CAN*Help* Working Group
Community Project Planning Committee
Research Agreement Template

Purpose of this Agreement:

The purpose of this agreement is to set out the structure of the Planning Committee ("Committee"), the role of each member, and the process to be followed by the Committee in decision-making for the [insert community project name] ("*H. pylori* Project"), to be conducted as a Canadian North *Helicobacter pylori* ("CAN*Help*") Working Group collaboration.

Purpose of the Committee:

The Committee will decide how the *H. pylori* Project will be designed and implemented, selecting from optional scientific approaches outlined by University of Alberta (UA) investigators.

Parties

Members of the Committee will include ***{modify as needed}***:

1) [insert name and affiliation or network, if any]
2) [insert name and affiliation or network, if any]
3) [insert name and affiliation or network, if any]
4) [insert name and affiliation or network, if any]
5) [insert name and affiliation or network, if any]
6) [insert name and affiliation or network, if any]
7) Community Health Representative or Health Director [insert name and position]
8) Nursing Staff Member [insert name and position]
9) CAN*Help* Working Group Staff [UA]
10) Sander Veldhuyzen van Zanten [UA Gastroenterologist and Co-Investigator]
11) Monika Keelan [UA Microbiologist and Co-Investigator]
12) Karen Goodman [UA Epidemiologist and Lead Investigator]

Time Period

This agreement provides a written record of the terms accepted by the Parties at the start of the *H. pylori* Project. It shall remain in effect for the duration of the *H. pylori* Project or until any of the Parties request that it be amended.

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General Role and Process

- The Committee will strive at all times to work by consensus
- Meetings will be held as needed by teleconference with any necessary materials provided to Committee members before the scheduled meeting by CAN*Help* Working Group staff
- Meetings will be held until the maintenance period for the data is set to expire (see Material Contributed by Research Participants: 1) Housing, Storage, and Sharing of Data and other Materials):
- At each meeting, notes will be taken by CAN*Help* Working Group staff and disseminated to the Committee
- A current research progress report will be made accessible to the Committee by CAN*Help* Working Group staff
- In the event of a dispute between the Parties relating to this Agreement, the Parties shall use their best efforts to resolve the dispute amicably. If the Parties are unable to resolve their dispute within sixty (60) days, the Parties agree to use mediation. During the mediation process the Parties agree to continue with their regular roles within this project.

Role of Committee Members not Affiliated with UA

Each Committee member agrees to:

1) Bring forward the perspective of their relevant networks and affiliations;
2) Help ensure that all aspects of the *H. pylori* Project are in accordance with the values and social priorities of their relevant networks and affiliations;
3) Provide relevant expertise for guiding research goals and implementation;
4) Provide advice on *H. pylori* Project materials and communications to ensure that they are appropriate in terms of local values, practices, and policies;
5) Facilitate communication regarding the *H. pylori* Project within their relevant networks and affiliations;
6) Review and provide feedback on project materials and reports within required time frames (as specified below);
7) Provide their perspective on how the research data will be used;

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Optional Section [Role of Community Organizations]

In addition to the roles outlined for Committee members, community organizations that Committee members are affiliated with will support the *H. pylori* Project as follows (***modify as needed***):

- Local governance:
    a. [insert name] will assist the [insert community project name] by: [insert description of role here];
    b. [insert name] will assist the [insert community project name] by: [insert description of role here].
- Health Centre
    c. Health Centre Nursing Staff will also assist the [insert community project name] by:
    [insert description of role here].
    d. Community Health Representative or Health Director
    The Community Health Representative [Health Director] will also assist the [insert community project name] by:
    [insert description of role here].

Role of the University of Alberta

UA, as represented by the Lead Investigator, will be responsible for the scientific research program. In doing so, it will:

1) Ensure that the research
    a. Is ethical and of high scientific quality,
    b. Conforms to UA policies and to scientific and professional norms for community-based research,
    c. Complies with Canadian Institutes for Health Research guidelines for conducting research in Aboriginal populations, and with policies of the funding agencies that support the research;
2) Abide by the CAN*Help* Working Group Statement on Stewardship and Dissemination of Knowledge Generated Collaboratively (attached);
3) Ensure that any collaborations with researchers external to the group adhere to this agreement;
4) Outline recommended scientific approaches for achieving community research goals for consideration by the Committee;
5) Manage the logistics and resources required to carry out the research;
6) Train and supervise the staff who carry out the research;
7) Approve the content and authorship of all research reports arising from the *H. pylori* Project;
8) Provide support to Committee members who wish to develop presentations, publications, or communications tools for disseminating knowledge generated by the *H. pylori* Project;
9) Inform the Committee of project progress by maintaining a current progress report on the CAN*Help* Working Group website.

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Material Contributed by Research Participants

Participants in the *H. pylori* Project may be asked to contribute responses to interview questions, biological samples such as exhaled breath, tissue, hair or blood, photographic images, voice recordings or other material that characterizes them as individuals. In the research process, information obtained from interviews and clinical examination of participants, and from laboratory analysis of biological samples, becomes data that researchers analyze to observe patterns and draw conclusions. For further details on the management of data and other material contributed by participants, refer to the Statement on Stewardship and Dissemination of Knowledge Generated Collaboratively.

