

I. General Considerations

1. Introduction

The RTOG Foundation Board of Directors **Publications Committee** oversees all aspects of publications for the RTOG. The intent of the Committee is to report the results of all of the RTOG's clinical trials and corresponding projects. The Publications Committee consists of Board and Advisory Committee members that represent RTOG's participating institutions. The **Publications Committee Chair** leads the Publications Committee and is appointed by the Board of Directors.

The RTOG **Publication Guidelines** apply to any publication – including abstracts, presentations, and manuscripts – which utilizes RTOG Foundation data or resources. These guidelines build on the *International Committee of Medical Journal Editors (ICMJE) Uniform Requirements for Manuscripts Submitted to Biomedical Journal*.

2. Roles and Responsibilities

A. Publications Committee

The role of the Committee is to disseminate RTOG research results to the scientific and lay communities by promoting and facilitating publication of RTOG trial results and corresponding projects in a timely manner. Committee members are nominated for two-year terms and are expected to fulfill all of the roles and responsibilities listed below. Members who do not fulfill their obligations may not have their terms renewed.

The Publications Committee and the Publications Chair will:

- i) Meet as required via conference call or face-to-face to review relevant publication issues.
- ii) Review the scientific merit of abstracts and papers prior to presentation/publication.
- iii) Determine authorship lines so that the appropriate contribution credit is recognized.
- iv) Advise on the deployment of RTOG resources toward the most important ancillary analyses, which includes reviewing and voting on ancillary analyses requests.
- v) Make recommendations on data sharing
- vi) Update the RTOG Publication Guidelines as necessary

B. Publications Executive Subcommittee

- i) The Publications Executive Subcommittee consists of the Board Chair, the Board President, the Publications Committee Chair, and the Statistician on the Board of Directors.
- ii) The Subcommittee makes executive decisions on behalf of the Publications Committee as needed regarding timely submission of manuscripts, manuscript primary author reassignment, ancillary analysis final approval, review of abstracts and manuscripts intended for meeting or journal submission, and other time-sensitive matters.
- iii) The Subcommittee adjudicates authorship disputes.

C. Primary Author

- i) The primary author is generally the corresponding author and guarantees the integrity of the work.
- ii) The primary author must follow the RTOG Publication Guidelines and decisions of the Publications Committee, including the designated authorship line.
- iii) The primary author is expected to complete appropriate quality control reviews (when applicable) prior to commencement of data analysis.

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- iv) The primary author is expected to submit and complete abstracts and manuscripts in a timely manner, as described in pre-publication procedures (section IV)
- v) The primary author will work with RTOG staff to distribute their abstracts and manuscript to all co-authors for review and feedback.
- vi) The primary author must submit the published version of their manuscript to the NIH PubMed Central online open-access repository, if not already done by publishing journal, and report this registration to RTOG Publications.
- vii) The primary author of an initial protocol endpoint paper cannot give authorship rights to another person. Exceptions can be requested of the Publications Committee in advance of the writing process.

D. Co-author/Contributor

- i) The co-author/contributor must review and approve abstracts, presentations, and manuscripts in a timely manner and complete required conflict of interest disclosures in order to maintain co-authorship.

II. Types of Analyses and General Guidelines for Resulting Publications**1. General Considerations**

- A. The RTOG name and study number must appear in the title of every publication, if allowed by the publisher.
- B. All abstracts, presentations, and manuscripts must be submitted to RTOG Publications for review prior to submission
- C. All RTOG Publications must acknowledge all applicable funding sources, including RTOG grants, and corporate support as appropriate.

2. RTOG Protocol-Specified Analyses

- A. In general, the first publication for a study is reporting of the primary endpoint unless an exception is made by the Publications Committee or the study protocol specifies otherwise.
- B. Primary Endpoint
 - i) Initial reporting of the primary endpoint is assigned to the study Principal Investigator.
 - ii) Updated publications on the same endpoint will be treated as separate publications and must also follow the RTOG Publication Guidelines.
- C. Secondary Endpoints
 - i) Reporting of secondary endpoints included in the original protocol is considered part of the protocol's planned publications.
 - ii) In some instances, reporting of secondary endpoints may be appropriate prior to reporting of the primary endpoint, and requires approval from the Publications Committee in consultation with RTOG leadership. Such analyses will typically also require approval from the study sponsor and oversight bodies (e.g. Data Monitoring Committee).
- D. The protocol endpoint manuscripts must include an appendix or table of all contributing institutions and the RTOG institutional PI at the time the study closes.

