

ETCTN Publication Policy

Manuscript Authorship

All ETCTN studies are a collaborative effort involving many individuals. The primary rewards for contributions to a given ETCTN study are not monetary, but consist of the opportunity to advance patient care and to receive academic recognition, which comes with authorship. Currently there is not a standard for authorship opportunities for those who have played a key role in an ETCTN study. We propose a *transparent* process for determination of potential authors for manuscripts based on findings from an ETCTN study.

The protocol study chair (s) should assign the role of “**writing team chair(s)**” to the person(s) responsible for directing/drafting the manuscript. The study chair(s) are usually the writing group chair(s) for the main manuscript for the study. It is proposed that when manuscript preparation of an ETCTN study begins, the writing group chair(s) should determine *potential* members of the *writing team(s)*. Multiple manuscripts may stem from a single ETCTN trial. The writing team chair and the list of writing team members may change dependent on the specific manuscript topic.

When possible, those responsible for protocol development and execution could be the core group for the writing team (especially for the primary objectives manuscript).

The “*writing team*” *should* include

1. The protocol chair (s)
2. The primary statistician(s) for the study
3. The translational science chair (if this role was assigned)

Others providing significant contributions to the manuscripts, e.g., pathologists (especially central review and adjudicating pathologists), pharmacologists, epidemiologists, basic scientists, laboratory scientists reporting on correlative studies should also be considered for the writing team and for authorship. Also, the grant PI of the Lead Academic Organization may be considered for authorship if he/she has played a significant role in the study.

In addition, an authorship role should be extended to one investigator from each ETCTN and EDDOP site who has enrolled at least one eligible patient for a study with a total accrual of less than 25 patients or who has enrolled at least 2 eligible patients for studies that accrued 25 or more patients, with some adjustments necessary in larger studies with many sites involved (e.g. at least 3 accruals for studies of more than 100 patients). It should be noted that, in accordance with the Uniform Publication Guidelines, patient accrual alone is insufficient for authorship. Therefore, these site investigators should also be given a role on the writing team, either as reviewers or some specific role in assessing

study eligibility or study endpoints or in verifying these parameters, or by helping to evaluate biomarker data in the context of outcome(s).

NCI staff may also be considered for authorship if it is felt by the writing team that the NCI staff member contribution significantly exceeded the statutory regulatory role of the medical safety monitor as the IND sponsor, such as making significant contributions in the design and execution of the study.

The Writing Team Chair(s) will communicate with the potential writing team members and assess who is interested in participating in the manuscript process, and will make writing team assignments.

Members of the writing team may be removed at the discretion of the protocol chair(s).

Data verification

The writing group chair(s), along with the study statistician, have the primary responsibility of assuring all eligibility criteria and endpoints for the trial have been verified and quality controlled.

Data submitted by investigators from ETCTN sites must be verified by a process decided upon by the writing team, and the writing team chair and lead study statistician have the primary responsibility for assuring that this occurs. For example, they should verify that the “math” of the tumor measurements is accurate and meets the CR/PR/SD/PD criteria. If a decision is made not to centrally verify response with re-reads by a radiologist, then this should be stated in the manuscript.

Manuscript Process

It is the responsibility of the Writing Team Chair(s) to coordinate and take responsibility for the preparation of the initial draft of the paper. This may include assigning manuscript sections to be drafted by different members of the writing and statistical team. Communication among the writing team may include circulation of multiple working drafts as well as a series of conference calls.

The Writing Team Chair(s) will circulate the proposed final revision to the Writing Team members for approval.

Manuscripts must be submitted to CTEP for immediate delivery to the collaborator for advisory review and comment prior to submission for publication. The collaborator has 30 days from the date of receipt to review the manuscript. An additional 30 days may be requested to ensure that confidential and proprietary data, or additional Collaborator intellectual property rights, are protected. Suggestions from CTEP or an additional collaborator will be given serious consideration, but will not be viewed as mandatory.

The Study Chair(s) will distribute copies of the manuscript to all participating institutions. Copies of the journal reviewers' criticism and of the final revised manuscript will be sent to all co-authors.

The authorship and its order for a given manuscript are determined by the following criteria: 1) overall workload contribution, 2) intellectual contribution and 3) patient accrual, in that sequence.

The inclusion and order of authorship, including first and senior author will be determined by the protocol study chair(s), and the writing team chair.

All authors should have masthead acknowledgement. Only journals without restrictive authorship policies should be considered for publication.

Manuscript Cover Page

All ETCTN manuscripts should acknowledge in the title of the paper that this is a group effort. A suggested mechanism is to follow the title of the paper with the phrase, "An NCI/CTEP Experimental Therapeutics Clinical Trials Network (ETCTN) Study."

The title section of the cover page of the manuscript will also indicate the ETCTN protocol by number. Each cover page will also indicate acknowledge support from NCI and the respective supporting grant numbers for all authors listed.

All papers must also contain a paragraph acknowledging all investigators who have enrolled patients on the study and other pertinent acknowledgements. Placement of this section will follow journal style, e.g. at the end of manuscript or electronic copy only.

Abstracts

Ideally, abstracts for meetings will follow the same rules for authorship as those for manuscripts. In cases where it is not feasible to include all authors who might be included in a full manuscript, it will be permissible for an abstract to list the study chair, and co-chair(s) and, when applicable, the biostatistician, and a phrase representing the ETCTN (e.g., "on behalf of the ETCTN-xxx study team"). The full manuscript will have the full author attribution list