



## RADIATION THERAPY ONCOLOGY GROUP

# PUBLICATION GUIDELINES

### A. ROLE OF THE PUBLICATIONS COMMITTEE

1. Promote and facilitate publication of RTOG trial results in a timely manner.
2. Assure authorship lines are correct so that the appropriate contribution credit is recognized.
3. Review the science of abstracts and papers.
4. Assure timely reporting by assigning or reassigning responsibility.
5. Update guidelines as necessary.

### B. GENERAL CONSIDERATIONS

1. Study Chairman has priority on the first report of a study. RTOG publications have adapted the *New Eng J Med* (NEJM) guidelines. However, the specifications will be used as suggestions, not requirements. The only time these specifications are required is when the paper is submitted to the *NEJM*.
2. There may be one Radiation Oncologist Co-Chairman when appropriate, a Medical Oncologist or Surgical Oncologist should be Co-Chairman where appropriate.
3. The Study Chairman (Institution) must contribute 5% or 10 patients (whichever qualifies) to his/her study to retain publication rights. If the Study Chair has accrued less than 5% or 10 patients, then the committee will review it on an individual basis.
4. Headquarters will identify those who have participated in reviewing a study so they appear on the authorline. The authorship line will include physicians and statisticians as appropriate. Data Managers will be recognized by acknowledgment when appropriate. The 1<sup>st</sup> author needs to request permission in writing when seeking to add additional people to the authorline.
5. The Publications Committee shall meet at each group meeting.
6. Study Chairman must have approval of their site/modality committees as necessary to begin to analyze and report a specific study. The Publications Committee will authorize the use of statistical services and formulate the authorship line with the Study Chairman at that time. The Study Chairman and the Publications Committee will agree upon a reasonable time for completion of the report.
7. The Publications Committee will review all abstracts and all publications before submission to a meeting or a journal. This review will be accomplished in one week for abstracts, one month for papers. No abstracts or manuscripts may be submitted without prior Publications Committee approval.



8. Initial papers reporting the primary endpoints of each protocol are routinely assigned to the Study Chair. These endpoints would be those that had been specified in the study initially. They might include not only disease endpoints but toxicity endpoints, quality of life endpoints and any other ancillary endpoints. Publication of these papers will follow the traditional publication guidelines. This will be looked at beforehand to determine “up front” what initial endpoints are contained in a protocol.
9. Updated papers on the same endpoint analyses will be reviewed separately by the Publications Committee.
10. **Secondary analysis follows additional guidelines as specified below.** *Please keep in mind, the initial treatment/primary paper must be **in press** prior to submitting a Secondary Analysis paper to a journal.*

A person is limited to 2 requests per calendar year. Members who have one set of data being worked on, and one pending, may *not* submit another request. All forms must be typed before submitting to headquarters. Handwritten forms *will not* be accepted.

- A. Secondary papers are those in which data are looked at for nonpredetermined endpoints and may cross several studies. *Prior to committee voting, the request needs to be reviewed and cleared by the site and/or modality chairs.* These papers are identified by individual investigators with an idea and will be approved by a subcommittee consisting of the Group Chair, Deputy Chair, Vice-Chair for Publications and Group Statistician before Headquarters and Statistical Unit resources are allocated to the Project. Preference will be given to investigators who have contributed to the study and/or the RTOG in the past.
- B. Secondary papers that are identified by the Study Chairman and/or Statistical Unit at the time the main paper is being written will be assigned to institutions with the largest accrual.
- C. The authorship of secondary papers will be identified in advance and will include the investigators from the institutions with the largest accrual plus the original study chair. *(please see Secondary Analysis authorship)*

### **Secondary Analysis Request Revisions effective June 2003**

Approval of a secondary analysis request is contingent upon the completion (submission of abstract or paper) of any previously requested analyses.

In most cases publication of a secondary analysis will not occur until the primary treatment paper has been accepted for publication. However, there may be times when a secondary analysis can occur prior to publication of the primary treatment paper. This will be determined by the Publication Committee in consultation with the disease site and study chairs.

### **Secondary Analysis Request Revisions effective June 2003 (cont.)**



Secondary analyses that are included in the original protocol objectives are considered routine and are part of the planned publications for the protocol and are assigned by the protocol chair(s).

