The Canadian Children Inflammatory Bowel Disease Network: A Partnership with the CH.I.L.D. Foundation

Policy: Publications and Presentations

1. Principles and Guidelines

a) The Canadian Children Inflammatory Bowel Disease Network: A Partnership with the CH.I.L.D. Foundation (herein called 'CIDsCaNN') will give rise to a substantial number of high quality peer-reviewed manuscripts.

b) Three fundamental problems to avoid in the approach to publications are:
i. Stagnation of data,
ii. Disputes over authorship,
iii. Transparency and quality of the research report (manuscript or abstract).
A Publications & Presentations Committee (PubPC) is established and an approach to authorship is outlined in this report to mitigate these potential pitfalls.

c) The approach to publications will encourage participation by CIDsCaNN members who are interested in and capable of abstract/manuscript preparation according to pre-specified timelines.

d) The approach to authorship/publications/presentations will be communicated in a transparent fashion through a formal policy document (this document) which is circulated and agreed upon by all members of CIDsCaNN.

e) The approach to authorship should be inclusive, equitable, and acknowledge the scientific contribution of CIDsCaNN members to each study. In addition, authorship should be guided by the International Committee of Medical Journal Editors (ICMJE) guidance (http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html). The ICMJE recommends that authorship be based on satisfying all of the following 4 criteria:

i. Significant contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
ii. Drafting the work or revising it critically for important intellectual content; AND
iii. Final approval of the version to be published; AND
iv. 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.

2. Definitions

First Author = Author(s) appearing first on a manuscript. Typically the person(s) responsible for the initial draft of the manuscript.

Lead Author or Senior Responsible Investigator = Author(s) appearing last on a manuscript in charge of supervising the First Author and organizing the study being reported in the manuscript.

Grant/Study Principal Investigator (Study PI) = Investigator(s) who was awarded the operating grant for the study in question. If no operating grant was awarded, this is the investigator(s) responsible for study operations and conduct. Typically, this will be the same person as the Senior Responsible Investigator.

Network Principal Investigators (Network PIs) = Co-Chairs of the Executive Committee of CIDsCaNN at the time of study conception or final analysis (as long as intellectual contribution is apparent)

Network Co-Principal Investigators (Network co-PI) = Chair-elect of CIDsCaNN from the Executive Committee (EC).

Recruiting site Principal Investigator (site PI) = Lead physician/researcher recruiting participants to CIDsCaNN. Typically this is the **clinical site lead**, however when multiple clinicians are engaged with CIDsCaNN and recruiting patients, the named site PI will rotate between those investigators, often in a project-specific way. Other site investigators will be included in a group authorship position at the end of the authorship list ("First Author, Middle Authors, Senior Author, and the *Canadian Children IBD Network*").

Publication Submission & Approval Roadmap = Documents outlining the main, planned manuscripts/abstracts, to which is added a list of novel manuscripts/abstracts. These documents are posted in Dropbox (*CIDsCaNN Shared Documents**CIDsCaNN Committees**PubPC**Policy & Roadmap*\).

3. The Publications and Presentations Committee (PubPC):

The time horizon of a CIDsCaNN project will be as follows:
1. Submission of research idea of scientific committee (CCRC, BTRC or HSR Committee) for review.
2. Review and approval of research idea by relevant committee.
3. Presentation, review and approval by CIDsCaNN Steering Committee.
4. Final approval by CIDsCaNN Executive Committee
4. Conduct of research, including (where applicable) regulatory approval, data accrual, data analysis. Progress will typically be reported periodically to the relevant committee.
5. Preparation of research abstract (for presentation at scientific conference) or scientific manuscript (for publication in a peer reviewed journal).
6. Submission and peer review of abstract or manuscript.
7. Publication of abstract or manuscript.
8. End-of-project knowledge translation activities.

The PubPC will become involved at the point of 'Preparation of research abstract or scientific manuscript' (Steps #5-7 above) unless called upon to resolve authorship conflicts or review publication plans by the CIDsCaNN Executive, scientific committee, or Study PI.

a. The PubPC will be typically made up of:
    i. A Chair
    ii. A clinical researcher (CCRC rep)
    iii. A basic/translational science researcher (BTRC rep)
    iv. A health services researcher (HSR committee rep)
    v. A member of the CIDsCaNN Executive
    vi. 1-2 additional Members-at-large

Each member will serve for a 3-year term.

b. Members of the PubPC will:
    i. Hold a track record in research and in publications, in order to be able to provide a critical review of the transparency and completeness of manuscripts submitted to the PubPC for internal review.
    ii. Be prepared to devote time to rapidly review prepared manuscripts.
    iii. Be invested in the success of CIDsCaNN as a national and collaborative initiative.
    iv. Understand that participation in the PubPC requires a substantial time commitment.

