CCTG Publication Policy

V004 2024AUG18

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1 Policy Description

It is Canadian Cancer Trials Group (CCTG) policy to ensure publication of results of Canadian Cancer Trials Group (CCTG) trials.

2 Introduction and Scope

Publication of the results of CCTG research is essential in meeting the Group's mission, which is "is to develop and conduct clinical trials aimed at improving the treatment and prevention of cancer with the ultimate goal of reducing morbidity and mortality from this disease". Group publications serve many purposes. Paramount among these is the need to contribute to the dissemination of new knowledge. Other important implications include ensuring that CCTG is accountable to the scientific community through its participation in rigorous peer-review processes, to its funders by demonstrating the value of the Group's research and acknowledging the source of funding that supported the work, and to its investigators by providing opportunities for authorship and acknowledgement.

The policies described below are intended to apply to publications that make use of data collected on CCTG trials.

3 Definitions

3.1 Terms

Relevant definitions are provided under section 4.0 Categories of Authorship.

3.2 Acronyms

CCTG	Canadian Cancer Trials Group
CIHR	Canadian Institute For Health Research
CCS	Canadian Cancer Society
DCTD	Division of Cancer Treatment and Diagnosis
OICR	Ontario Institute for Cancer Research
OSC	Operations and Statistics Centre
PCA	Participating Centre Agreement
PHS	Public Health Services
SOP	Standard Operating Procedure
US NCI CTEP	US National Cancer Institute Cancer Therapy Evaluation Program
WKI	Work Instruction

4 Categories of Publication

To assist in clarifying publication policies, the following definitions are provided.

4.1 Type of Publication

4.1.1 Abstract

An abstract is an abbreviated report that is generally less than 500 words and is usually intended to meet requirements for presentation at a scientific meeting.

4.1.2 Article

An article is a full report of some aspect of the design, conduct or analysis of a scientific project and is intended for publication in a peer- review scientific journal.

4.2 Types of Analyses

4.2.1 Primary Analysis

A primary analysis is the analysis that supports the initial report related to a study's primary objective.

4.2.2 Planned Secondary Analyses

Planned secondary analyses are reports supporting reports related to protocol-stated objectives that are not included in the primary analysis. Examples of planned secondary analyses include reports describing secondary objectives as listed in the study protocol, for example, quality of life, economic evaluations, correlative biology, etc.

4.2.3 Unplanned Secondary Analyses

Unplanned secondary analyses support reports describing objectives that are not included in the protocol. Examples of unplanned secondary analyses include reports describing endpoints that are not associated with protocol-stated objectives, unplanned subset analyses, and correlative biologic research performed on banked biospecimens when the specifics of this research are not included in the protocol. Unplanned secondary analyses include research conducted through access to data using CTG-POL-0043 Data Sharing and Access Policy.

4.2.4 Meta-analyses

Meta-analyses are reports describing use of CCTG data through a process of pooling. Pooling may be considered "internal" by exclusively using CCTG data (e.g. pooling of a series of CCTG trials to assess outcomes within a disease) or "external" by combining CCTG data with that of other research organizations.

5 Principles Related to Publication

5.1 International Committee of Medical Journal Editors' Uniform Requirements for Manuscripts Submitted to Biomedical Journals

The 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/).

5.2 Oversight of the CCTG Operations and Statistical Centre (OSC)

Material may not be submitted for presentation or publication without prior review by the CCTG OSC. This review is essential to ensure that the CCTG's authorship polices are respected, that an appropriate communication strategy has been developed, and that all contractual relations are

honoured, including those with academic institutions (e.g., US National Cancer Institute / Cancer Therapy Evaluation Program [US NCI / CTEP]) and industry collaborators and funders.

5.3 Acknowledgement of Funding Support

All publications concerning studies of the Canadian Cancer Trials Group should acknowledge the support of the Canadian Cancer Society. Other agencies, including the Canadian Institutes of Health Research (CIHR), the Ontario Institute for Cancer Research, and the US NCI/CTEP should also be acknowledged as appropriate.

5.4 Rights to Publish

The rights of each contributing centre to publish its own results are included in Article 4 of the CCTG's Participating Centre Agreement (PCA). The CCTG has developed a generic PCA; based on negotiations with individual centres, the language of the PCA signed by CCTG and individual centres may differ from the generic. The terms of the generic Agreement include the following clauses (*numbering reflects that used in Article 4 of the PCA*):

4.1 The parties recognize that the publication and/or other scientific or public presentation of the methods and results of the Studies in accordance with normal academic practice is intended. The parties further recognize that proprietary rights can be jeopardized by public disclosure of inventions prior to the filing of appropriate patent applications. Therefore, with respect to any disclosure by the Participating Centre of the results of Studies, the parties agree as follows:

(a) the Participating Centre shall not make any disclosure until the multi-centre data have been reported in full. However, if the multi-centre data have not been reported after twelve (12) months from the earlier of the completion or termination of the Study, the Participating Centre shall have the right to publish the methods and results from the Participating Centre of the Studies in accordance with section 4.1 hereof. Studies shall be deemed completed upon the validation and final analysis of each of the full Study databases.

