

POLICIES FOR PUBLICATION

AUTHORSHIP POLICIES

1.0 BACKGROUND

Publication of the results of Canadian Cancer Trials Group (CCTG) research is essential in meeting the Group's mission. The CCTG has four separate and related Policy Documents related to publication, which are:

1. Policy Overview
2. Policies for Authorship
3. Procedural Policies for Publication
4. Policies for Press Releases and Media Coverage

This document describes CCTG's Authorship Policies and includes general themes that apply to all CCTG activities. While the specifics described are intended to address most CCTG activities, supplemental documents may be developed for special Programs and circumstances. Specifically, application of some principles described within this document requires modification for the Investigational New Drug (IND) Program. Investigators and potential authors are asked to review the IND Program supplement to this document.

In CCTG's *Policies for Publication: Policy Overview*, different types of publication are described. In Section 2.0 of this current document, authorship policies relating to Primary Analyses will be addressed. Section 3.0 will address principles and other specifics related to Non-Primary Analyses.

As described in the *Policies for Publication: Policy Overview*, CCTG supports and subscribes to the policies of the International Committee of Medical Journal Editors' Uniform Requirements for Manuscripts Submitted to Biomedical Journals (<http://www.icmje.org/>). These Requirements state "Authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3." For the purposes of reporting results of clinical trials, CCTG will consider substantial contributions to patient accrual as meeting criterion 1), as accrual has important implications for the "acquisition of data".

2.0 CATEGORIES OF AUTHORSHIP

The following describes normal procedures for identifying authorship for CCTG projects and emphasizes the reporting of Primary Analyses of clinical trials. As roles may change over the conduct of a trial, the principles and policies described below may require trial-specific interpretation and application. For international intergroup collaborations led by CCTG, authorship policies may require unique determination based on the nature of the collaboration. When these trials require authorship policies that deviate from those described in this document, negotiation of the policies should occur prior to finalizing the protocol and should be included in the Section 15 Publication Policy of the protocol.

The stated parameters are contingent upon individuals meeting the requirements listed below, those described by the International Committee of Medical Journal Editors (see Section 1.0 above), and completing CCTG Conflict of Interest requirements in an acceptable manner.

These parameters are based on the expectation that following the availability of a final analysis, the results of a project (e.g. a clinical trial) will be presented at a scientific meeting within 6-12 months, a first draft of an article manuscript will be completed within 6 months, and the final manuscript will be submitted to a medical journal within 12 months. Failure to meet any of the above requirements may lead to revisions in authorship and authorship position.

In general, authors will be named as individuals with as many authors included as permitted by the intended journal. Situations may exist where it is more appropriate to have authors named under an umbrella term. In these situations, a Writing Committee will be named and will include members of the Trial Committee.

2.1 First Author

The First Author is the designated leader of the project. This position should be named at the beginning of the project. For clinical trials, the first author will be the Study Chair. For trials with co-chairs, options will include having the co-chairs included as the first and second authors, as co-first authors as designated with an asterisk, or with one co-chair as Senior Author.

Requirements for First Authorship include:

- leading the process to design the research (trial);
- actively participating in the project's conduct throughout the life of the project;
- leading the representation of the project at national and international meetings;
- participating in the analysis of data; and,
- taking direct responsibility to produce a manuscript.

A requirement of First Authorship for clinical trials is that the investigator has actively and directly participated in trial accrual.

2.2 Senior Author

The Senior (last) Author is an investigator who has played a central role in the specifics of the project and who also has had a major role in the development and oversight of the program on which the project is based.

Requirements for Senior Authorship include:

- a leadership role in designing the research (trial);
- actively participating in the project's conduct throughout the life of the project;
- leading the representation of the project at national and international meetings; and,
- participating in the analysis of data and overseeing the processes to produce a manuscript.

When the Senior Author is based at a CCTG member centre, a requirement of Senior Authorship for reports of clinical trials is that the investigator has actively and directly participated in trial accrual.

For the Primary Analysis of a clinical trial, providing that the above requirements are met, the Senior Author will generally be a Disease Site Chair. However, the life span of many trials is such that sustained leadership by a Disease Site Chair is not always possible, or instances may occur where the Central Office Senior Investigator or a member of the Trial Committee has more fully met the requirements; under these circumstances, one of these individuals will be the Senior Author.