c. Roles/Responsibilities of the PubPC:
    i. To steer and drive the publications and presentations process.
    ii. To develop and maintain roadmaps for projects and manuscripts, containing dates for planned manuscripts/abstracts submissions.
    iii. To ensure adherence to the principles of scientific authorship and CIDsCaNN policies regarding authorship.
    iv. To oversee and assist a process where the Study PI (Lead Author) will include (in consultation with the site PIs) one individual per institution to serve as an "institutional co-author" (typically the site PI, only from 'contributing centres') on each manuscript, if the institution is not already represented on the manuscript by the first author or by a named member of the writing group.
    v. If additional institutional co-authors are requested from a single institution, this should be justified to the PubPC with a description of the scientific contribution made by the additional co-author. The PubPC will then determine eligibility as a named co-author. If the additional co-author is declined, that co-author may qualify for inclusion in the group authorship ("First Author, Middle Authors, Senior Author, and the *Canadian Children IBD Network*").
    vi. To assist in identifying the journal to which a manuscript is being targeted.
    vii. To provide an internal review of all abstracts, manuscripts and presentations for transparency and completeness of reporting prior to submission to meetings/journals; scientific review will be the responsibility of the authors and relevant committee, but PubPC would contribute if asked to.
    viii. To ensure transparency of research and quality and completeness of reporting by

helping authors complete appropriate reporting guidelines checklists, and ensuring that all required items are adequately reported in the manuscript.

ix. To ensure timely submission of manuscripts and abstracts according to pre-specified timelines by re-profiling first authorship if manuscripts are not drafted on time.

x. To prevent and (if needed) resolve authorship disputes.

xi. To ensure the publication/presentation process unfolds according to the pre-agreed upon principles herein.

4. Approach to Authorship on Manuscripts

Principles of Authorship

a. Named Author and Group Author qualification should follow the International Committee of Medical Journal Editors (ICMJE) guidance (http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html). The ICMJE recommends that authorship be based on the following 4 criteria:

   v. Significant contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND

   vi. Drafting the work or revising it critically for important intellectual content; AND

   vii. Final approval of the version to be published; AND

   viii. 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.

   The First Author or Study PI will describe the contributions of the authors according to the above criteria; this will be verified by each author prior to submission.

b. Contributors who meet fewer than all 4 of the above criteria will not be listed as authors, but may be acknowledged in the manuscript. All contributors who are acknowledged will provide their written consent to be acknowledged to the First Author or Study PI.

c. The Network PIs, Network co-PIs and site PIs who contributed to the study will be named authors on manuscripts arising from CIDsCaNN collaborations and will take responsibility for the completeness and accuracy of the research presented in the manuscript.

   When multiple clinicians at a single site are engaged in CIDsCaNN and acting as Site PI, the site PI position will rotate amongst those clinicians. The clinical site will determine the rotation. If this cannot be agreed upon locally, the PubPC will mediate the selection of site PI named authors. Additional authors from the same institution may be requested by the Site PI for a manuscript (based on scientific or clinical contribution), but must be approved by the PubPC, and must qualify for authorship as per the ICMJE guidelines (see Section 3.c.v.).

d. Other site investigators will be included in a group authorship position at the end of the authorship list ("First Author, Middle Authors, Senior Author, and the *Canadian Children IBD Network*"). These investigators and clinicians must qualify for authorship as per the ICMJE guidelines. The Site PI will report on the qualifications and contributions of each author to the PubPC.

i. First Authorship

a. A First Author for a given manuscript will be the individual who made the greatest contribution towards a specific work, including study concept and design, data analysis and interpretation and drafting and finalizing the manuscript for publication. This individual may request to be the Senior Author for a publication and nominate a First Author, in line with ICMJE authorship guidelines and only with approval from the Study PI.

b. The First and Lead Authors will decide who will be the corresponding author for a manuscript but, in general, this will be the First or Lead Author unless neither the First Author nor Lead Author are the Study PI.

c. All proposed authors for a manuscript, including the decision about First and Lead authorship, must be agreed upon by the PubPC.

d. The First Author will be responsible for preparing the first draft of the manuscript.

e. Leadership on research projects will be decided upon by the relevant committees (CCRC, BTRC, HSR Committee) and the CIDsCaNN Executive. Authorship (Lead Author, First Author, Writing Group) will be decided upon by leadership on the research project in conjunction with the relevant committee. Agreements on authorship will be noted and tracked on a CIDsCaNN spreadsheet tracking authorship credits (Dropbox: *CIDsCaNN Shared Documents**CIDsCaNN Committees**PubPC*\<manuscript-project name>\).