Requests for secondary analyses that are unique and not part of the protocol objectives will be reviewed by the Publication Committee, in consultation with the disease site and study chairs, and assigned a priority.

11. A study cannot be reported until it is completed unless an exception is made by the Publications Committee.
12. The first author of an initial treatment paper cannot give authorship rights to another person. Exceptions can be requested of the Publications Committee.

### C. AUTHORSHIP

1. Contributors who register  $\geq 10\%$  of the evaluable cases of a nonrandomized study will be listed as co-authors. The designated author is the choice of the institution's principal investigator. If fewer than three institutions contributed  $\geq 10\%$  of the cases, then the top three accruing institutions will be listed.
2. Contributors who randomize  $\geq 5\%$  of the evaluable cases on a randomized study will be listed as co-authors. The designated author is the choice of the institution's principal investigator. If an institution places a large number of cases on the study, that institution will get an additional co-author for every 10% of the patients accrued, not to exceed a total of three co-authors. (Two co-authors for  $\geq 15\%$  accrual and three co-authors for  $\geq 25\%$  accrual.) If  $\geq 5\%$  of cases creates an author line that is too long, then the Publications Committee will revert to the 10% rule for case accession.

*Please Note: Accrual is based upon specimens submitted and used in the translational analysis. Only those institutions that participated with the submission of useable specimens will be eligible to receive authorship credit.*

3. The authorship line of an overview paper will consist of the following: The first author, study chairs from each study, statistician, and the top three total accruals, appropriate site or modality chair. The number of authors from the institutions depends on the percent of total accrual.
4. Membership and authorship representation rests with the institution. When an investigator leaves an institution, it is up to the Principal Investigator to assign someone to the authorship spot allocated for that institution. If a Study Chairman leaves an institution, he maintains his authorship rights with the permission of the Group Chairman and the Publications Committee if: 1) he has accessed patients to the study and 2) if he stays affiliated with RTOG and continues to place patients on the study and/or reviews the data within a reasonable time period.



5. If a statistician or reviewing pathologist has been involved with the study, he should be listed as a co-author.
6. If the Group Chairman or Associate Chairman have made a substantial contribution to a study their name may be included in the author line.
7. **The order of authorship for an initial treatment paper** for randomized studies will be: primary author, statistician, co-chairman contributing to data review and analysis, other modality chairmen e.g. pathologist (if applicable), and the institutional representatives. The remaining study co-chairmen not contributing to data review and analysis will be placed in an appropriate position as determined by the Publications Committee (if applicable).
8. **Secondary analysis authorship lines** will be identified as follows: 1st author (person who requested 2nd Analysis), statistician, study chair(s) (study databases used in analysis, by # of pts accrued in descending order), and site chair(s) who oversaw the conduct of the studies.
9. Every paper must include an appendix or table of all contributors to the study. (This does not apply to abstracts.)
10. Site or Modality Committee Chairmen may not publish a review article from material appearing in the RTOG minutes without the permission of the Study Chairman.
11. The Publications Committee will discuss their decisions on authorship with the principal author, but the Committee's decision will be final.
12. The RTOG Name and Study Number must appear in the title of every publication.
13. The authorship of any paper based totally on previously published RTOG data is left to the first author's discretion. It is recommended that RTOG authorship guidelines be followed, but it is not required. Any paper that publishes any new data (i.e. data that has not previously been published in a source that is suitable for reference and citation) must follow RTOG authorship guidelines exactly.
14. If a manuscript is overdue, that author loses authorship rights on that and any other pending manuscript and cannot take on new responsibilities within the Group.
15. An abstract approved for submission is only approved for a particular meeting. If it is rejected and the author wants to resubmit it to an alternative meeting, it must be treated as a new/separate issue.

#### **D. INTERGROUP GUIDELINES FOR STUDIES RTOG COORDINATES**

1. The authorship line will consist of the Study Chairman, RTOG Statistician, Study Co-Chairmen (all groups), institutional representatives contributing  $\geq 5\%$  of cases ( $\geq 15\%$  to get a second co-author) and additional Site/Modality Chairmen as appropriate. The order of authorship will follow the guidelines as stated above.



2. If  $\geq 5\%$  of cases creates an author line that is too long, then the Publications Committee will revert to the 10% rule for case accession.
3. The paper must include an appendix or table of all contributing institutions.
4. Points of discussion for other groups studies will be considered at that time.