1) Housing, Storage, and Sharing of Data and other Material

The Lead Investigator, supported by CAN*Help* Working Group staff, will provide stewardship of all data arising from the *H. pylori* Project, housing and maintaining the data at UA facilities in an organized database. Co-investigators will provide stewardship of all biological samples and other material arising from the *H. pylori* Project. The research participants will collectively own the aggregate data (that is, data unlinked to personal identifiers) generated by the *H. pylori* Project. A Committee member or affiliated community group can obtain, upon request, some or all of the aggregate data to use for specified purposes as outlined in the Statement on Stewardship and Dissemination of Knowledge Generated Collaboratively. Because different sets of personal information may lead to identification of individuals in small communities, the CAN*Help* Working Group staff will be responsible for removing personal identifiers on a case-by-case basis in accordance with ethical requirements. Database development and data entry, editing and cleaning will be carried out by CAN*Help* Working Group staff. The maintenance of biological samples and other collected material will be carried by CAN*Help* Working Group Investigators. Data and collected material arising from the *H. pylori* Project must be retained until [insert date] and then if the database or any collected material is still actively producing results, a revised date will be negotiated. The data and any remaining material will be archived by the Lead Investigator until they are no longer producing results.

2) Access to Data and Other Material by Third Parties

Investigators outside the original research team will be allowed to formally request access to de-identified aggregate data or biological samples, subject to approval by the Lead Investigator. Such requests will be granted only if the proposed uses of the data or material advance CAN*Help* Working Group research goals, and only if the external investigator agrees to adhere to this agreement and the Statement on Stewardship and Dissemination of Knowledge Generated Collaboratively. In keeping with their professional responsibilities, UA investigators will be free to authorize students to use data or collected material to undertake practice research projects for academic credit under their direct supervision. In such cases, it will be the responsibility of the investigator to ensure that the student adheres to this agreement. Students who are not supervised by the Lead Investigator or a Co-investigator can request access to data or other material, subject to approval by the Lead Investigator, which will be granted only if the proposed uses advance CAN*Help* Working Group research goals and only if the

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student agrees to use the data or material exclusively under the Lead Investigator's supervision and in accordance with the Statement on Stewardship and Dissemination of Knowledge Generated Collaboratively.

Handling Conflicts in Interpretation of Data

As described in the Statement on Stewardship and Dissemination of Knowledge Generated Collaboratively, PI-approved authors of reports and presentations that use data from the *H. pylori* Project will provide committee members the opportunity to review drafts with sufficient time for consideration of feedback before publication or presentation. The Committee will receive notification of new reports or presentations and time limits for receipt of comments. Authors will make every effort to allow adequate time, especially when newly generated results will be reported for the first time; however, there will likely be occasions when authors are required to produce reports or abstracts in a short time frame. If committee members can't meet a posted deadline, but wish to comment, they can request an extended deadline, and authors will accommodate this when possible. When newly generated results are presented to the committee for review, if any Committee member expresses objections to any member of the CAN*Help* Working Group about how these new results are being reported, these objections will be conveyed to the Lead Investigator, who will attempt to resolve the objection. If any concerns of Committee members cannot be resolved before report submission or presentation deadlines for newly generated results, the results in question will be removed from the report or release of the report will be delayed until a solution has been agreed upon for addressing all relevant viewpoints. In instances where Parties disagree on the interpretation of newly generated research results, the Lead Investigator will oversee a re-analysis of the data if needed to verify findings. If differences in interpretation of results remain between the authors and other parties, the lead author may choose to proceed with publication or presentation, and the other parties may choose to not be listed as a co-author on this particular publication or presentation. In such a case, the publication will contain a statement to acknowledge the disagreement between Parties. The Committee maintains the right to co-author alternate interpretations of data if the Committee's concerns are not incorporated into the revised publications or presentations, so long as the list of authors is limited to individuals who actively approve the content. These policies ensure academic freedom for University of Alberta investigators while safeguarding the Committee's right to maintain its own point of view. Should conflict arise between members of the Committee, any member is free to publish or otherwise post an alternate interpretation of the data, so long as authorship is restricted to individuals who actively approve the content.

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Authorship and Publications Based on Material Collected by the *H. pylori* Project

The UA Lead Investigator and Co-investigators are responsible to funding agencies to use the data and material collected by the *H. pylori* Project for conducting research as outlined in funded proposals, and to present findings at scientific conferences and in the peer-reviewed literature. Authorship criteria, as specified in the Statement on Stewardship and Dissemination of Knowledge Generated Collaboratively, vary somewhat depending on the forum, but generally require an identifiable contribution to the research, as well as active approval of the content being presented. All Committee members will have opportunities to present reports that highlight aspects of the *H. pylori* Project to communities, the general public, policy makers and/or scientists. Committee members will also have opportunities to contribute as authors to conference presentations by other research group members. For conference presentations, the list of authors will include Committee members who meet authorship criteria. Committee members will also have opportunities to the primary author and/or co-author of published articles, provided that they meet the relevant authorship criteria. Being primary author requires taking the lead on drafting the article and assuming responsibility for submitting it for publication. For all technical reports and summary reports to community organizations, each Committee member will be included in the list of authors. All published articles, oral presentations, posters, and any other reports on the *H. pylori* Project will acknowledge the Committee.

Work Beyond the Original Intent of the *H. pylori* Project

During informed consent, individuals who enroll as participants in this research will be asked if they wish to allow their personal information and any remaining material they provide for the *H. pylori* Project to be stored for use in future research. Beyond this, no new uses of the data are permitted without agreement of the Committee. New research proposals for carrying out related research in the community must be approved by the Committee.

The Committee will decide on a case-by-case basis whether data from this research project can be used in future national or international collaborative projects. Any future collaborators, including international colleagues, will be required to abide by this research agreement.

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