



Canadian Cohort Obstructive Lung Disease

Sample and data access policy and Data Release and Publication Policies

NB: these policies are full part of the CanCOLD governance document describing Administrative Structures, Organization and Policies (p. 17 to 20)

It is in the interest of all involved with CanCOLD that data generated by the study be used for ancillary projects and publications in respected of peer reviewed journals. However, policies are needed with respect to ownership and access to data, new research questions and publication, and presentations. The following policies have been implemented to assist in this process.

Ownership of Data

Each participating site owns its own data. Any researcher of a participating site can access site specific data under condition of the approval of CanCOLD Steering Committee. Any publications/presentations using site specific data, should acknowledge the site's use of the CanCOLD protocol and any support it received from CanCOLD national coordination members. A standardized text for acknowledgement of funding will be made available to all sites and can be supplemented with acknowledgements of additional local funding sources.

All analysis conducted on CanCOLD data should only be performed on the final datasets provided to the sites. This assures a consistent reporting of results in the literature. Upon receipt of the final datasets from the CanCOLD national coordination office (CanCOLD NCO), sites should duplicate the basic statistical report supplied by the CanCOLD NCO to assure that the same statistical methods are in use and that no damage to the dataset occurred during transfer.

Participating centers also grant other CanCOLD investigators access to their data for use in approved study-wide (all sites) analyses.

Sample and Data Access: New Research Questions

The Steering Committee will propose or receive new project/question development. These new projects may involve the entire cohort or limited number of centers. They will have to be approved, after a review by the Steering Committee. All new projects will need to include a formulation of main goals and outcomes. It will also include a formulation of budget and source of financial support. In cases where additional data collection or data linkage are involved, the investigators leading the analysis will have to provide required ethical certificates to access sample and/or data CanCOLD subsets.

At least one CanCOLD investigator must be included as a co-investigator on an ancillary study. This individual is responsible for presenting the study to the Steering Committee, monitoring the study to assure continuing compatibility with CanCOLD and serving as a liaison to the CanCOLD Steering Committee. In addition, each manuscript and abstract is generally expected to include at least one CanCOLD investigator as named individual author. Additionally, all publications on CanCOLD data should acknowledge the collective "The CanCOLD Research Group and the Canadian Respiratory Research Network".

An analytic database will track all analyses conducted and planned using CanCOLD data, and will include information on investigators leading the analysis, time lines for completion, and dissemination of results. This will be available at all time on the website of CanCOLD. The investigators will also accept to give back any relevant data analysis to CanCOLD (like genotyping data from DNA CanCOLD samples).

Review of the proposal for project requested Samples/data

The research proposal needs to be prepared according to a defined format and submitted electronically to the principal investigators and / or to the administrative director, who will distribute it to the Steering Committee. The format is:

- Title (clearly describing the study)
- (1-2 pages) key words (unique to the study objective) background and rationale
- Objectives
- Sample selection (inclusions/exclusions), sample size, and power
- (1-3 pages) list of variables requested;
- Description of analysis;
- Expected outcomes (publications; clinical outcomes; training etc.);
- Time line to complete the project and targeted journal;
- Funding source(s);
- (1-2 pages) references

Under the coordination of the administrative director, all members of the Steering Committee will receive the proposal and will have 4 weeks to make a review and send comments. The Steering Committee members will meet (tel conf) and final decision with recommendations will be provided to the investigator. The Steering Committee can ask an outside reviewer if needed.

The Steering Committee will review the proposal for: scientific justification for the objectives, methodological soundness, impact on CanCOLD (including workload imposed on the Analysis Centre and overlap with CanCOLD's own analysis planning), and dissemination plan (including conference and journal submissions).

The proposal may be approved, approved with changes, or not approved.

Following approval, the authors of the proposal will be notified of the release of data, and will sign an agreement, stating that they will only use the data for the purpose described, will follow the time line specified for the analysis, and will destroy the data files by (date).