3. RTOG Non-Protocol Specified Analyses

- A. Ancillary Analyses of Clinical and/or Biologic Material Data
 - i) Ancillary analysis papers are those in which data are analyzed for non-predetermined endpoints (not identified in the protocol) and may involve a single study or cross several studies. Ideas for ancillary analyses are proposed by individual investigators and must

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- be submitted to RTOG Publications. Proposals are vetted and approved by the Publications Committee for use of statistical, core lab, and administrative resources.
- ii) In general, ancillary analyses are performed after the relevant protocol-specified endpoints of a study have been reported. Occasional exceptions must be approved by the Publications Committee
 - iii) Review process is described in Section V-5.
- B. Methodologic Analyses primarily based on:
- i) Physics/Dosimetry
 - ii) Statistical Methods
 - iii) Process Studies (i.e. protocol development, administrative, publications)

4. Review & Statement Papers

- A. Review and Statement papers on radiation therapy and related fields provide a unique opportunity for RTOG leadership and recognized RTOG researchers to share the scope of the Foundation's research with the medical community.
- B. Review papers cover the history and current state of the science in a specific area, usually summarizing multiple significant studies and noting where additional research is necessary. These papers are frequently written by recognized experts in a specific field, and will be assigned or approved by the Publications Committee if the author is writing on RTOG studies or on behalf of the Foundation.
- C. Statement Papers (White Papers)
Statement or white papers are intended to detail RTOG's position or philosophy on a given topic. White papers are often written to summarize the conclusions of a working session convened on a specific topic.

III. Authorship and Contributorship Guidelines

RTOG believes strongly in recognizing investigators who significantly contributed to the scientific development of the study/project, the data analysis, and abstract/manuscript writing and review, as well as those who provide scientific data (patient accrual, clinical data, and biological material submission).

The Publications Committee determines the authorship line in close collaboration with the primary author based upon the Publications Guidelines. The total number of authors is subject to meeting/journal policies. The RTOG Publications-approved authorship line is final and must be used for submission. Unless otherwise determined, manuscripts will use the author byline determined for a corresponding abstract submitted to a conference for presentation.

1. Authorship Determination for RTOG Protocol Specified Analyses

- A. Authors
 - i) Primary Author
 - (1) The study Principal Investigator has priority to be the Primary Author on the initial reporting of the primary endpoint. The study Principal Investigator may not delegate this authorship right without permission from the Publications Committee.
 - (2) For secondary endpoints, the primary author will be the appropriate study co-chair.
 - ii) Co-authors
 - (1) RTOG Biostatisticians
 - (a) The primary study statistician will be listed as a co-author.

- (b) When appropriate, additional statisticians may be recommended for authorship.
- (2) Study Co-chairs
- (a) Co-chairs who appropriately contributed to the publication may be listed as co-authors. (For example, if a separate QOL publication is planned, the Quality of Life co-chair will not be included on the authorship line for the primary clinical paper.)
 - (b) If a study co-chair leaves an RTOG institution, he/she maintains authorship rights with the permission of the Foundation Chair and the Publications Committee, provided that he/she continues to fulfill his/her study co-chair and co-author responsibilities. The affiliation listing for such co-chairs will be decided by the Publications Executive Subcommittee.
 - (c) Inclusion of deceased authors will follow generally recognized authorship guidelines for medical journals
- (3) Accrual Authors
- (a) An effort will be made to maximize the number of accrual co-authors. The number of accrual co-authors will be designated by the Publications Chair.
 - (b) Authorship based on accrual will be granted to institutions which enrolled the largest number of patients to a study. Accrual numbers are based on the patient cohort used in the paper [for example, a publication on quality of life endpoints will use accrual based on patients enrolled to the quality of life portion of the study. Accrual for translational research analyses will be based on specimen submission].
 - (c) Authorship representation for accrual rests with the institution. The accruing institution's principal investigator (PI) designates the representative author for that institution. When an accrual representative leaves the institution, the institutional principal investigator has authority to assign a different author for that institution.
 - (i) The RTOG institutional PI may allow the previously designated co-author to retain his/her authorship rights, but this co-author must list their affiliation as with the institution where the data was collected/patients treated; if the journal/meeting allows co-authors to list multiple affiliations, the co-author may also list his/her current institution following their previous institution affiliation (i.e. "Thomas Jefferson University Hospital (during trial), Mayo Clinic (current)")
 - (ii) The RTOG institutional PI may elect another investigator currently at their institution to replace the previous representative, preferably one who also participated in the trial but did not receive authorship credit
 - (iii) The RTOG institutional PI may elect themselves as the accrual authorship representative to represent the entire institution's efforts on the trial
- (4) Senior Author
- (a) The Disease Site Chair at the time of study activation holds the right to senior authorship, subject to fulfilling his/her responsibility to have major scientific participation in the development, conduct, and analysis of the study. If the Disease Site Chair is the primary author of the study, he/she may recommend a study co-chair as senior author to the Publications Committee.
- (5) Foundation Leadership
- (a) If the Foundation Chair, President, or other Foundation leader has made a substantial contribution to a study, his/her name(s) may be included in the author

