

Publication Guidelines and Required Acknowledgements

Guidelines for authorship and publication have been developed to ensure that results published by the Ovarian Cancer Cohort Consortium (OC3) are timely and of the highest quality, that the research projects are effectively coordinated, and that the individual researchers and centers that contribute to the projects are given fair and appropriate credit. These guidelines have been developed and approved by the OC3 Steering Committee. We anticipate that these guidelines will change over time to reflect the needs and experience of the OC3.

1. General Principles

One of several objectives of the Cohort Consortium is to foster multidisciplinary collaboration among genomic researchers, epidemiologists, biostatisticians, and other scientists in large-scale prospective studies of ovarian cancer. We anticipate that the OC3 will generate many high impact publications. Recognizing the contribution of a large number of scientists to the collection and analysis of data in the ovarian cancer project, the OC3 has developed the following guidelines to coordinate and facilitate publications derived from this collaboration.

2. Authorship

The general approach to authorship will be inclusive rather than exclusive, although it should meet the criteria proposed by the International Committee of Medical Journal Editors (ICMJE) (Annals of Int Med 1988;258-304). The ICMJE specified that authorship credit should be limited to those who contribute substantially to all of the following:

- a) Conception and design, or acquisition of data, or analysis and interpretation of data:
- b) Drafting the article or revising it critically for important intellectual content:
- c) Final approval of the version to be published.

According to the ICMJE, none of the above contributions is sufficient by itself to justify authorship. However, in the case of the OC3, multiple centers have contributed to data collection by providing questionnaire and follow-up data on cohorts and/or by contributing to the statistical analyses. A center is defined as an institution that is participating in the OC3, while a cohort is defined as an individual study that resides at a center. Note that some centers will have multiple participating cohorts.

It is proposed that each cohort that participates in a particular analysis will have 2 co-authors (an author may represent more than one cohort), not counting the writing group, listed on that particular manuscript. Cohorts can request that the steering committee make an exception if more than two authors are required for certain cohorts. This approach is compatible with the ICMJE view that, "A test to help determine whether a center should be included in the author list is 'could the work have been completed without the center'? If not, then each center that provided data should be represented in the authorship."

The author list will begin with the members of the writing team (except the senior author). Listed after the writing team will be all other researchers (in alphabetical order) who meet the criteria for authorship. The last author will be the senior researcher responsible for that particular manuscript/project. Additionally, if the journal permits it, the writing group should be specified in a footnote or acknowledgement.

Each writing team will consist of five or six researchers who have worked on a specific exposure of interest or proposal and/or been most active in developing the OC3. When the senior or first author circulates a proposal to the participating cohorts for approval, he/she should also solicit participation on the writing team. Cohorts participating in the project can request that an individual from that cohort be on the writing team. The person who submitted the proposal will assemble the writing team from among those who expressed interest, spreading membership across the cohorts as much as possible. One researcher (generally determined by the senior researcher) on the writing team will take primary responsibility for data analysis and writing, and will be considered first author. The senior researcher will be the person who submitted the original proposal or is the mentor of the person who submitted the proposal; their role is to edit the paper and accept full responsibility for its content. Either the lead or senior investigator will serve as the corresponding author. The remaining order in which other authors on the writing team will be listed will be determined based on contribution to the writing team.

The duties of the writing team are as follows:

1. Advice on conducting data analysis
2. Assistance/insight in interpreting results
3. In-depth reading and feedback on draft manuscripts prior to circulation to the full group

These duties should be completed in a timely fashion to ensure that an analysis is completed within the timeframe that the OC3 has put forward (see below).

If major imbalances appear between groups, and if these imbalances do not fairly reflect the level of contribution, the authorship lists will be negotiated with the Steering Committee.

Final decisions about who should be considered full authors on collaborative papers will be made by members of the Steering Committee, not by the journal or PubMed/NML. Other mechanisms for acknowledgement are discussed below.

A. Acknowledgement of Other Contributions

All papers will acknowledge the source of funding as follows:

Dept. of Defense Ovarian Cancer Research Program (OC110197)

Any other sources of funding for participating studies will also be recognized after acknowledgement of the Consortium funding source. The Steering Committee will develop a list of acknowledgements for each cohort/center and post it on the website.

B. Manuscript preparation, review, and approval

A major challenge in large collaborative undertakings is to ensure timeliness and effective coordination in developing manuscripts. Given the funding period, timeliness is particularly important. Accordingly, we will establish a priority list of manuscripts, mechanisms for writing and incorporating feedback, and expected dates for submission that respects competing demands on collaborating members but maintains a pace that is appropriate for the priority of the undertaking.

The following checklist is proposed to encourage each writing team to designate responsibilities and to establish a timeline for manuscript development. A number of these steps can be addressed simultaneously rather than sequentially.

- Clearly delineate the role(s) of each member of the writing team
- Work with data coordinating center to complete basic analyses; three possible options are:
 1. The data coordinating center conducts all analyses under the direction of the first and senior authors;
 2. The person conducting the analyses will be granted access to the data coordinating center computer system. This will require modifying or setting up a new DUA to allow the analyst access to the data; or
 3. DSAs are set up to allow transfer of a dataset from the data coordinating center to the Institution of the person conducting the analyses. This option may require setting up three-way agreements between the Institution, the data coordinating center, and individual cohorts. The approach for each project should be discussed with Dr. Shelley Tworoger who oversees the data coordinating center.
- Develop outline of main analyses, table shells, and selection and format of figures
- Identify and conduct secondary analyses
- First draft of title, abstract, results, tables, & figures
- First draft of methods
- Complete literature review and draft of introduction and discussion.
- First draft of full manuscript
- Incorporate secondary analyses
- Review and revision by authors
- Review by Consortium

We propose the following guidelines for manuscript review by the overall Consortium.

- Each of the contributing centers or group of cohorts will identify a contact for coordinating their input to any given manuscript (i.e., the designated contributor). This contact is also responsible for obtaining any signatures or other paperwork necessary for final submission to the journal.
- Preliminary tables of results will be circulated along with the outline of the paper. When a draft manuscript is circulated, co-authors are expected to provide feedback within 2 weeks of receiving the draft. Once the first author has received feedback from the group, he/she has two weeks to incorporate the feedback and produce an updated version of the manuscript.
 - The submission of comments to the first author should be coordinated by the designated contributor from each cohort group, combining input before forwarding to the writing team.
 - Ideally comments will be ranked into two levels, (a) essential analytic and factual changes, and (b) possible grammatical and other editorial changes
 - Revisions of the manuscript will specifically address responses to the category (a) items noted above. (However, changes in category (b) above will also be accommodated as appropriate in the manuscript.)

- Revised manuscripts will be circulated to all co-authors with the understanding that a timely response is essential to the overall success of this research undertaking. Any further revisions should be returned to the first author within 2 weeks.
- The final manuscript will be submitted within six to eight weeks after any final comments are sent to the first author. This will allow for all necessary cohort-specific review processes (which will be listed on the website and in the table below) that must occur before submission. The first and senior authors are responsible for ensuring that these review processes are met.
- If comments are not sent within the appropriate time frame, these additional suggestions might be incorporated during the peer review process.
- If the journal that accepts the manuscript does not automatically deposit the manuscript into PubMed Central, the first author must take responsibility for doing so.

For this overall process to work smoothly, the writing team and all co-authors will be placing very high priority on the collaborative manuscripts. Clear communication and quick responses will be essential for success.