month
*Work starts when **first author and analyst** are available*	-
First author leads kick-off call, including **large writing group** if possible (otherwise including **small writing group**). **SCC** will schedule call unless you can meet during a recurring group call.	1 month
Analyst develops data specifications, working with **small writing group**	2 weeks
Large writing group agrees to data specifications	2 weeks
Programmer or analyst creates project dataset	1 month
Analyst finishes first set of analyses	2 months
First author and small writing group reviews first set of tables	1-2 weeks
Analyst updates analyses based on feedback from small writing group	2-4 weeks: simple, 1-2 months: complex
First author develops final tables, summarizes results, and meets with **large writing group** to review and approve tables and main points	1-2 months
First author writes first draft of paper and circulates to **small writing group** for review. **First author** can involve **small writing group** in drafting the paper.	2-3 months
Large writing group reviews and comments on outlines and drafts	2 weeks
First author incorporates coauthor comments	1 month
*Typically, 2 drafts circulated to **large writing group** before submission*	**-**
Steering Committee reviews and approves final manuscript	1-2 weeks
***First author** submits manuscript to journal*	-
First author responds to journal review and revises manuscript	2 weeks (sooner if required by journal)
Coauthors review revised manuscript and response	2 weeks (sooner if required by journal)

Overview of BCSC Collaborative Writing Guidelines



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