**National Cancer Institute Breast Cancer Surveillance Consortium (BCSC)**
**Guidelines for Internal BCSC Manuscript Development**
**Version 2.1: December 20, 2008**

The BCSC collaborative writing guidelines are in place for any manuscript that arises from the use of pooled BCSC data from 1 or more consortium sites that use the SCC to conduct analyses. This is the second version of the guidelines. It is designed to promote more up-front work before analyses start in order to increase efficiency and improve manuscript development.

Our guidelines outlined below are designed to enhance:

- Communication,
- Organization,
- Timeliness,
- Process and
- Planning,

The BCSC requires an updated ***working proposal*** and ***title*** that are updated every 6 months (in time for the BCSC meetings) to reflect the main study hypotheses and objective of the analyses. The **working proposal** is an updated version of the approved proposal with changes reflected in such things as inclusion/exclusion criteria.

**Manuscript proposal development and approval process:**

1. Lead author: develop initial idea for a paper/abstract involving project specific information, identify supporting data sources and submit the BCSC proposal form to BCSC Steering Committee through a site Principal Investigator for approval. This should include a list of the lead author and all proposed contributing authors.
2. PIs should circulate the abstract to individuals from their site who may have interest in participating on the manuscript to identify persons for the small and large writing group. [See Table 1 for a summary of the differences in responsibility between small and large writing group members].
3. BCSC Steering committee reviews the proposal. If appropriate, members of the Steering Committee will contact the lead author to designate a co-author from the PIs site to participate in the large or small writing group.
4. If necessary, lead author will revise working proposal and communicate any changes resulting from BCSC Steering Committee review to all contributing authors.
5. The small and large writing groups should be identified and reported to the SCC within 1 month of manuscript approval.

**Between approval process and start of SCC analysis:**

1. The lead author will organize a meeting of the large writing group to review the approved proposal when notified by the SCC or Steering Committee that the analysis will begin in the next 6 months. Before the large group meeting, the lead author (or designee) should complete an updated literature review to ensure the approved proposal addresses the current state of scientific knowledge. The lead author will work 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.
2. The SCC will review the revised working proposal with specific attention to the study population, proposed definitions and analytic plan.
3. The large working group will specifically review: 1) Inclusion/exclusion criteria including years of data being used, 2) Definitions (with details if not standard BCSC definition), 3) main purpose of the analysis, and 4) draft working manuscript tables. The writing group may request some preliminary data analyses by the SCC to finalize inclusion/exclusion criteria.
4. The SCC analyst and lead author (with or without the small writing group) will meet following the large working 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 will send draft tables to the lead author. The lead author will send draft tables to the small writing group for review; the small writing group will have 1-2 weeks to review. The lead author must involve designated members of the SCC in all data analyses, except where de-identified or limited datasets are provided directly to an investigator.
2. The small writing group will work closely with the lead author and SCC analyst to conduct rigorous review of data tables generated using planned methods, definitions, relevant coding and analyses as defined above and will revise approach as necessary.
3. The lead author will present the main points of the analyses at a BCSC meeting or on a monthly scientific Steering Committee call (this may happen before or after the 2nd large writing group call – discussed in number 4 below).
4. The lead author will organize a conference call with the large writing group for sign-off on all study methods, tables, and outline of manuscript before the manuscript is drafted. The large writing group should review and agree to the: common objective, working proposal, methods, completed study tables, main points of the manuscript and target journal before the manuscript writing begins.

**Drafting the manuscript**

1. The lead author should work closely with the small writing group (ideal size 1-2 people aside from SCC analyst and lead author) during the drafting of the manuscript. The lead author is responsible for sending out drafts of the manuscript to coauthors.
2. 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 the title of the manuscript.
3. Every author will have up to 2 weeks to review the manuscript and send comments to the lead author. If a coauthor cannot complete the review in the 2 week period, there must be communication to the lead author with a date for when comments can be returned.