## E. COMPLEMENTARY STUDY GUIDELINES

1. If Complementary Study information has been included in a study, then the Complementary Study Chair should be listed in the authorship line.
2. The Complementary Study Chair can write the Complementary attribute based paper following author guidelines but the Study Chair must be included.
3. Approval for publication of the Complementary Study information, prior to the first paper, has to be approved by the Publications Committee.

## F. PRE-PUBLICATION PROCEDURES

### 1. PAPERS

- A. It is the responsibility of the 1<sup>st</sup> author to distribute the draft of a manuscript to all co-authors and obtain approval from them for submission of manuscript to the journal. ***At the same time the draft is received at headquarters, the Publication's Assistant will distribute the manuscript to the appropriate site and modality chairs.***

Once all authors are in agreement and the manuscript is in the final version, it is to be submitted to the RTOG Publications Administrative Assistant (Lisa Morabito) at headquarters who will then send it to appropriate reviewer as well as a statistical reviewer if an endpoint paper. This review will be completed within a two-week period. Once reviewed, headquarters will notify the 1<sup>st</sup> author of the next step. (i.e.: submission to journal or changes required.)

- B. Papers and abstracts may be submitted to journals or meetings only after publication review by the RTOG office. If a paper is being submitted to the *New England Journal of Medicine*, please let RTOG Headquarters know prior to your submission date. Dr. Walter Curran, RTOG Group Chair, will write a cover letter to accompany RTOG manuscripts submitted to the *New England Journal of Medicine*. His letter will explain the significance of your findings and their impact. The purpose of his letter is to make sure RTOG studies are properly interpreted by the NEJM reviewers.

### 2. ABSTRACTS



- A. It is the responsibility of the 1<sup>st</sup> author to distribute the draft of an abstract to all co-authors and obtain approval from them before submitting to the Publications Committee for approval. *At the same time the draft is received at headquarters, the Publication's Assistant will distribute the abstract to the appropriate site and modality chairs.*

## **G. 2ND ANALYSIS OF BIO-MARKERS AUTHORSHIP GUIDELINES**

### **1. Author line Support for Physics and Biologic Science**

Authorship for secondary analysis involving physics and biologic science is a unique strength of RTOG. The intent of authorship is to give credit to those who perform the work.

In the case of the biologic sciences, the first authors should be the scientific investigators, stat office, study and site chairs, and those institutions who contributed the material.

In the case of a physics only study, the rules will now permit the names of physicists to be on the abstract or publication as well as the study and site chairs who have contributed material.

## **H. TRP QUESTIONNAIRE, GUIDELINES AND AUTHORSHIPS**

Before an author line can be developed for TRP studies, the first author is asked to complete a questionnaire, which is supplied by RTOG Publications.

Once this questionnaire is returned to RTOG Publications, an authorship is developed and sent to the first author.

Documentation of IRB approval of a translational research proposal must be documented in the submitted manuscript. Location of the information is at the discretion of the author and the journal.

Please see the following pages for TRP Questionnaire, guidelines and authorship lines.

## **I. META-ANALYSIS GUIDELINES FOR DATA REQUEST**

In light of the increasing probability of future requests for data from non-RTOG members, guidelines and a scoring sheet will be developed to help the committee determine the feasibility of projects and assign priority.

- A. All requests must be submitted on the "Request for Data by Non-RTOG Members" form. (see following pages for request form)
- B. Only data that has been previously published in a peer-reviewed publication may be released.



## **META-ANALYSIS GUIDELINES FOR DATA REQUEST (cont.)**

- C. A copy of the protocol (research plan) for the analysis must be received and reviewed by Publications Committee and the disease site committee chair before data is released. The protocol must include: names of investigators; objectives; background; type of data requested; analysis plan; and, authorship line for future anticipated publication(s).
- D. Protocols that will add to the knowledge base of the disease site or modality will receive a higher priority.
- E. RTOG recognition on the authorship line and in the acknowledgements is required.
- F. A stipend for preparing the data may be requested depending upon the source of the request.



