

SOUTHWEST ONCOLOGY GROUP

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Policy Memorandum No. 24
Subject: Guidelines for Publication
Departments Affected: All

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PROCEDURAL GUIDELINES FOR ALL SOUTHWEST ONCOLOGY GROUP PUBLICATIONS

The timely publication of major Southwest Oncology Group findings is central to the mission of the Group and is a primary means by which the Group's accomplishments can be evaluated. Timely presentation of a study's findings and results is especially important when the Data and Safety Monitoring Committee recommends the public release of this information. The Southwest Oncology Group Office is responsible for monitoring the timely preparation and submission of all Group publications for peer review. It is anticipated that preliminary results of major Phase III trials would be presented at a scientific meeting within six to eight months of the study analysis (if not sooner based on the relevance of the results) and a manuscript on the study results would be prepared and submitted for publication within one year of the availability of the study results or within one year of the presentation of the preliminary results at a scientific meeting.

Publication of work done via the Group's Cooperative Agreement requires appropriate acknowledgment of NCI support. In addition, all Group publications must reference the NCI protocol title in the abstract or manuscript title whenever relevant to the publication.

Publication is defined to include Group abstracts, press releases, print-media articles/manuscripts, electronic media articles/presentations, letters, etc., related to the findings and results from Group studies. Details and requirements concerning certain types of publication are set forth below.

ABSTRACTS

Abstracts prepared for submission to any society meetings or seminars must be submitted to the Group Office at least two weeks prior to submission for authorship review and circulation to appropriate reviewers. Co-authorship assignment will adhere to the same guidelines for manuscripts as outlined in the following section. Abstracts must be approved by the appropriate Disease and Research Committee Chair, Biostatistician and all co-authors prior to submission for publication. If timelines do not allow this review prior to submission, the Primary Author is responsible for notifying (either orally or in writing) the Disease and Research Committee Chair, appropriate Biostatistician and all co-authors of the impending submission. In addition, abstracts may also require review by a pharmaceutical company(s) or the NCI prior to submission, with such review facilitated by the Group Office.

Copies of the submitted abstracts for all Southwest Oncology Group related studies must be sent to the Group Office to be included in the Group bibliography. The full abstract citation along with a copy of the published abstract must be sent to the Group Office when published.

Abstracts reporting the preliminary or highlighted results of a Southwest Oncology Group study will not eliminate the necessity for preparing a full manuscript for publication.

MANUSCRIPTS

Once a study is closed, the Group Office is notified and begins to track the data compilation and analysis. Once the data are deemed mature, the Group Office will contact the Study Coordinator to describe the steps needed for a manuscript to be created, reviewed and submitted for publication.

While the Group office will work with the primary study coordinator related to the publication, it is the responsibility of the Study Coordinator to submit a manuscript for publication within one year after closure, unless the Data and Safety Monitoring Committee decides that publication is premature. This includes negative trials and, if possible, studies closed prematurely (due to poor accrual or lack of benefit). If a manuscript is not provided within the specified timeline, it will then be considered delinquent. A delinquent manuscript is tracked with regular notifications to the primary study coordinator, relevant Disease & Research Committee Chair and Group leadership until the manuscript is submitted. Failure to respond to the notifications may result in the Study Coordinator responsibility being reassigned and a loss of credit for that investigator/institution.

Prior to submission of a manuscript to a journal, the following procedures are necessary:

1. The proposed draft manuscript must be submitted to the Group Office, where a face sheet will be formulated. The Group Office will circulate the manuscript to the following individuals for review:
 - A. Relevant Disease and Research Committee Chair
 - B. Appropriate Biostatistician. (The Biostatistician must be listed as second author. For certain large studies, inclusion of additional biostatisticians and/or the data coordinator as co-authors may be appropriate.)
 - C. Appropriate Discipline Chair
 - D. Co-authors
 - E. Group Chair

The Group Chair may, at his discretion, ask that the manuscript be reviewed by an individual other than those listed above.

Copies of the reviewer's comments must be returned to the Group Office or the Primary Author. Courtesy would dictate that the senior author respond to the reviewers who have substantive criticism on the manuscript so as to avoid conflict within the Group. The Group Chair must get copies of this correspondence.

Based on study contract specifications, manuscripts may also require review by a pharmaceutical company(s) or the NCI prior to journal submission. The Group Office will notify the Primary Author of these contract specifications and will request written authorization to circulate the manuscript to the company(s) named in the contract. The timelines for NCI and pharmaceutical review is minimally 30 days prior to submission for publication, although up to 60 days may be necessary to ensure the protection of company confidential or proprietary information or for the handling of intellectual property rights.

2. Selection of Co-Authors: Group Policy dictates that the Primary Author is the Study Coordinator. The contributing Biostatistician is listed as second author followed by the other Study Coordinators involved in study management and evaluation (e.g., radiation therapy, surgery, pathology, etc.). The Disease and Research Committee Chair will be listed as the senior author. The Statistical Center will provide a list of patient contributions by institution for each protocol and the Group Office will select top accruing institutions, with the cutoff occurring at either the natural break, or at a total of ten co-authors.