f. First authorship can be assigned to individuals who are named and approved by the Study PI and CIDsCaNN Executive Committee at study inception or at any point through the research process. Alternatively, a first author can be suggested by the PubPC when the manuscript or abstract is ready to be written.

ii. Writing Group Authorship

a. The Writing Group will optimally be named at study initiation, however additions to the Writing Group may be named during any phase at the study with the approval of the Study PI and study team.

b. The Writing Group will be comprised of members of the research team who have significantly contributed to the study and/or who have contributed significantly to CIDsCaNN academic activities (such as through development of the protocol, analysis and interpretation of results, recruitment of participants (site PIs) and/or consistent

participation in CIDsCaNN meetings).

c. The Writing Group membership will vary with each manuscript. The PubPC will track authorship and Writing Group membership on various manuscripts to ensure equitable distribution of opportunities for Writing Group membership amongst all CIDsCaNN members. Individuals who are not named to a Writing Group will still share the opportunity to be part of named authorship on manuscripts, potentially through "institutional authorship" (see next sections).

d. The members of the Writing Group for a given manuscript will be named authors on the manuscript/abstract, and must be willing and able to take responsibility for the accuracy of the data and interpretation of the analysis. The members of the Writing Group members will have all provided a critical review of the manuscript (**within 2-3 weeks of manuscript distribution**).

e. Writing Groups must adhere to the timelines specified by the Lead Author. If there is an unacceptable lag in submission of the manuscript/abstract to the Lead Author after internal review, the Lead Author has the right to review the Writing Group membership and re-assign the members of the group. Extensions to the 2-3 week time available for review may be negotiated with the Study PI and/or PubPC, and will be granted under exception circumstances (illness, vacation, parental leave, exceptional clinical responsibilities).

f. A Writing Group member should have the following profile:
   - Have a track record in co-authorship of manuscripts for peer-reviewed publications.
   - Have a strong understanding of the research methods that have formed the basis of the CIDsCaNN research program to date (such as through regular and consistent participation in CIDsCaNN meetings).
   - Be familiar with the research and thereby be able to accurately critique the manuscript in the context of current knowledge.
   - Understand the way in which CIDsCaNN results add to the existing literature.
   - Be prepared to critically review a manuscript according to strict, pre-defined timelines (typically within 2-3 weeks of manuscript distribution). A critical review will involve careful appraisal of the content of the manuscript.
   - Be readily available and willing to receive feedback from the CIDsCaNN team on the manuscript, in accordance with a timeline (typically within 2-3 weeks of manuscript circulation).

g. Authorship order in all CIDsCaNN manuscripts will appear as follows:
   1. **First Author** (study lead, Study PI or approved delegate),
   2. **Writing Group authors**, in order based on level of contribution as determined by the Study PI, in consultation the Network PIs and Network co-PI.
   3. **Site PIs**, in order of proportionate contribution (number of patients enrolled in the study) if not first/principal author, senior author or in Writing Group author

positions above).

4. Assigned investigators, in alphabetical order, as determined by the first/principal author,
5. **Data analysts, lab technicians, research associates, other paid/unpaid scientific contributors** involved in the project in order of decreasing scientific contribution, as determined by the Study PI,
6. Other CIDsCaNN investigators involved in design, interpretation, analysis of the project, in alphabetical order, as determined by the Study PI.
7. **Lead author** (senior responsible investigator, Study PI, or approved delegate).
8. **CIDsCaNN Group Authorship** position (other clinicians and investigators who contributed patients or scientific expertise to the research but not noted in the above positions), noted as "…and the Canadian Children IBD Network" and indexed in Medline/Pubmed.

v. Additional Information

a. Trainees of CIDsCaNN investigators and collaborators may express their interest in participating in a main, planned manuscripts

b. Trainees of CIDsCaNN investigators and collaborators may also take the First Author position on a planned manuscript, as determined by the Study PI.

c. The publishing fees on main, planned manuscripts will be paid for through grant funding for CIDsCaNN. Reprint fees will not be funded. Fees for other manuscripts will typically be funded by the lead investigator/s.

d. All studies using some or all of the original inception cohort (from CIDsCaNN Phase 1.0) should reference the protocol registration at ClinicalTrials.gov (NCT02308917 - https://clinicaltrials.gov/ct2/show/NCT02308917) in the Methods and/or Acknowledgements sections of the manuscript.

