Statement on Knowledge Generated Collaboratively in CAN*Help* Working Group Community Projects

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CAN *Help* WORKING GROUP

Statement on Stewardship and Dissemination of Knowledge Generated Collaboratively in CAN*Help* Working Group Community Projects

Guiding Principles

- Research questions are developed with input from community project planning committees, who represent research participants
- Research participants donate personal information, including that arising from biological material, to community research projects
- Knowledge takes shape from information donated by participants through:
  - Scientific observation and measurement that turns information into scientific data
  - Analysis that reveals patterns in data
  - Interpretation of data patterns
- Researchers are bound by ethical, professional, scientific, contractual, and other legal standards to be responsible stewards of the information donated by participants; this entails using this information for no other purpose than to achieve explicitly shared research goals
- Any member of the CAN*Help* Working Group who contributes to a particular research project may contribute to the interpretation of the data patterns; when consensus is not possible, different viewpoints will be reported
- All members of the CAN*Help* Working Group who contribute to a particular research project are entitled to be acknowledged for their contributions (either as a group or individually depending on practical considerations)
- In keeping with professional and ethical standards, individuals who make key contributions to specific research reports will be acknowledged as authors
- After following CAN*Help* Working Group guidelines for review of research results by relevant collaborators, results will be made accessible to the public to ensure open access to knowledge generated through the support of public resources, as required by funding agencies and the university
- The CAN*Help* Working Group research director, Karen Goodman, has ultimate responsibility for ensuring that these guiding principles are upheld

These principles cover matters pertaining to the academic and legal domains of intellectual property. Because this research endeavor is a community-researcher collaboration aimed at improving the health of communities, the product of this research is knowledge generated collaboratively for the common good rather than the intellectual property of individuals. To operationalize these principles, the following guidelines have been elaborated (see below): Research Project, Data Use, Authorship, Acknowledgement, and Data Dissemination Guidelines.

Research Project Guidelines

These guidelines pertain to projects that use information or biological specimens, including bacterial isolates, donated by participants in one or more CAN*Help *community projects.

How to Obtain Approval for a CAN*Help* Research Project

- Before commencing work on a project, the lead investigator (or designated trainee) must obtain written approval from the Research Director, who is responsible for the stewardship of all information arising from community projects
- To obtain approval:
  - Request a project description and agreement form from the Research Management Lead
  - Prepare the form according to the instructions provided
  - Read the CAN*Help* Investigator Agreement and indicate in the project description and agreement form that you have read and will adhere to this agreement
  - Submit the form to the Research Management Lead
- The Research Management Lead will review the project description and inform the lead investigator or trainee of any needed clarifications or suggested modifications
- When the Research Management Lead is satisfied with the project description, she will seek approval from the Research Director
- If the Research Director does not approve the project, she will inform the lead investigator or trainee of the reasons and suggest an alternate project if appropriate
- If the Research Director approves the project, she will determine whether community review is required before the research can commence
- If your project requires information from one or more CAN*Help* databases, refer to the CAN*Help* Data Use Guidelines

Investigator Agreement

In conducting my project, I will adhere strictly to this agreement to ensure that my project conforms to all research agreements the CANHelp Working Group is bound to uphold. I agree to:

- ❖ Abide by the Statement on Stewardship and Dissemination of Knowledge Generated Collaboratively in CAN*Help* Working Group Community Projects
- ❖ Carry out my project without going beyond the approved project description unless I get written approval from the Research Management Lead of a modified project description
- ❖ Notify the Data Dissemination Lead about any abstract, report or presentation I plan to prepare from my work on this project, following the timeline indicated in the Data Dissemination Guidelines
- ❖ Refrain from publishing or reporting any information from my project without written approval from the Research Director
- ❖ Submit to the Research Management Lead a summary of my work when I stop working on this project, whether or not I complete it, along with a final copy of any written abstract, report or presentation arising from my project

