

SWOG CANCER RESEARCH NETWORK
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Policy Memorandum No. 24

Subject: Guidelines for Publication

Departments Affected: All

Page 1 of 7 pages

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**PROCEDURAL GUIDELINES FOR ALL
SWOG PUBLICATIONS**

The timely publication of SWOG study 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 Group Publications Office, with oversight by the SWOG Publications Committee, 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 90 days of the presentation of the results at a scientific meeting.

Publication of work done via the Group's Cooperative Agreement requires appropriate acknowledgment of NCI support, as well as industry support where applicable. In addition, the SWOG name and study number must appear in the title of primary study results publications, if permitted by the publisher. The SWOG name should also appear in all secondary results publications resulting from SWOG-coordinated/directed research, if permitted by the publisher. Publication is defined to include Group abstracts, articles/manuscripts, press releases, print-media, electronic media articles/presentations, letters, etc., related to the findings and results from Group-coordinated/directed studies. Details and requirements concerning certain types of publications are set forth below.

ABSTRACTS

It is requested that abstracts prepared for submission to any society meetings or seminars be submitted to the Group Office (pubs@swog.org) no later than two weeks prior to submission, or as determined by contractually bound timelines, to allow for authorship review and circulation to appropriate NCI and industry 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/Discipline Committee Chair, Biostatistician and all co-authors prior to submission for publication. In addition, abstracts require review by NCI/CTEP and may also require review by a pharmaceutical company(s) prior to submission, with such review facilitated by the Group Office.

Copies of the submitted abstracts for all SWOG 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 SWOG study will not preclude the necessity for preparing a full manuscript for publication.

MANUSCRIPTS

Once a study is closed, the Group Publications 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 Chair to describe the steps needed for a manuscript to be created, reviewed and submitted for publication. While the Group Publications Office will work with the primary Study Chair related to the publication, it is the responsibility of the Study Chair to submit a manuscript for publication to the Group

Publications Office within one year after completion and availability of the data analysis, and at least 30 days in advance of submission for publication to a journal, unless the Data and Safety Monitoring Committee decides that publication is premature. This includes negative trial results 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 Study Chair, relevant Disease/Discipline Committee Chair and Group leadership until the manuscript is submitted. Failure to respond to the notifications may result in the Study Chair responsibility being reassigned and a loss of credit for that investigator/institution.

Furthermore, a Study Chair must submit a draft manuscript of definitive primary endpoint study results, translational medicine/correlative sciences analysis(es), or single study/multiple studies dataset analysis(es) to SWOG's publications office (pubs@swog.org) within three months of the date on which those results are presented as an abstract at ASCO, ASH or an equivalent national or international professional society or association meeting. If an investigator misses this three-month deadline, the Chair of the Disease/Discipline Committee concerned may ask another investigator to prepare the manuscript. Where lead authorship is reassigned to another investigator due to delinquency in the preparation of the manuscript, placement of the original investigator may be designated either as co-first author with second author placement, or with third author placement based on level of contribution at the discretion of the Disease Committee Chair.

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 Publications Office (pubs@swog.org) 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 (with primary responsibility for conducting a n a l y s i s)
 - C. Appropriate Discipline Chair
 - D. Co-authors

Copies of the reviewer's comments must be returned to the Group Publications 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.

Based on study contract specifications, manuscripts may also require review by a pharmaceutical company(s) and/or the NCI/CTEP or NCORP prior to journal submission. The Group Publications Office will notify the first/lead author of these contract specifications and will request written authorization to circulate the manuscript to NCI/CTEP or NCORP and/or to the company(s) named in the contract. It is requested that manuscripts prepared for journal submission be submitted to the Group Office (pubs@swog.org) no later than 30 days prior to journal submission, or as determined by contractually bound timelines, to allow for authorship review and circulation to appropriate NCI and industry reviewers.