# Questionnaire

## RTOG Publications TRP Authorship

Please complete the following questionnaire and return to Lisa Morabito (either by FAX or e-mail [lmorabito@phila.acr.org](mailto:lmorabito@phila.acr.org)) at RTOG Headquarters ASAP so an authorline can be generated.

Dear **Prospective Author**:

Attached you will find the RTOG "TRP Authorship Guidelines". The purpose of this questionnaire is to give creditable people involved in this abstract/manuscript a deserving authorship slot. Please review the Guidelines and answer the following questions. Once you have returned this questionnaire to RTOG Headquarters, an author line will be generated and returned to you for your comments.

Below, you will find the proposed authorship line, per RTOG rules. Your responsibility includes contacting the principal investigator at each of the listed institutions and asking the principal investigator who should represent his/her institution. You must also make sure that each of the co-authors has received a copy of the abstract/manuscript in a timely manner before submitting to RTOG for approval.

**1<sup>st</sup> Author, Statistician, Junior Investigator, Pathologist, Institution Representative #1, Institution Representative #2, etc. [add study or site chairs if appropriate] and Senior Author**

Yes, there was a Junior Investigator and I would like to assign this slot to: \_\_\_\_\_  
\_\_\_\_\_

Accruing institutions that contributed material for this study (based upon the # of tissue submissions used in the analysis) (*headquarters will complete this info before sending to 1<sup>st</sup> author*)  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Please edit this list of study and site chairs (included in light of their contribution to this project): (*headquarters will complete this info before sending to 1<sup>st</sup> author*) \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

I would like to assign the senior author slot (if applicable) to: \_\_\_\_\_  
\_\_\_\_\_

Additional Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
(1<sup>ST</sup> Author's Name) *please sign*





## RADIATION THERAPY ONCOLOGY GROUP

### TRP Authorship Guidelines

#### **Author line Support for Scientific Work and Tissue Bank Submissions**

*Authorship for TRP publications should be considered on the following basis:*

The intent of authorship is to give credit to those who perform the work as well as the institutions who have submitted the tissue samples for review.

RTOG Publications will write to the first author of the abstract/manuscript asking for the creditable people involved who are deserving of an authorship slot. The first author will also be allowed to select who is made “senior” (i.e. last) author on the authorship line. The letter will also state the accruing institutions that contributed the material for the study and that these institutions will be allowed an authorship slot depending on how many patients with tissue submissions were used in the TRP analysis. The principal study chair for any trial used in TRP analysis does not automatically receive an authorship slot. The listing of study and site chairs included on the authorship line will be made on a case-by-case basis, after consultation between the first author and the RTOG Publications Committee.

An example authorship line may look like:

1st author, statistician, junior investigator (if any), pathologist, institution #1 (XX tissue submissions), institution #2 (XX tissue submissions), (study and site chairs, if applicable) and senior author.

#### **IRB Approvals in TRP Publications**

Documentation of IRB approval of a translational research proposal must be documented in the submitted manuscript. Location of the information is at the discretion of the author and the journal.



## RADIATION THERAPY ONCOLOGY GROUP

### 2<sup>nd</sup> Analysis of Bio-Markers Authorship Guidelines

#### **Author line Support for Physics and Biologic Science**

Authorship for secondary analysis involving physics and biologic science is a unique strength of RTOG. The intent of authorship is to give credit to those who perform the work.

In the case of the biologic sciences, the first authors should be the scientific investigators, stat office, study and site chairs, and those institutions who contributed the material.

In the case of a physics only study, the rules will now permit the names of physicists to be on the abstract or publication as well as the study and site chairs who have contributed material.



## *Request for Data by Non-RTOG Investigators*

**To:** RTOG Publications Committee

**From:** \_\_\_\_\_ **Affiliation** \_\_\_\_\_

**Date:** \_\_\_\_\_

**RTOG Study #(s):** \_\_\_\_\_

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All requests must be accompanied by a protocol (research plan) for the proposed analysis. The protocol must include: names of investigators; objectives; background; type of data requested; analysis plan; and, authorship line for future anticipated publication(s).

**What data is being requested?**

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*To be completed by Publication Committee Member*

Committee Member Name: \_\_\_\_\_ Date: \_\_\_\_\_

Scientific Merit: (1=low – 5=high) \_\_\_\_\_

Feasibility: (1=low – 5=high) \_\_\_\_\_

Comments: