



POLICIES FOR PUBLICATION

POLICY OVERVIEW

1.0 BACKGROUND

Publication of the results of NCIC CTG 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". These publications serve many purposes. Paramount among these is the need to contribute to the dissemination of new knowledge. Other important implications include ensuring that the NCIC CTG 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.

Policies for publication include four separate and related Policy Documents, 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 NCIC CTG's Policy Overview.

2.0 CATEGORIES OF PUBLICATION

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

2.1 Type of Publication

- 2.1.1 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.

2.1.2 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.

2.1.3 Other: Other categories of publications can include monographs, book chapters and books. Where applicable, NCIC CTG policies related to article publication will apply to these forms of publication.

2.2 Types of Analyses

2.2.1 Primary Analysis: The primary analysis refers to the main reporting of the scientific project's primary objective. For a clinical trial, the primary analysis will usually describe the final analysis addressing the primary objective. Additional outcomes may also be included. For phase III trials that include an interim analysis, and when the NCIC CTG's Data Safety Monitoring Committee recommends that the results of this analysis be released, the reporting of this analysis will be considered an additional primary analysis (see *NCIC CTG Policy for Data Safety Monitoring Committee* - http://www.ctg.queensu.ca/dsmc/dsmc_policy.html).

2.2.2 Planned Secondary Analyses: Planned secondary analyses are reports describing protocol-stated objectives that are not included in the Primary Analysis. Examples of planned secondary analyses include reports describing secondary objectives (e.g. in a clinical trial quality of life, economic evaluations and correlative biologic research may lead to secondary analyses) or reports describing subsets analyses of the endpoint used to assess the primary objective.

2.2.3 Unplanned Secondary Analyses: Unplanned secondary analyses are 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 will include research conducted through access to data using NCIC CTG's Data Sharing Policy (see *NCIC CTG Data Sharing Policy*).

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

2.4.5 Methodologic and Related Research: Methodologic and related research includes reports describing the processes and significance of scientific research. Examples include descriptions of trial methodology, trial conduct (including operational aspects) and the providing of context of research, both in specific and general terms.

3.0 PRINCIPLES RELATED TO PUBLICATION

Specific policies related to publication procedural processes, authorship and press releases and media coverage are included in separate documents. The following is a listing of general and additional specific items.

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

The NCIC CTG 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/>).

3.2 Oversight of the NCIC CTG Central Office:

Material may not be submitted for presentation or publication without prior review by the NCIC CTG Central Office. This review is essential to ensure that the NCIC CTG's authorship policies are respected, that an appropriate communication strategy has been developed, and that all contractual relations are honoured, including those with academic institutions (e.g., the Ontario Institute for Cancer Research [OICR], the US National Cancer Institute / Cancer Therapy Evaluation Program [US NCI / CTEP]) and industry collaborators and funders.

3.3 Acknowledgement of Funding Support:

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

3.4 Rights to Publish:

The rights of each contributing centre to publish its own results are included in Article 4 of the *NCIC CTG's Participating Centre Agreement (PCA)*. The NCIC CTG has developed a generic PCA; based on negotiations with individual centres, the language of the PCA signed by NCIC CTG and individual centres may differ from the generic. The terms of the generic Agreement include (*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 NCIC CTG with a copy of the proposed disclosure. Within thirty (30) days of receipt by NCIC CTG of the proposed disclosure, NCIC CTG 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 NCIC CTG, the Participating Centre shall remove from the proposed disclosure any Confidential Information provided by NCIC CTG. 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) NCIC CTG 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 NCIC CTG'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 NCIC CTG. After expiration of such ninety (90) day period, the Participating Centre shall be entitled to proceed with the publication without further notice to NCIC CTG or a Study's industry sponsor, if applicable.
- 4.2 Unless agreed otherwise, the Participating Centre shall acknowledge the contribution of NCIC CTG and/or the industry sponsor, if any, in any publication arising from the Studies.

3.5 Open Access Publication:

The NCIC CTG supports and complies with the policies of open access publication as described by the Canadian Cancer Society Research Institute (http://www.ncic.cancer.ca/research/Policies%20and%20Administration/Policy/Open%20Access.aspx?sc_lang=en), Canadian Institutes of Health Research (<http://www.cihr-irsc.gc.ca/e/34846.html>) and the U.S. National Institutes of Health (<http://publicaccess.nih.gov/>).

3.6 Conflicts of Interest:

All publications associated with the NCIC CTG should include specific statements regarding real or potentially perceived conflicts of interest. These statements should comply with the NCIC CTG's Conflict of Interest Policy (<http://www.ctg.queensu.ca/private/committees/ConflictofInterestPolicy-Feb2009.pdf>) and that of the journal to which the potential publication is submitted.