(b) At least thirty (30) days prior to any disclosure of the methods and results of a Study, the Participating Centre shall provide CCTG with a copy of the proposed disclosure. Within thirty (30) days of receipt by CCTG of the proposed disclosure, CCTG shall provide the Participating Centre with any comments it may have on the proposed disclosure or request an additional sixty (60) days for review by a Study's industry sponsor, before providing its comments. At the request of CCTG, the Participating Centre shall remove from the proposed disclosure any Confidential Information provided by CCTG. Notwithstanding the foregoing, the Participating Centre shall have the right to include in any disclosure, information relating to the Study methods used in the performance of the Studies.

(c) CCTG shall have the right within the thirty (30) day review period to advise the Participating Centre as to the patentability of any inventions included in the proposed disclosure and of CCTG's or the Study's industry sponsor's desire to file patent applications claiming such inventions. The Participating Centre shall delay such proposed disclosure provided that any such delay does not exceed ninety (90) days from the date of receipt of the proposed publication by CCTG. After expiration of such ninety (90) day period, the Participating Centre shall be entitled to proceed with the publication without further notice to CCTG or a Study's industry sponsor, if applicable.

4.2 Unless agreed otherwise, the Participating Centre shall acknowledge the contribution of CCTG and/or the industry sponsor, if any, in any publication arising from the Studies.

5.5 Open Access Publication

The CCTG supports and complies with the policies of open access publication as described by the Canadian Cancer Society http://www.cancer.ca/en/research/policies-and-administration/policies/open-access-policy/, Canadian Institutes of Health Research https://cihr-irsc.gc.ca/e/32005.html and the U.S. National Institutes of Health (http://publicaccess.nih.gov/).

5.6 Conflicts of Interest

All publications associated with the CCTG should include specific statements regarding real or potentially perceived conflicts of interest. These statements should comply with the CCTG Conflict of Interest Policy (https://www.ctg.queensu.ca/public/policies) developed in accordance with applicable regulations and guidelines including applicable Canadian regulations and guidelines, Public Health Service (PHS) regulation entitled “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and Responsible Prospective Contractors” (42 CFR Part 50, 45 CFR 94, final rule published 8/25/2011), and the National Cancer Institute (NCI)/Division of Cancer Treatment and Diagnosis (DCTD) Conflict of Interest Policy for NCI/DCTD-supported Cooperative Group or National Clinical Trials Network Randomized Phase 2 and Phase 3 Clinical Trials (August 2012), in addition to that of the journal to which the potential publication is submitted.

6 Authorship

As previously stated, 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/). With respect to authorship 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. 4) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Authors should meet conditions 1, 2, 3, and 4.” For the purposes of reporting results of clinical trials, CCTG considers substantial contributions to patient accrual as meeting criterion 1), as accrual has important implications for the “acquisition of data”.

6.1 Categories of Authorship

The following describes normal procedures for identifying authorship for papers using CCTG data 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 polices that deviate from those described in this document, negotiation of the policies should occur prior to finalizing the protocol and should be included in Section 14 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 6.0 above) and completing CCTG Conflict of Interest requirements in an acceptable manner. In

addition, failure to complete required tasks outlined Appendix 13 in the timeframe described there may results in the loss of an 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. Which authorship format will be used should be decided before trial activation.

6.1.1 **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.

6.1.2 **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
- 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 OSC 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.

6.1.3 **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 OSC 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;
- 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.

6.1.4 **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;
- 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.

6.1.5 **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.

6.1.6 **Other Contributing Authors**

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

i) Investigators who are members of the Trial Committee (*CTG-TOR-0087 Study Chair and Trial Committee Terms of Reference*)) will be included provided that these individuals have actively participated in the project's conduct throughout the life of the project, including, for clinical investigators based at CCTG member centres, making contributions to accrual. The requirement to contribute to accrual does not apply to investigators whose are members of the Trial Committee as representatives of endpoint committees (Quality of Life, Health Economics, Correlative Sciences/Tumour Biology).

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 OSC will provide that centre's Qualified Investigator with the OSC'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 they 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 6.0 above.

6.1.7 **CCTG Staff**

When possible and appropriate, CCTG OSC 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 OSC 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).

6.2 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 OSC staff with direct project-specific responsibilities will also be acknowledged. Acknowledgements of funding support are described in Section 5.3.