line. Authorship is not granted for general oversight nor for solely obtaining funding.

(6) Other Co-authors

(i) The primary author and/or the senior author may request to the Publications Committee/Publications Chair to add additional contributors to the authorship line. Justification must be provided for such requests.

B. Order of Authorship for Protocol Specified Endpoints

- i) The order of authorship will be as follows: primary author, primary RTOG Biostatistician, applicable co-chairs, accrual authors, senior author.
- ii) Additional authors, if applicable, will be listed between the accrual authors and the senior author.

C. Order of Authorship for Patient-Reported Outcomes (PROs)/ Quality of Life (QOL)/ Comparative Effectiveness (CE) Protocol Analyses

- i) Primary Author (ie, QOL/CE protocol investigator); RTOG Biostatistician; other research investigators who are critical to the development and conduct of the study; clinical study PI; accrual authors (based on QOL/CE submission); QOL/CE Co-Chair; Senior Author

2. Authorship Determination and Order for RTOG Non-Protocol Specified Analyses

A. Ancillary Analyses of Clinical Data and Biological Material

Order of authorship for such analyses will mirror the stated clinical authorship guidelines, incorporating the unique realities of team-based basic and translational research.

Authorship shall be predicated upon the degree of contribution to the overall effort, representing the sum of the scientific effort, patient accrual that led to acquisition of relevant biorepository specimens, and the biostatistical/bioinformatics work required for proper analysis of resultant data.

Prospective authors should be identified in advance at the time of the Translational Science (TS) ancillary analysis application, when possible.

i) Authors

Primary author is the investigator who requested the analysis and who led the specific TS effort. He/she will assess the relative contributions of all putative co-authors, in consultation with RTOG Publications.

Team science can involve contributions from many investigators with roughly equivalent degrees of effort. In such cases, the primary author may include all of them.

It is the responsibility of the lead author to verify and to assume responsibility of the integrity and accuracy of the data, inclusive of the clinical, translational, and basic science components.

(1) Co-authors:

- (a) RTOG biostatistician(s) involved in performing the ancillary analysis
- (b) additional requesting investigators (up to 3) significantly involved in the development of the ancillary analysis proposal
- (c) Principal Investigators of all studies included in the ancillary analysis, as space allows, listed alphabetically.
- (d) Accrual authors – when possible and applicable [see section III.1.A.ii.(3)]
- (e) Senior author

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- (i) For non-TS analyses: the disease site chair at the time of the ancillary analysis
- (ii) For TS analyses: the site-specific TS liaison and
- (f) Foundation Leadership (see section III. 1.A.ii.(5)).
- (g) Other co-authors – see section III. 1.A.ii.(6).

ii) Order of Authorship

(1) Ancillary analysis authorship lines will be identified as follows: primary author, RTOG Biostatistician, additional requesting investigators, second statistician (if applicable), Other co-authors (if applicable), protocol PIs of studies used in analysis, accrual authors, senior author.

(a) Primary Author; RTOG Biostatistician; other translational research investigators who are critical to the development and conduct of the study; clinical study PI (if appropriate); accrual authors (based on specimen submission); protocol TS/Correlative Biology Co-chair (if different from PI); TS Disease Site Liaison; Senior Author

(2) Order of Authorship for Physics/Dosimetry-Based Ancillary Analyses

(a) Order of authorship will generally follow order of authorship for other types of ancillary analyses: primary author, biostatistician (if applicable), investigators critical to the development and conduct of the study, protocol PI, investigator(s) or representatives of institutions contributing data (“accrual” authors), senior author

(4) Order of Authorship for PROs/QOL/CE Ancillary Analyses

(a) Primary Author; RTOG Biostatistician; other PROs research investigators who are critical to the development and conduct of the study; clinical study PI (if appropriate); accrual authors (based on QOL/CE submission); protocol QOL/CE Co-Chair if different from primary author); QOL/CE CoChair; Senior Author

B. Methodology analyses and publications focused on: Physics/Dosimetry, Statistics, Other (including but not limited to Process-Related, Economics, and Comparative Effectiveness studies)

(1) The primary author may submit a written statement with suggested authors, including justification for each author’s inclusion.