The Conflict of Interest Sub Committee will work with the appropriate Disease and Discipline Committee Chairs and the Group Chairs Office when publications arise from studies involving individuals with conflict of interest management plans in place.

When selecting co-authors based on accrual, the Principal Investigator at the corresponding institution will be named. It is the responsibility of that Principal Investigator to reassign authorship to the appropriate individual at that institution (individual who treated majority of patients on study). The Group Office and the Primary Author should be notified, in writing, of the change.

3. The Group Office will provide a face sheet (cover page) listing the following:

- A. Title
- B. Primary Author and Co-Authors
- C. Institutions
- D. Grant Numbers (Institutions, Statistical Center, Group Office)
- E. Address for Editorial Correspondence
- F. Reprint Request Address

This face sheet **MUST** be included with your manuscript when it is submitted for publication.

4. **Manuscript Submission to Journal:** Prior to submitting a manuscript to a journal, the Primary Author must request a final review of the manuscript and receive written approval to submit from the appropriate Disease and Research Committee Chair.

- A. **Submission:** The Primary Author is responsible for submitting their manuscript to a journal. A copy of the Disease and Research Committee Chair's final approval, letter of submission to the journal, and a clean copy of the final manuscript must be sent to the Group Office.

The Group Office will then distribute copies of the final manuscript to the co-authors, the Group Chair, and the NCI.

- B. **Acceptance:** When the journal notifies the Primary Author that it has accepted a manuscript for publication, the Primary Author must send a copy of the acceptance letter to the Group Office. The Group Office must also be notified if a manuscript is not accepted, and what course of action the author intends to pursue. Copies of journal reviews should be sent to the Group Office.
- C. **Galley Proofs:** All galley proofs are to be sent from the journal to the Primary Author. If the proofs should happen to come to the Group Office, they will immediately be returned to the Primary Author.
- D. **Final Acceptance by Journal:** In accordance with Division G, Title II, Section 218 of PL 110-161 (Consolidated Appropriations Act, 2008) the NIH Public Access Policy, previously voluntary, is now mandatory effective April 7, 2008. The Primary Author is responsible for submitting to the NIH National Library of Medicine's PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH (via research grant and career development award mechanisms, cooperative group agreements or contracts). The author's final manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. Upon acceptance for publication, it must be made publicly available no later than 12 months after the official date of publication. The NIH Policy applies to all peer-reviewed journal articles, including research reports and review, but not including non-peer-reviewed materials, such as correspondence, book chapters and editorials. Also effective April 7, 2008, authors of articles arising from NIH funds are responsible for insuring that publishing agreements allow for full compliance with this policy. These manuscripts will be preserved permanently in the PMC archive for use by the public, health care providers, educators, scientists, and NIH.

Furthermore, beginning May 25, 2008, anyone submitting an application, proposal or progress report to the NIH must include the PMC or NIH Manuscript Submission reference number when citing application articles that arise from their NIH funded research. Non-

compliance with the policy will have negative funding implications. The new NIH policy will have direct impact on all peer-reviewed articles resulting from Southwest Oncology Group studies. While the Group's publication office, upon notification of manuscript acceptance, will remind the primary author regarding the NLM PubMed submission requirement, actual submission to NLM PubMed Central is the responsibility of the primary author. It will also be the responsibility of the primary author to notify the publications office of the PMC or NIH Manuscript Submission reference number, as well as article PDF file, when available. The following are links regarding the new policy which may be useful to the membership:

<http://publicaccess.nih.gov/>
<http://publicaccess.nih.gov/FAQ.htm>
http://publicaccess.nih.gov/PublicAccess_training.ppt
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html>

- E. Reprints: Inasmuch as most scientific journals now provide authors with a complimentary number of PDF copies of their published articles, reprints will only be ordered/dispensed by the Group Office if legitimate need can be demonstrated by the primary author.

PUBLICATIONS CREDIT

All Southwest Oncology Group abstracts and manuscripts must be forwarded to the Group Office at the time of submission, prior to publication. Failure to submit abstracts and manuscripts to the Group Office will result in the loss of institutional/investigator credit for the publication (credits for publications are tallied and reported in each Group Continuation and Competitive Renewal).

DATA DISCLOSURE AND REPRODUCTION OF DATA

Unauthorized or premature disclosure of data is prohibited.

Reproduction of Southwest Oncology Group study data by journals without express approval by the primary author, committee chair, Group chair and original publication is prohibited. In addition, the Group Office will verify the acceptability of the journal before granting final permission for publication.

REPRINT OF ARTICLES PRODUCED BY THE GROUP COMMUNICATIONS PROGRAM

All requests for reprints of articles in Group publications, such as the Group Newsletter, CHOICE - the Newsletter for SELECT Men, and Keeping Abreast must be approved by the Group Office.

The quality of the publication requesting reprint permission and their mission will be verified to ensure it is a suitable venue for Group material. The requestor must also agree to properly credit the Southwest Oncology Group when the material is published.

PRESS RELEASES

Any press release related to Group activities must be coordinated with Group's Public Relations Officer. The Public Relations Officer will communicate, as needed, with the NCI and/or pharmaceutical companies to ensure compliance with grant and contractual obligations for the public release of Group study findings or study information. SWOG press release policy is detailed in Policy #45.