2. Selection of Authors:

- A. Primary Results/Primary Endpoint Abstracts and Manuscripts: Group policy dictates that the first/lead author is the Study Chair (or alternate as assigned by the Chair of the Disease/Discipline Committee in the event of delinquency as described above under "Manuscripts" paragraph 2), and may not delegate this authorship. The lead/contributing biostatistician is listed as second author followed by the study co-chairs involved in study management and evaluation as listed in the protocol (e.g., radiation therapy, surgery, pathology, etc.). For certain large studies, inclusion of additional biostatisticians and/or the

data coordinator as co-authors may be appropriate. The Disease/ Discipline Committee Chair will be listed as the senior author. Inclusion of the Disease/ Discipline Committee Vice Chair, Organ Site or Subcommittee Co-Chair in authorship will be determined at the discretion of the Disease/Discipline Committee Chair. Because NCORP committees have 2 co-chairs, senior author placement will be determined by the co-chair with the proportionately larger role/contribution to the study.

If a study has a PRO/QOL analysis, the level and significance of the PRO/QOL analysis in a primary endpoints paper should be determined and the Symptom Control/QOL investigators/co-chairs included in authorship at the discretion of the lead author and Disease/Discipline Committee Chair.

The Statistical Center will provide a list of patient accrual contributions by SWOG institution. Each SWOG institution that enrolls at least 5% of the entire study sample will be accorded one author slot, with the institution SWOG PI responsible for identifying the author designee. Each institution will be entitled to an additional author slot for each additional 10% of the overall accrual. For example, if an institution enrolled 15% of the study patients, that institution would be accorded 2 co-author slots; if 25% of the study patients were enrolled, that institution would have 3 coauthors. The total number of institution accrual co-authors will not exceed an overall total of ten co-authors for a manuscript. If more than 10 institution coauthors are eligible for slots according to the criteria noted above, priority will be given to the higher accruing institutions.

- B. Secondary Results/Secondary Endpoint Abstracts and Manuscripts (i.e., translational medicine/correlative sciences analyses, single study or multiple studies dataset analyses, or SCQOL or other such analyses of the primary disease-related study:
1. Selection of co-authors for translational medicine/correlative or dataset analysis that relies on data from a single study: The first and last authors and the lead statistician from the primary endpoints paper should be included as coauthors. Additional co-authors, including study co-chairs and accrual authors, will be selected at the discretion of the primary investigator (lead author) of the secondary analysis based on contribution. Geographic placement of authors will be at the discretion of primary investigator, however, the lead statistician of the secondary analysis should be accorded second author slot. The appropriate TM Subcommittee Chair may be assigned as senior author at the discretion of the Disease/ Discipline Committee Chair based on contribution.
 2. Selection of co-authors for translational medicine/correlative or dataset analysis on multiple studies (meta-analysis), especially where multiple disease sites are involved: The primary investigator (lead author) will prepare a list of recommended investigators for inclusion in authorship as deemed appropriate based on level of contribution/participation in the analysis, including senior authorship, for approval by the Disease/Discipline/TM Sub- Committee Chair. Where dataset analysis involves 1-4 primary disease sites, the Disease Committee Chairs of those disease sites (refer also to Section H) will be considered for authorship.
- C. Regarding NCORP Committees' trials/analyses which involve a specific disease site, inclusion of disease specific chair in authorship will be considered at the discretion of the Discipline Committee Co-Chairs based on contribution to the design or conduct of the study.
- D. Intergroup Study Publications: Once finalized, recommendations of the NCTN Intergroup Publications Authorship Policy Working Group will be incorporated in a subsequent update of Policy 24.

SWOG disease site/discipline committee chairs will have the ability to include additional authors from the other participating cooperative groups in SWOG-led intergroup study publications (e.g., members of designated intergroup steering committee for site protocol would be included in authorship; other committee chairs representing a specified disease site/discipline would routinely be included to the reports of collaborative intergroup clinical trials) as long as not in conflict with either SWOG policies or NCTN Intergroup Publications Authorship Policy Working Group recommendations.