(2) RTOG Publications will determine the author line based on the primary focus of the paper, and will include as many authors as are feasible and appropriate.

3. Review Papers

The author line of an RTOG overview paper will consist of the following: primary author, statistician(s), study chairs from each study, accrual co-authors (if appropriate), disease site and/or modality chairs, and RTOG leadership (if appropriate).

IV. Pre-Publication Procedures

All correspondence with RTOG Publications and the Publications Committee should be conducted via RTOG-Publications@acr.org.

1. Abstracts

A. General Procedures for all RTOG-related Abstracts

i) For abstracts with RTOG statistical support, the process is as follows: the statistician sends the analysis report to the primary author. The primary author drafts the abstract

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- and sends back to the statistician. The primary author and statistician work together to finalize the draft of the abstract in preparation for co-author review.
- ii) Authorship is determined by RTOG Publications based on RTOG Publication Guidelines for authorship (see section III). RTOG Publications will provide the primary author with the abstract author line and with the appropriate funding acknowledgments to be included with the abstract.
 - iii) It is the responsibility of the primary author to work with RTOG to distribute the draft of an abstract to all coauthors and obtain their approval before submitting to RTOG Publications for approval (via the responsible statistician co-author, if applicable).
 - iv) The final abstract is due to the responsible statistician at least 2 weeks prior to the meeting's abstract submission deadline. The statistician will submit the abstract to RTOG Publications for approval. For abstracts not including an RTOG statistician co-author, the primary author will submit the abstract directly to RTOG Publications
 - v) RTOG Publications circulates the abstract for review to RTOG Publications leadership, including the Foundation Chair, President, Statistician, the Publications Chair, and appropriate RTOG committee chairs.
 - vi) The RTOG will simultaneously distribute the abstract for review to appropriate commercial entities providing study support.
 - vii) The primary author will be notified of the abstract approval and/or required or suggested changes, and will submit the abstract to the designated meeting. An abstract approved for submission is only approved for a particular meeting. Any further submissions to other meetings must be treated as new/separate abstracts.
 - viii) The primary author must inform RTOG Publications and all co-authors of the abstract's acceptance or rejection upon notification by the meeting.

2. Presentations

A. General Procedures for all RTOG-related Meeting Presentations

- i) All RTOG presentations must use the RTOG presentation templates (oral presentations slides and posters), which are available on the RTOG website under Publications.
- ii) For presentations with RTOG statistical support, the process is as follows: the primary author drafts the presentation and sends it to the statistician. The primary author and statistician work together to finalize the draft of the presentation in preparation for co-author review.
- iii) It is the responsibility of the primary author to work with RTOG to distribute the draft of the presentation to all coauthors and obtain their approval before submitting to RTOG Publications for approval (via the responsible statistician co-author, if applicable).
- iv) The final presentation is due to the responsible statistician at least 10 days prior to the first day of the meeting. The statistician will submit the presentation to RTOG Publications for approval. For presentations not including an RTOG statistician co-author, the primary author will submit the presentation directly to RTOG Publications
- v) RTOG Publications circulates the presentation for review to RTOG Publications leadership, including the Foundation Chair, President and Statistician, the Publications Chair, and appropriate RTOG committee chairs.
- vi) The RTOG will simultaneously distribute the presentation for review to appropriate commercial entities providing study support.

3. Manuscripts

A. General Procedures

- i) Authorship is determined by RTOG Publications based on RTOG Publication Guidelines for authorship. Manuscript authorship may be different than what was established for the