The lead author will:

1. 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, including following the agreed upon timetable.
2. Identify an appropriate mechanism to share drafts and communicate effectively, and use it consistently (i.e., e-mail, fax, express mail, FTP site, wiki). Provide reasonable deadlines for each review/revision and promote an understanding among collaborators that these will be adhered to unless scheduling issues are discussed with lead author before a review deadline.
3. Circulate an **outline** of the manuscript for review by the large writing group that outlines the main points for the introduction and discussion. These should be agreed upon based on the 3 main points of the manuscript and the target audience.
4. Determine authorship order based on the relative contributions of each co-author and communicate any changes that occur to SCC via e-mail (scc@ghc.org) or directly on the SCC website. Authorship order can be changed at any point during the writing process.
5. Monitor all areas of controversy that exist among coauthors and effectively communicate the rationale for any revisions made/not made (to the manuscript) to all co-author(s) before subsequent related reviews. The NCI project director can serve as mediator for any issues where lack of consensus occurs, and a final decision will be made by the lead author, the working group members, and the NCI project director. If an author cannot agree with the final consensus (where the NCI project director has determined that the majority of authors have come to a reasonable consensus), then an individual can withdraw authorship, recognizing that the paper will still go forward.

All coauthors reviewing manuscripts should send manuscript comments to all coauthors for review.

**Finalizing draft and submission**

1. The lead author must declare when the final draft is ready, and all collaborators will have 2 weeks to review and approve the final manuscript.
2. The manuscript must properly acknowledge BCSC for their contributions to the manuscript (see BCSC Data Request Process Guide).

3. If the author group includes an NCI scientist, clearance from NCI must be obtained before manuscript submission for peer-review. This review process usually will be completed within 2 weeks.
4. The lead author will inform all coauthors and the SCC contact (or scc@ghc.org) when the manuscript has been rejected, received a revise and resubmit, or been 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 projects and publications database, and post the most recent version of the manuscript.

**Manuscript revisions after submission**

The likelihood that manuscript revisions will be required is high. To facilitate this process, the lead author should select one or two of the most active writing participants to respond to the review comments and rewrite the manuscript within 2 weeks notification that revisions will be required. The revision should then be circulated to the final author group for comment and any response should be made within a 2 week period, so that total turn around time is one month (unless reanalysis of data makes this timeline impossible to meet, in which case, the lead author should develop a timeline and share it with the final author group).

If deadlines are not consistently met and work is not progressing, the PI, program director or lead author may request changes in membership of the contributing author list. The initial timetable and requests for reasonable extensions of the deadlines must be considered before any authorship change.

Table 1. Summary table of roles and responsibilities of small and large writing group members

| | Small writing group | Large writing group | Steering Committee |
|---|---|---|---|
| Approving initial proposal | X | X | X |
| Signing off on working proposal before analysis begins with specific attention to inclusion/exclusion criteria, definitions, main purpose of the analysis and draft manuscript tables | X | X | |
| Conducting rigorous review of data tables generated using planned methods, definitions, relevant coding and analyses as defined above and revising approach as necessary | X | | |
| Outlining the manuscript in its entirety with specific highlights of the unique contributions the work makes to the literature. Help with identifying main points of the manuscript and preparation/approval of presentation to BCSC steering committee | X | | |
| Review interim drafts of the manuscript with the lead author | X | | |
| Reviewing final manuscript tables before manuscript drafting begins. Involved in this process is agreeing to outline, main points and target journal for the manuscript | X | X | |
| Taking responsibility for the accuracy and content of the manuscript in its entirety | X | X | |
| Responding to recommended revisions as they occur after peer review | X | X | |
| Final passive-consent sign-off of manuscript from PIs from each site | | | X |

**Authorship and Acknowledgements** - 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 (1):

1. Substantial contributions to conception, design, or acquisition of data or analysis and interpretation of data, such as providing statistical expertise, obtaining funding, providing administrative, technical or material support, or supervision;
2. Drafting the article or revising it critically for important intellectual content; and
3. Final approval of the version to be published.