If the analysis has not been completed by the date specified in the time line, then the authors will relinquish "rights" to that analysis, so that it may be carried out by other interested CanCOLD investigators.

Once a proposed analysis is approved, the process for vetting abstracts and manuscripts will focus on information-sharing with the Steering Committee, rather than a scientific review of the material.

Data Release and Publications Policy

Manuscript involving study-wide data

Any CanCOLD investigator can propose a manuscript based on study-wide data. Any such manuscript must be approved by the Steering Committee. Before analyses can begin on any manuscript involving study-wide data, agreement must be reached concerning authorship (including lead author) and priority for analysis. Journal policy permitting, all manuscripts based on analysis of study-wide data shall include a list of all sites whose data are included in the paper. In addition, all manuscripts based on analysis of study-wide data shall include “The CanCOLD Research Group and the Canadian Respiratory Research Network” as part of the author line unless this is not permitted by the journal. The CanCOLD NCO may provide limited assistance in conducting analyses for, and writing up the results of, wide-specific papers.

Abstracts involving study-wide data

Trialwide abstracts should acknowledge the financial support of the various sponsors who provided support for the CanCOLD National Coordination, and if permitted include “The CanCOLD Research Group and the Canadian Respiratory Research Network” in the author line.

Ancillary or Substudies: Review of publications and presentations

Manuscript proposals based on analysis using some of all data from the CanCOLD database require approval of the CanCOLD Publication Committee (steering committee). All publications, presentations and abstracts from an ancillary study must be reviewed and approved by the Publications Committee (Steering committee) prior to submission or presentation, in accordance with the CanCOLD general rules for publications and presentations.

Site-specific or limited site-specific manuscript

Principal investigators are encouraged to publish site-specific findings in a timely manner, if possible within one year of completion of each survey. Publication of these papers should not wait for completion of the whole study in all sites. The CanCOLD NCO may provide limited assistance in conducting analyses for, and writing up the results of, site-specific papers.

Members of the CanCOLD NCO who made substantial contributions to site-specific papers may be invited to be co-authors on an individual basis. The order of authors’ names in publications based on site-specific analyses is also the responsibility of the principal investigator at the site. Authorship should follow international recommendations (see section authorship): all authors should have contributed substantially (see http://bmj.com/advice/article_submission.shtml).

Site-specific abstracts

Manuscripts and abstracts from individual CanCOLD sites should acknowledge the support of the CanCOLD National Coordination and its sponsors, as well as any local sponsor who provided cash or in-kind contributions.

Presentations at local, regional, and international meetings

Site team members are encouraged to present COLD/CanCOLD results from their sites at local, regional, and international meetings. Acknowledgement of COLD/CanCOLD support should be included in all presentations. See section: Funding agency acknowledgement for CanCOLD manuscripts and presentations.

Intellectual property

The intellectual property policy of each site will be applied in case of an invention resulting from the analysis of CanCOLD data subsets.

Authorship

The following criteria of authorship have been developed by the International Committee of Medical Journal Editors and are to be applied to CanCOLD publications. "Each author should have participated sufficiently in the work to take public responsibility for the content. Authorship credit should be based only on substantial contributions to:

- a) conception and design, or extraction and analysis of the data, or interpretation of data;
- b) drafting the article or revising it critically for important intellectual content;
- c) final approval of the version to be published.

Conditions a), b), and c) must all be met."

It is recommended that these guidelines be followed, but it is also recognized that any CanCOLD researcher may make a case for his/her inclusion on a given publication. The first/responsible author shall have the right and responsibility to determine the final author list and order of naming. CanCOLD investigators, may consider doing so on the side of inclusion rather than exclusion. In the case of a project designed for credit for an MSc degree or PhD degree only the student and immediate mentors need be included as authors. In any case, all publications will name the "The CanCOLD Collaborative Research Group and the Canadian Respiratory Research Network" as last author.

Funding agency acknowledgement for CanCOLD

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The project is led by researchers of RI-MUHC at McGill University and Icapture Centre, University of British Columbia."