2.3 Second Author

In general, the principles for naming a Second Author will follow those for naming of the Senior Author. For the Primary Analysis of a clinical trial, the Second Author will generally be the Central Office Senior Investigator. When it is more appropriate that the Senior Investigator be named as the Senior Author, the Second Author will either be the Study Co-chair, the Disease Site Chair, or the individual who has otherwise best met the criteria of:

- participating in designing the research (trial);
- actively participating in the project's conduct throughout the life of the project;
- leading the representation of the project at national and international meetings; and,
- participating in the analysis of data and the writing of the manuscript.

When the Second Author is based at a CCTG member centre, contributions to accrual will be an important criterion for selection.

2.4 Third Author

The principles for naming a Third Author include those described for the naming of the Senior and Second Author. In addition, for Intergroup trials, the Third Author will be the designate from the cooperative group that has accrued the most patients, provided that this total is at least 25% of all accrual and this group has:

- contributed to the design of the research (trial);
- actively participated in the project's conduct throughout the life of the project;
- led the representation of the project at respective national and international meetings; and,
- participated in the analysis of data and processes to produce a manuscript.

When the Third Author is based at a CCTG member centre, contributions to accrual will be an important criterion for selection.

2.5 Co-Senior (Second Last) Author

For the reporting of Primary Analyses of CCTG-led trials, the CCTG denotes that the second last author position represents co-senior authorship. The CCTG Senior Biostatistician will occupy this position and, therefore, the essential role and leadership of the statistician in conducting the research is recognized. This designation of co-Senior Author will be included in all relevant CCTG communications at Queen's University, including in all annual faculty reports and evaluations, including those related to promotion and tenure.

2.6 Other Contributing Authors

Other authorship positions will be based on contributions to the conduct of the project (trial). The following principles will be used to name and to determine the order of these authors:

- i) Investigators based at CCTG centres who are members of the Trial Committee will be included provided that these individuals have actively participated in the project's conduct throughout the life of the project, including making contributions to accrual.
- ii) For Intergroup trials, a member of a cooperative group that has contributed at least 5% to the total accrual will be included. An additional member from that group will be included for each additional increase of 10% to the total accrual (i.e. 2 authors for > 15%, 3 authors for > 25%, etc). Each cooperative group will be asked to identify the author(s) to be named.

- iii) Additional authorship positions will be determined by CCTG member institution accrual. In general, an investigator from each of the highest accruing centres that are not otherwise represented with authorship will be identified. The responsibility for identifying this investigator rests with the participating centre. The CCTG Central Office will provide that centre's Qualified Investigator with the Central Office's attribution of that centre's accrual so that the Qualified Investigator can identify the appropriate author. If there are disputes in identifying this individual, the CCTG Director will contact the centre's Centre Representative and request that he/she mediate a decision.

When a centre has contributed a disproportionately large percentage of accrual, additional authors from that centre may be selected.

- iv) For research conducted with an industry collaborator, a representative of the company may be included when the nature of the collaboration is associated with meeting the criteria stated in Section 1.0 above.

2.7 CCTG Staff

When possible and appropriate, CCTG Central Office Staff will be considered for inclusion as Other Contributing Authors. Examples include the Study Coordinator and, for projects with detailed statistical analysis, the staff statistician (SAS Programmer). The life span of many projects and the operational structure of the CCTG Central Office may mean that sustained involvement by a single Study Coordinator is not possible. In these circumstances, all staff with direct project-specific responsibilities will be included in the Acknowledgements (see below).

2.8 Acknowledgements

Where journal policies permit, all investigators who played a contributing role in the trial, including to its accrual, will be included in an Acknowledgement section. CCTG Central Office staff with direct project-specific responsibilities will also be acknowledged. Acknowledgements of funding support are described in Section 3.3 of *Policies for Publication: Policy Overview*.