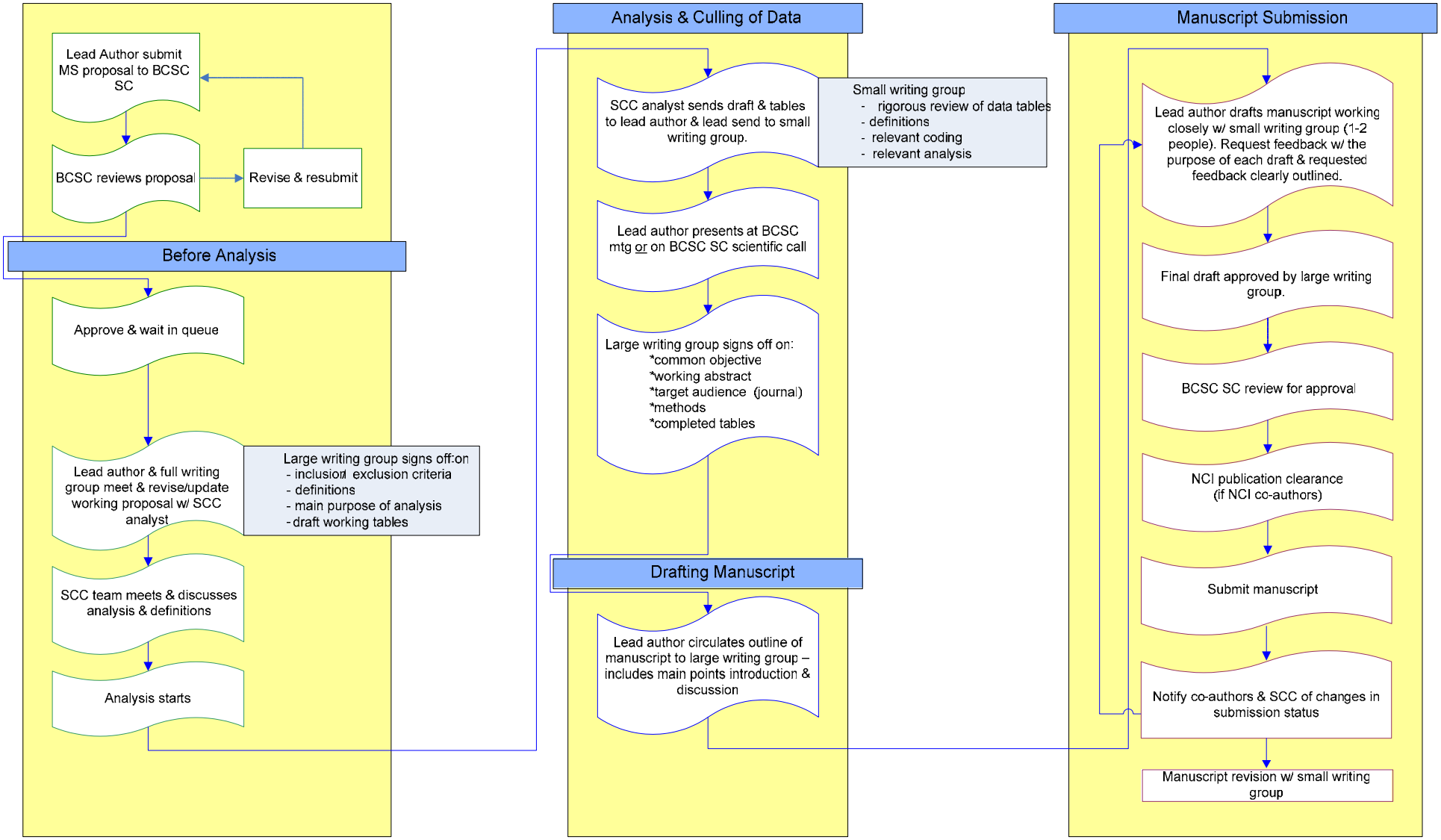
Acquisition of funding, the collection of data or general supervision of the research group by themselves do not justify authorship and should be acknowledged. Using JAMA Authorship Responsibility, Criteria and Contributions, the following must hold for any submission:

- 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; and
- 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.

**Citations**

1. International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Updated May 2000 (http://www.icmje.org).

# Overview of BCSC Collaborative Writing Guidelines




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