Data Use Guidelines

Procedures for Obtaining Data from CAN*Help* Community Projects

- Before undertaking a data analysis project, the lead investigator must obtain written approval from the CAN*Help* Working Group Research Director, who is responsible for the scientific integrity of all CAN*Help* Working Group data analysis
- To obtain approval:
  - Obtain a data request form and a list of available CAN*Help* datasets and variables from the Data Quality Lead
  - Prepare the form according to the instructions provided
  - Read the Data User Agreement and state in the indicated space in the request form that you have read and will adhere to the Data User Agreement
- Submit the data request form to the Data Quality Lead, cc'd to the Data Dissemination Lead Data Quality and Data Dissemination Leads will review written data requests and inform the lead investigator of any needed clarifications or suggested modifications
- When the Data Quality and Data Dissemination Leads are satisfied with a written data request, the Data Quality Lead will seek approval from the Research Director, and inform the lead investigator of any further modifications suggested by the Research Director
- When a written data request has been approved by the Research Director, the Data Quality Lead will provide the dataset and codebook to the lead investigator

Data User Agreement

- Users will use only the variables approved in their data request; if they wish to use additional variables, they must submit a new data request
- Users will save their own data file and codebook with a name that identifies their analysis
- Before analyzing data, users will follow the CAN*Help* Data Preparation Procedures (see appendix)
- Users will not edit any data in their file; if data errors are suspected, users must alert the Data Quality Lead, who will provide a corrected data file if errors are confirmed
- While conducting the analysis, users will follow the CAN*Help* Analysis Procedures (see appendix)
- Users will leave dataset variables unmodified in their data file (although they are free to drop variables they don't need); users can create new variables in their own data file as long as they are given a new variable name and defined precisely in their own codebook
- Upon completion of the analysis, users will follow the CAN*Help* Post Analysis Procedures (see appendix) and submit the designated files and documentation to the Data Quality and Data Dissemination Leads
- When reporting results, users will adhere to the CAN*Help* Working Group principles and procedures for Stewardship and Dissemination of Knowledge Generated Collaboratively
- *Users will adhere strictly to this agreement to avoid duplication of effort and inconsistencies across CAN*Help *analyses*

Authorship Guidelines

- Authorship on a report conveys both credit for the work and responsibility for the accuracy of the content
- The CAN*Help* Working Group Research Director is responsible for ensuring the scientific integrity and coherence of all reporting and, for this reason, must:
  - Determine whether reports written by members of the CAN*Help* Working Group are CAN*Help* reports or independent work when the context is ambiguous
  - Approve the authorship of all CAN*Help* reports (including but not limited to journal articles, presentations, abstracts, and book chapters)
- To varying degrees, the content of CAN*Help* reports combines information collected from community projects with ideas of the report writers; some reports are written to present the authors' perspective rather than present data collected from community projects; this balance must be assessed to identify the appropriate list of authors
- With the exception of progress reports, newsletters, and funding agency reports, all CAN*Help* reports will reveal the individual authors; when other group members make contributions that don't warrant individual authorship, the CAN*Help* Working Group will be named as an author
- Individually named authors will be those who play a key role in compiling the report, and others who play a key role in generating or securing the information reported. Eligible co-authors must fulfill each of the following:
  - Major contribution to the research design or analysis on which the report is based
  - Participation in the preparation of the manuscript/report
  - Consent to be named as a co-author
  - Active approval of the completed manuscript/report
- The order of authorship will follow the level of contribution of each co-author
- The lead investigator (including students) of a data analysis project will have the option of assuming the first author role, which requires taking the lead on drafting the manuscript/report and overseeing completion (and/or submission for publication) within a reasonable amount of time, to be negotiated with the Research Director
- Community collaborators will be supported in taking a lead author role on relevant reports at their request
- The lead author will assist the Research Director in assessing the level of contribution of the co-authors
- Papers presenting findings central to the original aims of the research program will include as authors co-investigators who helped design and launch relevant aspects of the study

Acknowledgement Guidelines

Lead authors of reports derived from the CAN*Help* Working Group research program must:

- Consult the Research Director to determine which acknowledgements are relevant to what they are reporting
- Consult the Research Management Lead to find out which funders are relevant to what they are reporting
- Consult the Data Quality Lead to find out which communities have contributed data, for reports based on community-project data
- Ascertain and adhere to current acknowledgement requirements of funders

Journal Articles

- The acknowledgement section should mention:
  - Individuals who made key contributions to the reported research but are not eligible for authorship
  - Planning committees of communities providing data, if relevant
  - Relevant funders and partners who provided in-kind support
  - The funding reference number (FRN) of any relevant CIHR grants
- Any paper that includes the CAN*Help* Working Group as an author should use the following statement, amending the list of grants and funding reference number mentioned as needed:

  "At the time this research was conducted, the CAN*Help* Working Group research program was supported by grants from the Canadian Institute of Health Research (FRN: 115031) and ArcticNet Network of Centres of Excellence..."
- Any paper on which Karen Goodman is an author should include the following statement:

  "Karen J Goodman was a Health Senior Scholar (2008-2015) supported by Alberta Innovates Health Solutions."
- Any paper with authors whose salary is supported by a designated grant or stipend should acknowledge that support as well

Presentations (Poster or Oral)

- Logos of relevant funders should be displayed (see below for a list of logos)
- Logos of partner organizations that contributed to the work can be displayed with consent of relevant collaborators
- For presentations that include data from community projects, planning committees of communities providing the presented data should be acknowledged

Major Supporters:

CIHR

ArcticNet

AIHS

Olympus

Training Grant Support:

Nasivvik Centre for Inuit Health and Changing Environments

UAlberta North

Institutional Logos:

CAN*Help* Working Group

University of Alberta

Data Dissemination Guidelines

Procedures for Review of New Results from Community Projects

It is imperative that *all* relevant research partners be given *sufficient time* to review any new results derived from data or samples collected in community projects *before* they are presented outside the CAN*Help* Working Group in any form or forum. It is also imperative that all proposed co-authors are given sufficient time to provide feedback and approval.

- Adherence to review procedures is the responsibility of:
  - Lead investigators of analyses that generate new results from community projects
  - Lead authors of reports that present new community project data for the first time
- Relevant reviewers include co-authors, planning committees of communities with data included in the report, and other relevant collaborators to be determined in consultation with the Data Dissemination Lead
- When new results are to be presented outside the CAN*Help* Working Group in any form or forum (for example, in a course report, abstract, oral or poster presentation, or manuscript), the lead investigator/author must notify the Data Dissemination Lead
- The lead author should prepare a draft of the report for review with sufficient lead time; the required length of time will be determined by the Data Dissemination Lead
- If there is a reason to seek review before the report is completed, a Results Summary can be reviewed as an alternative at the discretion of the Data Dissemination Lead
- Once the report or Results Summary is ready for review, the lead author should submit it to Data Dissemination Lead to circulate to relevant reviewers, or inform the Data Dissemination Lead that they wish to circulate the report for review
- Reviewers should be given an explicit deadline allowing at least one week for feedback; they should always be told they can request more time if needed
- If relevant reviewers express objections to how results are being reported to any members of the CAN*Help* Working Group, these objections should be conveyed to the Data Dissemination Lead and/or the Research Director who will confer to determine an appropriate response
- ***If any concerns of relevant reviewers cannot be resolved before report submission or presentation deadlines, the results in question will need to be removed from the report or release of the report will need to be delayed until a solution has been agreed upon for addressing all relevant viewpoints***

Guidelines for Preparing a Results Summary

- The summary should include:
    - Aim of the presentation
    - Brief description of the background/context
    - Succinct description of the methods
    - Summary of results and interpretation
- Two versions of the summary should be drafted
    1. Co-author version with appropriate detail for co-author review and approval
    2. Plain-language version (to be prepared with assistance from the Data Dissemination Lead) for review by relevant community partners
- If the new results are to be presented in a poster or slide format and written content is finalized but the formatting is incomplete, a word document containing the content can be used in the summary
- Once the report has been drafted, it should be circulated to the co-authors and community representatives/partners who reviewed the Results Summary

Abstract Submission Guide for Lead Authors

When you decide to submit an abstract that reports community project data (at least 4 weeks before the submission deadline):

- Notify the Data Dissemination Lead about:
  - What you will be presenting
  - If using community data, which communities the data came from
  - Who your proposed co-authors are
  - Which conference your abstract is for and what the submission deadline is
  - Who you would like to coordinate the review process (you or someone selected by the Data Dissemination Lead)
- Contact proposed co-authors (or ask the Data Dissemination Lead to do so) regarding:
  - What will be presented and where
  - Whether they agree to be an author
  - What the timeline for completion and review of the abstract is
- If you will be reporting new results from community projects, follow the Procedures for Review of New Results from Community Projects
- If you require data from community projects:
  - Follow Procedures for Obtaining Data in the Data Use Guidelines
  - Add an extra week to the review timeline for the Data Dissemination and Data Quality Leads to verify the data analysis before others review it