7 Polices Associated with Non-Primary Analysis Publications

Other types of analyses are described in Sections 4.2.2, 4.2.3, and 4.2.4 and include Planned Secondary Analyses, Unplanned Secondary Analyses, and Meta-analyses. Principles for naming authors to these manuscripts include:

7.1 General Principles

7.1.1 **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 Section 6.0, 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 and the Correlative Sciences/Tumour Biology representative) 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 one of these committees plays a specific role in a project, authorship may be warranted.

7.1.2 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.

7.1.3 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.

7.1.4 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.

7.2 Specific Policies

7.2.1 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 including:

- 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.

The number of CCTG authors will typically be determined by the policies of the Group leading the study. CCTG will ensure that study co-chairs (or champions for NCTN studies) are aware of these policies.

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 7.1.3 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.

7.2.2 CCTG led NCTN trials.

Authorship for other groups in CCTG led NCTN trials will be determined as described in Section 6.1.6 ii. In addition, CTEP and NIH have policies regarding abstract and manuscript review, timeliness of publication, and open access that must be followed. These are described in Section B 1.1.5 in the document at the following URL:
https://ctep.cancer.gov/initiativesPrograms/docs/NCTN_Program_Guidelines.pdf

7.2.3 Platform trials

Platform trials are structured in a way that a single master protocol can include multiple sub-studies and new sub-studies can be added over time. Usually, a chair and trial committee members are appointed for the master protocol, but sub-studies may have separate chairs and

committee members. Thus, the overall study chair holds a position similar to the disease site chair in the conventional “one-off” trial setting and should be considered for a senior authorship position on the basis of the principles in section 6.1.2 when individual sub-studies are published, while the sub-study chair would normally be the first author. Whether the disease site chair should have an authorship position in publications arising from platform trial sub-studies depends upon their role in the overall study and should be decided in advance.

7.2.4 **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 6.0 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.

8 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.

Alternatively, the Director may form an ad hoc subcommittee from the CCTG’s Clinical Trials Committee, excluding OSC faculty, to help arbitrate a conclusion.

9 Appendix

Section 13. Appendix. Publication Policy Process

10 References

CTG-POL-0043 Data Sharing and Access Policy

CTG-TOR-0087 Study Chair and Trial Committee Terms of Reference

11 Revision History

Version Number	Version Date	Brief Description of Revision(s)
V003	2021JUN24	- 3 year review of CTG-POL-0016 Publication Policy-Overview and CTG-POL-0015 Publication Policy – Authorship were completed - Policy converted to the current CCTG Policy Template.

		- Separate policies covering the overview and authorship were combined into one document now referred to as V003 Publication Policy. - Administrative updates made to the document including updating of relevant links. - References now included to link to key CCTG policies and SOPs including Data Sharing. - Scope of the policy now refers to publications using CCTG data. Methodologic papers, editorials not included. - Process appendix reference to coordinate and administrate the publication process is now included as an appendix.
V004	2024AUG18	- 7.2.1 Clarified process for intergroup trials led by others - 7.2.2 Added process for CCTG led NCTN trials - 7.2.3 Added process for platform trials - 13.3.2 Clarified timeline for IND trials

12 Signature

Signature of Responsible Group Leader:	Dr. Janet Dancey	On file	2024OCT11
	Name	Signature	Date

13 Appendix: Publication Policy Process

13.1 BACKGROUND

The OSC 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 and a manuscript describing study results would be prepared and submitted for publication within one year of the availability of the study results.

13.2 RESPONSIBILITIES

Preparation of publication material is a collaborative effort. It is essential that all relevant participants both have an opportunity to contribute and take responsibility for their respective roles. The following describes some of these responsibilities; while flexibility is needed based on circumstances, the roles described below should be considered default positions.

13.2.1 **CCTG Senior Investigator (SI)**

The SI has leadership roles for coordinating the process that extends from review of the Statistical Analysis Report (SAR) to ensuring closure with the publishing body (e.g. professional society for abstracts; journal for manuscripts). The SI must assure that CCTG processes have been followed and that individuals have completed their respective roles and responsibilities. The SI is responsible for ensuring all Group accountabilities associated with reports are met (e.g. contracts with industry; cooperative group and funding body notification). The SI must sign off on all submissions.

13.2.2 *CCTG Senior Biostatistician (SB)*

The SB is responsible for producing the SAR, preparing its presentation to the relevant groups for review, drafting selected sections of the manuscript (e.g. Methods, Table, Figures). The SB must sign off on all submissions prior to submission.