- corresponding abstract presentation(s) due to varying journal allowances for number of co-authors. If the study was not presented at a meeting or conference, RTOG Publications will provide the primary author with the appropriate approved authorship and required funding acknowledgments. Changes in authorship must be requested and approved by RTOG Publications in consultation with the Publications Chair.
- ii) The first draft of a manuscript should be completed and submitted to the study statistician and RTOG Publications at the time of the results' presentation.
 - iii) In order to ensure adequate and consistent reporting of randomized, controlled trials (RCTs), the CONSORT (Consolidated Standards of Reporting Trials) Guidelines should be followed. It is the responsibility of the RTOG first author and statistician to remain up to date on the latest reporting guidelines.
 - iv) For manuscripts with RTOG statistical support, the process is as follows: the statistician sends any additional analyses for manuscript, if needed, to the primary author. The primary author drafts the manuscript and sends back to the statistician. The primary author and statistician work together to finalize the draft of the manuscript in preparation for co-author review.
 - v) It is the responsibility of the primary author to work with RTOG to distribute the draft of a manuscript to all coauthors and obtain their approval before submission of the manuscript to RTOG Publications (via the responsible statistician co-author, if applicable) for internal peer review. RTOG will work with the primary author to determine the journal to which to submit.
 - vi) The RTOG peer reviewer is an expert in the field, and will provide written comments within a 3-week period. The manuscript is also reviewed simultaneously by an RTOG statistical reviewer if it is the first reporting of a primary endpoint. The manuscript is also submitted to any commercial entity supporting the study. Once the reviews are complete, RTOG Publications will notify the first author of the next step (i.e., submission to journal or changes required).
 - vii) If a paper is being submitted to NEJM, JAMA, Lancet, or another high-impact journal that does not focus on oncology, the RTOG Foundation Chair may choose to write a cover letter to accompany the manuscript to explain the significance of the findings, their impact, and the alignment with the journal profile.
 - viii) If the manuscript is not submitted to the journal by RTOG staff the primary author must forward the journal's confirmation of manuscript receipt to RTOG Publications with a copy of the submitted version of the manuscript. This must be done for each re-submission of the manuscript to an alternate journal if not initially accepted.
 - ix) The manuscript statistician and the co-authors (as appropriate) should be involved in responding to the journal reviewers' comments.
 - x) The primary author will forward RTOG Publications an electronic copy of the final published version of the manuscript to be submitted to the co-authors and for the purpose of inclusion in the RTOG Publications library.
 - xi) All published RTOG manuscripts will be submitted to PMC by either the primary author or the publishing journal in order to comply with the NIH Public Access Policy. The primary author must provide the published manuscript's PMC reference number to RTOG Publications so that it may be included with NIH applications, proposals, and progress reports
- B. Manuscript Submission Timeline
- i) The manuscript first draft is due to the RTOG statistician at time the study results are publicly presented.

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- ii) If a manuscript draft is not submitted as specified above, primary authorship may be reassigned by decision of the RTOG Publications Committee or its Executive Subcommittee.
- iii) If no appropriate substitute primary author is identified by the Executive Subcommittee after discussion with the disease site chair, the manuscript may be reassigned to an investigator from the highest accruing institution in conjunction with the RTOG Institutional PI.
- iv) If the manuscript is reassigned, the primary author may risk losing a slot on that paper if the journal allows only a certain amount of authors on the author line or if the previously assigned primary author did not make a significant intellectual contribution.

V. Ancillary Analysis Requests & Evaluation

1. Approval of an ancillary analysis request is contingent on the completion (i.e., submission of abstract or paper) of any previously requested analyses.
2. In most cases publication of an ancillary analysis will not occur until the primary treatment paper has been accepted for publication. On rare occasions, an ancillary analysis may occur before publication of the primary treatment paper, but only if it will not compromise publication of the protocol endpoints. This will be determined by the Publications Committee in consultation with the Disease Site and Study Chairs.
3. The authorship of ancillary analysis papers will be identified in advance and will include the investigators from the institutions with the largest accrual plus the original Study Chair (see *Ancillary Analysis authorship*).
4. Process:
 - A. It is recommended that ancillary analysis ideas be informally discussed with the Disease Site Chairperson to determine if the idea is of interest and is not significantly overlapping with ongoing research projects. A formal ancillary analysis request is initiated by submission of the RTOG Resource Request Form and the Ancillary Analysis Request Submission Form with the corresponding proposal document to the RTOG Publications mailbox. A funding source to support the time needed to prepare and analyze the data must also be identified at the time of the request.
 - B. The request will be forwarded to the appropriate Disease Site Chairperson for preliminary review (the Senior Statistician, the Foundation Statistician, and the Publications Chair will receive concurrently). If the proposal is not feasible due to lack of pertinent data or other limitations, the requestor will be notified. If the proposal requires additional details or clarifications, the requestor will be contacted and advised regarding submission of a revised proposal.
 - C. The proposal and accompanying completed submission form will be sent to the Publications Committee for final consideration.
 - D. The Publications Committee will review and vote on the proposal. Requests will be reviewed on a quarterly basis. Decision letters together with a budget to support the analysis will be sent to the requesting investigator. Work on the analysis will not begin until the appropriate funds are committed.