At least 2 weeks before the submission deadline:

- Send the draft abstract to the Data Dissemination Lead
- In consultation with the Data Dissemination Lead, develop and execute a plan to circulate the draft abstract to co-authors and other relevant reviewers
- Give co-authors and reviewers an explicit deadline allowing at least one week for feedback; let them know they can request more time if needed
- If you complete statistical analysis, follow Data Analysis Procedures (see appendix)

At least 1 week before the submission deadline:

- If reviewer feedback is incorporated, develop and execute a plan in consultation with the Data Dissemination Lead to re-circulate the revised abstract to co-authors and other relevant reviewers

When the timeline specified in this guide cannot be met, it may be possible to proceed with the preparation of an abstract if the Data Dissemination Lead decides that circumstances warrant a tighter timeline. Additionally, if the draft abstract cannot be circulated for review 2 weeks before the submission deadline, the lead author may instead circulate a Results Summary, prepared according to the Results Summary guide, and then circulate the draft abstract as soon as it is prepared. When a Results Summary or abstract cannot be circulated 2 weeks before the submission deadline, lead authors should submit the abstract to a conference with a later submission deadline, unless there is a compelling reason to proceed *and* permission is obtained from the CAN*Help* Working Group Research Director.

Presentation (Poster & Oral) Guide for Lead Authors

When you assume the lead on preparing a presentation, bear in mind:
You must give relevant research partners sufficient time to provide feedback on the draft presentation, as specified below. If you are not able to draft the finalized presentation with sufficient lead time, you can request approval from the Data Dissemination Lead for circulating a presentation summary following the Results Summary guidelines.

If no abstract was required or if you wish to add data that was not reported in the abstract, at least 4 weeks before the presentation date:
(If an abstract was required and you do not need new data, skip to "At least 2 weeks…)

- Notify the Data Dissemination Lead about:
  - What you will be presenting (including which communities the data will be from)
  - Who the proposed co-authors are
  - Which meeting you are presenting at, and the day and time of the presentation
  - Who you would like to coordinate the review process (you or someone selected by the Data Dissemination Lead)
- Co-authors should be contacted (either by the Data Dissemination Lead or Lead Author) regarding:
  - What will be presented and where
  - Whether they agree to be an author
  - What the timeline for completion and review of the presentation is
- If you are reporting new results from community projects, follow the procedures for Review of New Results from Community Projects
- If any additional data from community projects are required, follow the Procedures for Obtaining Data in the Data Use Guidelines

At least 2 weeks before the presentation date:

- Send the draft presentation or presentation summary to the Data Dissemination Lead
- In consultation with the Data Dissemination Lead, develop and execute a plan to circulate the draft abstract to co-authors and other relevant reviewers
- Give co-authors and reviewers an explicit deadline allowing at least one week for feedback; let them know they can request more time if needed
- If a summary is circulated, provide a date by which research partners can expect to see the draft presentation
- If you complete statistical analysis, follow Data Analysis Procedures (see appendix)

At least 1 week before the presentation date:

- If reviewer feedback is incorporated, develop and execute a plan in consultation with the Data Dissemination Lead to re-circulate the revised presentation to co-authors and other relevant reviewers

Manuscript Preparation Guide for Lead Authors

- Members of the CAN*Help* Working Group who wish to take the lead on drafting a manuscript for a journal article should inform the Data Dissemination Lead who will provide advice on a suitable scope for the article and secure approval from the Research Director for the proposed article
- If the manuscript will report new results from community projects, the lead author must follow the Procedures for Review of New Results from Community Projects
- Lead authors of journal articles are responsible for ensuring adherence to CAN*Help* Working Group Data Use, Authorship, and Acknowledgement guidelines
- Lead authors should confer with the Data Dissemination Lead to identify a target journal for formatting the manuscript
- Lead authors should keep the Data Dissemination Lead informed of their progress and seek her support to overcome any obstacles encountered
- If the manuscript reports data from community projects, once it has been drafted, the lead author should submit it for review to the Data Dissemination Lead who will check any reported data for errors with assistance from the Data Quality Lead
- When the Data Dissemination Lead has approved the manuscript for co-author review, she will confer with the Research Director to identify co-authors and relevant reviewers
- In consultation with the Data Dissemination Lead, the lead author will develop a plan for review/approval by designated co-authors and other relevant reviewers
- When the manuscript has been approved for submission by the co-authors, the lead author will be responsible for ascertaining and implementing journal requirements for submission, seeking assistance from the Data Quality Lead as needed
- When the manuscript has been finalized for submission, the lead author must
  - Obtain approval of its adherence to journal requirements from the Data Quality Lead
  - Obtain approval of its content from the Research Director
  - Follow journal instructions to submit the manuscript
- Lead authors are responsible for ensuring that a public access option is in place for published articles if the content of their paper requires this (see below)