e. Members are encouraged to utilize open-access options of journals. Open-access publishing is encouraged but not required, unless required by an institution co-funding a CIDsCaNN project (e.g., CIHR) as funds are available.

f. The major funding source (The CH.I.L.D. Foundation) is to be acknowledged in all publications.

g. All named authors will be required to submit a list of their past and present disclosures by including this information on the drafted manuscript once it is circulated for review. Disclosures include direct, indirect, or perceived conflicts of interest, as required by the journal. Failure to submit disclosures is a serious offence and failure to submit prior to manuscript submission will preclude authorship. Disclosures will be stored at (Dropbox: *CIDsCaNN Shared Documents**CIDsCaNN Committees**PubPC**Disclosures*).

5. Process for Preparation and Submission of Manuscripts

Note: The PubPC will oversee the below process to ensure that it proceeds within the timeline specified below, except in exceptional circumstances.

a. The Study PI will name a First Author and a Writing Group for a given manuscript topic, as per the principles discussed previously (**Section 4**). The Network PIs, Network Co-PI, study team, and site PIs may suggest a First Author be assigned to a manuscript, however this must be approved by the Study PI and CIDsCaNN Executive Committee. The names of the Lead Author, First Author (if different from Lead Author), and Writing Group members will be transmitted to the PubPC by the Study PI and/or Scientific Committee at the time of study approval. This will be tracked in (Dropbox: *CIDsCaNN Shared Documents**CIDsCaNN Committees**PubPC*\<manuscript-project name>\).

b. The Study PI will inform the PubPC at the time a study is ready for preparation of an abstract or manuscript. The PubPC will suggest the appropriate manuscript reporting guidelines (and relevant extension) from the Equator Network (www.equator-network.org) which shall be used in ensuring completeness of reporting and transparency of the research. The PubPC will also make note of proposed timelines for the abstract/manuscript as provided by the Study PI (Dropbox: *CIDsCaNN Shared Documents**CIDsCaNN Committees**PubPC*\<manuscript-project name>\).

c. At the time of initiation of writing of a manuscript, the Study PI will identify the site PIs to be named authors on the study, which will include all Site PIs in CIDsCaNN. The list of Site PIs will be forwarded to the PubPC.

d. The Study PI will inform each Site PI that they will be provided authorship on the manuscript, and the order in which authorship will be granted. The Site PI will provide the Study PI with a list of names of CIDsCaNN investigators at each site who qualify for authorship (contributed patients and meet criteria for authorship as per ICMJE guidelines). The Site PI will confirm that each suggested author meets all criteria for authorship.
   N.B.:
   - Named authorship should be reserved for investigators who contributed to the scientific study design, conduct, analysis and interpretation *to a significant degree*.
   - Those with minor scientific contribution and clinical recruitment but who meet ICMJE standards for authorship should be included in the group authorship position.
   - Those without minor scientific contribution and who do not meet ICMJE standards for authorship should be thanked in the Acknowledgements section of the manuscript.
   - Some site PIs may decide to rotate authorship between site members in an attempt to include more contributing members over time.

e. The Study PI will forward the list of authors, position of each author (including those to be included in the group authorship position), and qualifications for authorship to the PubPC. This list will be maintained by the PubPC in the shared folder for reference and to ensure adherence when the manuscript is finalized (Dropbox: *CIDsCaNN Shared Documents**CIDsCaNN Committees**PubPC*\<manuscript-project name>\).

f. The First Author and Writing Group members will adhere to timelines and targeted journals as outlined on the manuscript roadmap.

g. The First Author will write the first draft of the manuscript, adhering to the appropriate reporting guidelines. The First Author will complete the relevant reporting guideline and provide to all co-authors at the time of circulation of the manuscript for review. The reporting guideline checklist will be uploaded with any journal submission.

h. The First Author or Study PI will circulate the initial manuscript draft and completed reporting guideline checklist to the Writing Group members for their critical review (**within 2-3 weeks of manuscript circulation**).

i. All versions of the manuscript will be version-controlled using the following methods:

   i. The First Author will draft the main version of the manuscript and add the date to the filename, with the format as follows: "Manuscript – CIDsCaNN <study name> – YYYY-MM-DD"
      e.g. "Manuscript – CIDsCaNN AMBITION-CD – 2020-01-01"
   ii. Each reviewing author will add their initials to the manuscript filename, but will not change the date in the file name, as follows:
      e.g. "Manuscript – CIDsCaNN AMBITION-CD – 2020-01-01 eib srm dhb eo"
   iii. The First Author will then revise the manuscript, altering the date in the file name to the most recent revision date and removing the initials:
      e.g. "Manuscript – CIDsCaNN AMBITION-CD – 2020-04-21"

g. The First Author and Study PI are responsible for ensuring that the manuscript includes the relevant conflict of interest disclosure statements, reference to ClinicalTrials.gov protocol for the inception cohort, and funding acknowledgements.