- E. Other co-authors: Other authors may be included as deemed appropriate by first/lead author, but justification regarding nature of contribution meriting authorship should be provided. Consideration should be given to the executive officers, vice-chairs or disease chair for inclusion in authorship when appropriate,
- F. Policy for dual or co-primary/lead and dual or co-senior authors: In some rare instances, two investigators share primary (dual) or co-senior authorship in recognition of equal study contribution. This may also be true in the case of intergroup studies, where the co-study chairs are from different NCTN Groups. Dual authorship, as well as sequence, will be determined at the discretion of the Disease/Discipline Committee Chair.
- G. Posthumous recognition: Every effort should be made to include in authorship investigators who significantly contributed to the work reported in manuscripts or abstracts, but who died prior to abstract/manuscript preparation, unless the target journal prohibits or makes such inclusion in authorship unwieldy (e.g., excessively complex or prohibitive copyright/legal issues), in which case the investigator will be included in acknowledgements, at the discretion of the Disease/Discipline Chair.
- H. Term limits for Disease/Discipline Committee Chairs and senior author selection for primary endpoints papers where time period of study involved leadership overlap: The Disease/Discipline Committee Chair who was responsible for study inception, design and implementation/initial activation will be accorded senior authorship on such study publications. Any other arrangement by the current committee chair, appointed after the study was already actively running/recruiting, must be discussed with the Publications Committee Chair and, as required by the Group Chair for approval.
- I. Editorials authored by SWOG investigators and which are influenced by SWOG work, or include discussion of SWOG work, should acknowledge Group membership of author(s) in affiliations, provide study identification where applicable, and be described in content where possible.
- J. Exceptions to policy and procedure will be adjudicated by the SWOG Chair of Publications Committee and, as required, by the Group Chair.
- K. SWOG PowerPoint template must be used for oral presentations at scientific meetings reporting findings of SWOG studies, and SWOG/NCI combined logo must be used in poster presentations. Other institutional logos may be included in presentation or poster at the discretion of the investigator.
- L. Acknowledgements: Non-Author Contributors: Contributors who meet fewer than all four of ICMJE criteria for authorship should not be listed as co-authors in a publication, but should be considered for acknowledgement in recognition of their efforts. Those whose contributions do not justify/merit authorship may be acknowledged individually or together as a group, and their contributions should be specified (e.g., "served as patient advocate" "served as scientific advisors," "critically reviewed the study proposal," "collected data," "participated in writing or technical editing of the manuscript", "reviewed consent or other

forms associated with study”, “participated in trial information dissemination”, “provided administrative support for protocol implementation” or other). Authors are specifically encouraged to be inclusive of patient advocates when justified. At discretion of Study Coordinator and Disease/ Research Committee Chair and where journal policy permits, primary manuscripts may also acknowledge each institution that enrolled participants on the study (in acknowledgements or, where required by journal, as an appendix/ supplement). SWOG Operations or Statistical Center or other support or administrative staff with direct project-specific responsibilities may also be acknowledged.

The Conflict of Interest Sub-Committee will work with the appropriate Disease/Discipline Committee Chairs and the Group Publications 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 investigator at that institution (generally the investigator who treated the majority of patients on study). The Group Publications Office should be notified via written communication of the change.

1. The Group Office will provide a title page to include the following:

- A. Title
- B. Lead/First Author and Co-Authors
- C. Institutional Affiliations
- D. Grant Numbers (Accruing Institutions/Other NCTN Groups), Statistical Center, Group Office), as well as Industry Support where applicable
- E. Corresponding Author and Contact Information

This title page must be included with manuscript when submitted for publication.