3.0 POLICIES ASSOCIATED WITH NON-PRIMARY ANALYSIS PUBLICATIONS

Other types of analyses are described in Section 2.2 of *Policies for Publication: Policy Overview* and include Planned Secondary Analyses, Unplanned Secondary Analyses, Meta-analyses, and Methodologic and Related Research. Principles for naming authors to these manuscripts include:

3.1 General Principles:

3.1.1 *Respect of Leadership:* The CCTG supports the leadership roles played by the Study Chair, the Disease Site Chair, the Senior Investigator and the Senior Biostatistician. Provided that each has participated in a manner consistent with the principles of authorship described in Sections 1 and 2 above, these investigators would be expected to be co-authors of manuscripts reporting the results of a project resulting in a non-primary analysis publication.

The CCTG further respects the leadership roles of designated leaders who are Trial Committee members. In this context, these investigators (e.g. the Quality of Life Coordinator, the Economic Analysis Coordinator) are expected to be the First Author of publications related to the reporting of secondary outcomes associated with the role these individuals play on a Trial Committee. In situations where the Chair of an Endpoint Committee (e.g. the Quality of Life Committee, the Working Group on Economic Analysis, the Correlative Sciences / Tumour Biology Committee) plays a specific role in a project (trial), authorship may be warranted.

3.1.2 *Respect of Concept Ownership:* The CCTG respects the need to recognize the originator of a concept. In general, the originator of a concept will be provided with the opportunity to meet the additional criteria that result in being named First Author.

3.1.3 *Respect of Group Principles:* The nature of a cooperative group requires that collaborations be nurtured. The most prestigious of authorship positions (First Author, Senior Author) must therefore be appropriately distributed among the individuals eligible for these positions across the reports associated with a project. Similarly, positions of Other Contributing Authors should be distributed to account for contributions to a project, including trial accrual.

3.1.4 *Promotion of New Investigators:* The training and promotion of new investigators is a stated strategic priority of the CCTG. Opportunities to engage new investigators, particularly in forms of non-primary analyses, should be considered.

3.2 Specific Policies

3.2.1 *Authorship for Intergroup Trials Led by Other Groups:* It is expected the CCTG's Study Co-chair will be designated as the CCTG author for Intergroup trials led by other groups. This should be discussed with the lead group at the outset of the trial. It is expected that the requirements

for authorship will be consistent with the CCTG's policies for authorship and include:

- actively participating in the project's conduct throughout the life of the project (including actively and directly participated in trial accrual);
- leading the representation of the project at national meetings; and,
- participating in the analysis of data and the processes to produce a manuscript.

When CCTG centres have entered more than 15% of all patients accrued, the Group will enter into discussions with the lead group about naming additional authors.

When an Intergroup-led project results in multiple reports, the CCTG will perform a review of trial conduct, including accrual, at Canadian centres to ensure that Group principles (Section 3.1.3 above) are respected. A process to identify a sequence for naming deserving authors will be developed by the Senior Investigator in conjunction with the Disease Site Chair and the CCTG Study Co-chair.

3.2.2 Authorship on Meta-analyses: Meta-analyses are complex collaborations and, given the large number of potential collaborating groups, opportunities for authorship from a single group, such as CCTG, may be limited. To be a candidate for authorship, an investigator must have played a substantial role in each of the criteria for authorship listed in Section 1.0 above. Furthermore, the potential author must play a participating role in the meta-analysis collaboration. When there are multiple candidates for authorship, a process to identify a sequence for naming deserving authors will be developed by the Senior Investigator in conjunction with the Disease Site Chair, the CCTG Study Co-chair and the Senior Biostatistician.

4.0 DISPUTE RESOLUTION

The responsibility for initiating resolution of disputes in authorship rests with the Senior Investigator. In general, this process should include the Disease Site Chair and the Study Chair. When disputes involve identifying the contributing author from a high-accruing centre, the CCTG Director will contact that centre's Centre Representative to request that he/she mediate a decision. In circumstances where the above processes do not resolve an authorship issue, the CCTG Director has ultimate responsibility for mediating a resolution and / or determining a final naming of authors. Where applicable, the Director may choose to form an *ad hoc* subcommittee from the CCTG's Clinical Trials Committee, excluding Central Office faculty, to help arbitrate a conclusion.