h. After Writing Group comments are provided to the First Author or Senior Responsible Investigator, the PubPC will follow-up with them after **4 weeks** to ensure that progress has been made to address these comments.

i. Once feedback from the Writing Group has been taken into consideration, the First Author will submit the revised manuscript to CIDsCaNN Executive Committee for review. The First Author is then required to make any suggested changes.

j. Manuscripts, once they have received an acceptable review by the CIDsCaNN Executive Committee, will be emailed to all named authors, as well as those in the group authorship. *All authors must respond with revisions or approval* ***within 2-3 weeks****.* Failure to respond/review/approve could or will result in removal of the author from the paper. The PubPC will consider extensions to this timeline under exceptional circumstances.

k. The First Author, Senior Responsible Investigator, Study PI or their delegate will then be responsible for organizing the final submission of the approved manuscript to the targeted journal (i.e. uploading the manuscript, obtaining appropriate copyright signatures etc.). This will be **within 4 weeks** of receiving feedback from the CIDsCaNN Executive and co-authors.

l. The Writing Group members must make themselves readily available to the First Author or Senior Responsible Investigator around the time of submission so that the necessary forms/signatures can be expedited. If the Senior Responsible Investigator is unable to access the investigators participating in the Writing Group for these purposes, the Writing Groups member's authorship may be withdrawn. Similarly, all authors must avail themselves to providing signatures and failure to do so in a timely manner will jeopardize authorship.

m. The Senior Responsible Investigator will take responsibility for manuscript revisions/resubmissions to the journal and for fees related to the submission.

6. Approach to Authorship on Abstracts

a. Abstracts are investigator-initiated; that is, the wish to compile an abstract will come from the investigators, including the Study PI, Network PIs, Network co-PI, and/or site PIs.

b. The approach to authorship on abstracts is the same as for manuscripts (see above section 4.).

c. The CIDsCaNN study team and scientific committee lead(s) may suggest abstract topics. Additional abstract topics can be suggested by submitting a request to the CIDsCaNN Executive Committee.

d. Based upon the character/word restrictions of an abstract submission, CIDsCaNN members across the country who are not named investigators on the study but who have contributed may not be included as co-authors. Group Authorship ('the Canadian Children IBD Network (CIDsCANN)') may be used in place of naming all contributors. Space permitting, site PIs should be prioritized for named authorship.

e. The Lead Author position will typically be taken by the Study PI except where the Study PI has first-authored the abstract or suggests another to that position. In that case, the Study PI may assign the Network PIs or Network co-PI as Lead Author.

f. Trainees may be named authors or First Authors on abstracts. Trainees should not be named

as Lead Author or Senior Responsible Investigator.

g. For abstracts resulting from ancillary studies and non-planned manuscripts based on novel ideas, the same principles apply as for authorship on planned abstracts, except that the Network PIs and Network co-PI may not be assigned Senior/Lead Author position. This position will be held by the Study PI.

h. For abstracts, the same version-control strategy as manuscripts will be used (**Section 5.g.**).

i. The First/Lead Authors should allow all named authors **at least 5 days to review** an abstract prior to submission. If less than 5 days were provided to named authors, the PI reserves the right to prohibit submission of the abstract.

7. Process for Preparation of Posters and Presentations Arising from Abstract Submissions, and Preparation of General Presentations (Grand Rounds, Invited Speaker)

a. The First Author or Study PI will take responsibility for preparation and payment of posters.

b. If there is insufficient space to name all authors on the abstract submission (see point 6.f.) "Canadian Children IBD Network" will be listed as a Group Author.

c. For Oral Presentations, the logo for the Canadian Children IBD Network should be included on the first slide (with title and author names). These logos are available in the shared folder (Dropbox: \\CIDsCaNN Shared Documents\CIDsCaNN Logos & Branding\).

d. For Oral Presentations, funding from the CH.I.L.D. Foundation must be acknowledged on an Acknowledgements slide. Similarly, on posters the CH.I.L.D. Foundation should be acknowledged in the bottom-right portion of the poster.

e. CIDsCaNN members will submit posters and slides for oral presentations to CIDsCaNN administration so that these materials can be made available to all CIDsCaNN members on the CIDsCaNN website.

f. The PubPC would be available for consultation for abstract presentations, posters and non-published presentations if desired.