13.2.3 **Study Chair**

For all reports describing the results of primary analyses, the Study Chair is responsible for drafting the first version of the report (e.g. abstract, manuscript), leading the process of editing, and submitting the report. The Study Chair will be provided in confidence with the SAR so that these responsibilities can be met. For reports of non-primary results, the parameters described above are the responsibility of the first author.

13.2.4 **Other Co-authors**

Other co-authors will be identified according to *CTG-POL-0016 Section 6.1.6 Other Contributing Authors*. Other co-authors are responsible for reviewing all versions of the planned report, signing off on final versions and meeting the requirements of the publishing body (e.g. completion of conflict of interest reports, copyright transfer).

13.2.5 **Site Committee Chair (Site Chair)**

As per *CTG-POL-0016 Section 6.1.6 Other Contributing Authors*, the Site Chair may be a co-author and may be designated as a senior author. Roles and responsibilities will thus vary according to circumstance. In all cases, the Site Chair will be informed of reports in development, results of analyses, and progress associated with report submission. The Site Chair, together with the SI, has responsibilities for resolving issues associated with irregularity in the preparation and submission process. The Site Chair will share coordinating responsibilities with the SI when the Site Chair is designated as the senior author.

13.2.6 **OSC Staff**

Staff have essential roles in report preparation and submission including:

13.2.6.1 Study Coordinator

Assist the SI in preparation of material and review processes.

13.2.6.2 SAS Statistician

Assist the SB with preparation of material, including figures and tables.

13.2.6.3 Publications Coordinator

Oversee all final reports prior to submission to ensure all funding acknowledgements are cited, reports are captured within the Group Bibliography, and open access policies are followed.

13.2.6.4 Director

The Director is responsible for ensuring systematic processes exist for report preparation and submission and for participating, as appropriate, in resolution of issues associated with compliance with these processes.

13.3 SPECIFIC REPORTS

13.3.1 **Abstracts**

Abstracts of CCTG-led trials prepared for submission to any meetings or seminars must be submitted to the appropriate SI at the OSC at least two weeks prior to submission for authorship review and circulation to appropriate reviewers. The Publications Coordinator will be notified of the receipt of the abstract. Abstracts must be approved by the appropriate SI, SB and all co-authors prior to submission. Copies of the submitted abstracts for all Group-related studies must be sent to the Publication Coordinator to be included in the Group Bibliography. The full abstract citation, along with a copy of the published abstract, must be sent to the OSC when published.

13.3.2 **Manuscripts**

Production of the first draft of a report is the responsibility of the Study Chair (or first author). A first draft of a manuscript is expected within 6 months (3 months for IND trials) of the Study Chair receiving the confidential SAR. If, after a period of six months, the draft is not substantially complete, the SI reserves the right to make other arrangements to ensure timely publication. Any process to re-assign authorship responsibility will be led by the SI in conjunction with the Site Chair.

Following the production of a first manuscript draft, the following procedures are necessary:

1. The proposed draft manuscript must be submitted to the SI so that OSC procedures can be initiated. The publications coordinator will be notified of the receipt of the manuscript. The manuscript will be circulated to the following individuals for review:

   A. Relevant Disease and Research Committee Chair

   B. Appropriate Biostatistician

   C. Appropriate Discipline Chair

   D. Co-authors

   The Group Director may, at his/her discretion, ask that the manuscript be reviewed by an individual other than those listed above.

   The reviewer's comments should be communicated to the senior author and the appropriate SI.

   Based on study contract specifications/source of funding, manuscripts may also require review by a pharmaceutical company(s), the NCI US, or others prior to journal submission. The SI will notify the Primary Author of these contract specifications and will request written authorization to circulate the manuscript to the company(s) named in the contract. The timelines for NCI and pharmaceutical review is minimally 30 days prior to submission for publication, although up to 60 days may be necessary to ensure the protection of company confidential or proprietary information or for the handling of intellectual property rights.

2. The Publications Coordinator will review the final version of the manuscript to ensure that group policies have been followed.

3. Manuscript Submission to Journal: Prior to submitting a manuscript to a journal, the Primary Author must request a final review of the manuscript and receive written approval to submit from the appropriate SI and Site Chair.

    A. Submission: The primary author is responsible for submitting the manuscript to a journal. Either the primary author or the SI will circulate the submitted manuscript to co-authors and others as needed.

    B. Journal response: If a submitted manuscript is accepted without revision, the primary author should notify the relevant SI. If revisions are needed or the manuscript is rejected, the primary author and the SI will discuss next steps.

    C. Galley Proofs: All galley proofs are to be sent from the journal to the Primary Author who is responsible for their timely processing.

13.4 DATA SHARING

While unauthorized or premature disclosure of data is prohibited, CCTG is committed to responsible sharing of the data supporting its publications as outlined in CTG-POL-0043 Data Sharing and Access Policy.