Open Access

CIHR requires that all journal publications reporting results of research they fund are accessible to the public within 12 months of publication. This can be achieved by publishing in open access journals. Some other journals offer authors the option of purchasing open access at the time of publication. Some permit authors to archive the manuscript in an institutional data repository. As an alternative, most health science journals have a mechanism for complying with public access requirements; for this to work, authors must follow the funders' acknowledgement rules when preparing a manuscript for publication and ensure that the journal editors agree to make the appropriate provisions.

Data Preparation Procedures

Purpose: Before data analysis, data verification, cleaning and editing must be done to optimize the accuracy of the analysis.

- Data Verification and Cleaning
  1. Visually verify that the file contains a unique subject ID number for each subject to be included in the analysis. If you find duplicate IDs, seek assistance from the Data Quality Lead.
  2. Tabulate the number of subjects with missing responses for each variable and report this to the Data Quality Lead, so the completeness of your data file can be confirmed, and so you can make plans for dealing with missing data.

     EXAMPLE COLUMN HEADERS:

Variable name	Number of subjects with missing responses

  3. Inspect frequency distributions of each variable for implausible or out-of-range values.
  4. Perform appropriate cross-tabulations to check for inconsistent values.
  5. Alert the Data Quality Lead to suspected errors by submitting a tabulation of implausible, out-of-range, or inconsistent values as shown below.

     EXAMPLE COLUMN HEADERS:

ID	Dataset name	Variable name	Value

- Data Editing
  1. Do not edit any values of variables from CAN*Help* datasets. Seek guidance from Data Quality Lead about any required editing of dataset variables. If appropriate, the Data Quality Lead will provide a corrected data file. ***(This is crucial to avoid inconsistencies across data analysts.)***
  2. You can recode variable values for purposes of grouping them or transforming their scale. If you want to recode any values, create a new variable with a new name, save it in your data file, add it to your codebook, and document the code used to create new variables in a do file or output file.

Be mindful:

The integrity of data analysis results depends on the integrity of the collected and entered data. The process of data verification, cleaning, and editing is crucial to the research. This is the process during which we correct errors and continue to flag and track down missing data. Follow these procedures faithfully and contact the Data Quality Lead regarding any questions.

Data Analysis Procedures

- Retain electronic copies of relevant *.do files and output file(s) that document all aspects of the data analysis including results left out of reports
- Edit the output files to
  - Eliminate erroneously typed commands and erroneously generated results
  - Add annotation so that another person can understand what was done and why
- When creating a new form of a variable (e.g. creating categories from a continuous variable or otherwise transforming its values) or creating a new composite variable from other variables in your data file, make sure to add it to your codebook
- For each new variable added to your codebook, include clear code definitions that document the scale or category boundaries if relevant, along with documentation and justification of rules used to code or recode the variable
- If you wish to change the analysis plan approved in your data request, consult the Data Dissemination Lead, who will determine whether the approval of the Research Director is needed in order to make the desired changes

Post Analysis Procedures

After analysis, submit the following:

- To the Data Quality Lead:
  - Your data file
  - *.do files or output files that show the code used to modify your data file
  - Your codebook

- To the Data Dissemination Lead:
  - Annotated output files that document your analysis
  - Data tables and figures created from your analysis
  - A summary of analytic methods, including all relevant references
  - A copy of any abstract(s) submitted to professional meetings
  - A copy of any slides used to present findings from the analysis

Interpreting and Reporting your Data Analysis

Any written or oral report you generate from your data analysis must adhere to the CAN*Help* Working Group principles and procedures for Stewardship and Dissemination of Knowledge Generated Collaboratively.