2. Manuscript Submission to Journal: Prior to submitting a manuscript to a journal, the first/lead 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 lead/first author is responsible for submitting his/her manuscript/ abstract to the journal/professional society scientific conference, and for submission fee and any publication fee. The Disease/Discipline Committee Chair's final approval, journal submission notification, and a clean copy of the final submitted manuscript must be sent to the Group Publications Office. The Group Publications Office will distribute copies of the final manuscript to the co-authors, NCI/CTEP and industry collaborator, where appropriate.
- B. Acceptance: When the journal notifies the first/lead author that it has accepted a manuscript for publication, he/she must send a copy of the acceptance letter to the Group Publications Office. The Group Publications Office must also be notified if a manuscript is not accepted, and what alternative course of action the author intends to pursue.
- C. Galley Proofs: All galley proofs are to be sent from the journal to the first/lead author. If the proofs should happen to come to the Group Publications Office, they will immediately be forwarded to the first/lead 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 became mandatory effective April 7, 2008 (<http://publicaccess.nih.gov/>). The first/lead author must submit the published (accepted) version of the study manuscript to the NIHMS Manuscript Submission System/NIH PubMed Central

online open-access repository if not already done so by the publisher, and report this registration to the SWOG Publications Office. If the first/lead author is unable to make this submission, he must notify the Group Publications Office as soon as possible for assistance.

- E. Reprints: Reprints will not be ordered or dispensed by the Group Publications Office inasmuch as most scientific journals now provide authors with a complimentary number of PDF copies of their published articles, or the articles are freely available online.

RELEASE OF RESULTS

For phase III, phase II/III and blinded randomized phase II trials, any release of outcome data [either internal to SWOG, to NCI personnel not members of the DSMC, or external (e.g., a paper presented at professional society meetings, seminars, papers, etc.)] prior to the final approval of general dissemination of results must be reviewed and recommended for approval by the DSMC to the designated Group Chair. In general, outcome data from phase III, phase II/III, and blinded randomized phase II trials would not be routinely made available to individuals outside of the DSMC until accrual has ceased and all patients have concluded their randomized treatment. After this time point, the DSMC may recommend the release of outcome data on a confidential basis to the Study Chair for planning the preparation of manuscripts, and/or to a small group of individuals for purposes of planning future trials. The DSMC will consider special requests for information from the disease committee chair prior to that time point. The DSMC should be made aware of any communication of analysis results from phase III, phase II/III, and blinded randomized phase 2 trials outside of the statistical center at any time. The Group Chair may not be able to accept the recommendation of the DSMC to release data for a specific trial if SWOG and/or NCI/DCTD/ CTEP has a binding agreement with a company collaborator (or other entity) that specifies data exclusivity for the trial without discussing the release with CTEP (for SWOG trials with a CTEP binding agreement) and/or the company or other collaborator (for SWOG studies that are under other binding agreements).

DATA SHARING DERIVED ANALYSES, AND PUBLICATIONS RESULTING FROM DATA REQUESTS

Requests for SWOG data to be released and analyzed by an outside investigator are governed by the SWOG Data Sharing Policy/Agreement. Only data from studies that have been previously published in a peer-reviewed publication may be released. Furthermore, single institution-data use and publication should occur only after a formal data request has been submitted to SWOG and, if approved, a DUA executed. No such single institution data use and publication should occur before the main study publication(s) have been completed. SWOG recognition in the acknowledgements, including appropriate grant acknowledgement, is required. Prior to journal submission, manuscript draft must be sent to SWOG publications office (pubs@swog.org) to insure compliance with Group policy.

PUBLICATIONS CREDIT

All SWOG abstracts and manuscripts must be forwarded to the Group Publications 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 SWOG study data (e.g., tables or figures) by journals/individuals without express approval by the first/lead author, Disease/Discipline Committee Chair, Group Chair and original publication journal is prohibited. In addition, the Group Office will verify the acceptability of the journal before granting final permission for publication.

Page 7 of 7 pages

Subject: Guidelines for Publications

Policy Memorandum No. 24

PRESS RELEASES

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