

GUIDING PRINCIPLES AND DISCLOSURE FOR JOINT COLLABORATION ON THE FIRST NATIONS FOOD, NUTRITION AND ENVIRONMENT STUDY

Funding for the First Nations Food, Nutrition and Environment Study (FNFNES) is provided by the First Nations and Inuit health Branch of Health Canada through contribution agreements, with the University of Northern British Columbia (UNBC) and the Université de Montréal (U de M).

The FNFNES is conducted by investigators representing the Assembly of First Nations (AFN), the First Nations and Inuit Health Branch of Health Canada, UNBC, and the U de M (collectively, the “Parties”).

In the context of this project, the Health Canada based investigators have “in-kind” roles and responsibilities as defined in this document, but are not funded partners in the project. Health Canada-based investigators are under the direction of the FNFNES Steering Committee (see section 4) and have no role on the Steering Committee except as non-voting, ex officio members, and observers. They will be requested to report on activities within their areas of responsibility and provide their comments, perspectives and feedback to the Steering Committee upon request.

1. Scope of Study

1.1 Between October 22, 2008 and March 2017, at least one hundred First Nation communities across Canada will be invited to participate in the FNFNES through a process of stratified random selection.

1.2 The FNFNES will assess the diets of First Nations peoples living on reserves south of the 60th parallel across Canada, who rely on a combination of traditionally-harvested and store-bought foods. Sampling plans will be developed to collect representative data for each of the 8 Assembly of First Nations regions. A total of about 8000 participants from 100 selected communities will be invited to participate during the course of this study.

1.3 There are five components to the study:

- 1.3.1 household interview (one-year traditional food frequency questionnaire, 24-hour food recall, and social, health and lifestyle questionnaire);
- 1.3.2 drinking water sampling for trace metals;
- 1.3.3 surface water sampling for pharmaceuticals;
- 1.3.4 hair sampling for mercury; and
- 1.3.5 traditional food sampling for nutrient and contaminant analyses.

1.4 The study will develop a portrait of nutritional benefits and environmental contaminant challenges that are intrinsic to the modern diets of First Nations

people living on reserves by obtaining baseline data on food use patterns among First Nations Peoples. The data will be used to:

- 1.4.1 determine consumption patterns of traditional and market foods on reserve within each AFN region;
- 1.4.2 determine dietary intake of selected contaminants through collection of traditional foods and drinking water samples within each AFN region;
- 1.4.3 estimate intake of macronutrients and selected micronutrients for each participating community;
- 1.4.4 determine availability, accessibility and scarcity of traditional and market foods on reserve within each AFN region;
- 1.4.5 characterize current mercury exposure of First Nations' people on reserves; and,
- 1.4.6 characterize contamination of the aquatic environment on First Nations reserves by pharmaceutical products
- 1.4.7 report to participant First Nations and the funding agency study results in a manner that is complete, clear and understandable, and where necessary provide recommendations for developing intervention strategies or taking corrective action.

1.5 The participatory nature of the study will enable capacity building within communities.

2. Guiding Principles

2.1 The Parties will be guided by following principles in their collaboration throughout and subsequent to the research project:

- 2.1.1 Ensure the highest standards of research ethics, including those of First Nations communities by respecting community protocols;
- 2.1.2 follow the CIHR Guidelines for Health Research Involving Aboriginal People (<http://www.cihr-irsc.gc.ca/e/29134.html>), as well as respect principles of OCAP, the First Nation "Ownership, Control, Access, and Possession (OCAP) or Self-Determination as Applied to Research (<http://www.research.utoronto.ca/ethics/pdf/human/nonspecific/OCAP%20principles.pdf>);
- 2.1.3 respect the individual privacy rights and collective interests of First Nations' people; and,
- 2.1.4 recognize the value of capacity building at all levels; and support First Nations and FNIHB regional processes, including the analysis and dissemination of survey results.

2.2 Health Canada will use data and information received through the FNFNES only for public health purposes and will not disclose this data and information for any other secondary purpose than public health. Health Canada will not release community level data, in cases when such data becomes available to Health Canada-based investigators, outside the federal government without the prior consultation, accommodation and informed written consent of the Chief and Band Council of the concerned First Nation community.

3. Roles & Responsibilities

- 3.1 Each party will be involved in the entire scope of the project through the planning, implementation, data analysis and reporting stages. Under no circumstances will Health Canada or its investigators be provided with or receive personal information that will in any way identify the individual associated with the data. Health Canada shall not attempt to match data with any other data for the purposes of re-identification of any kind.
- 3.2 UNBC (Principal Investigator Laurie Chan) will assume primary interest in and responsibility for food sampling and food, tap water and surface water laboratory analysis for contaminants and will also ensure sample collection for hair and tap water sampling. Further, UNBC (Principal Investigator Laurie Chan) will be responsible for the overall synthesis and reporting of results of the study, including the reporting of individual results to individual participants in the event that hair sample testing reveals high levels of mercury or where drinking water testing levels exceed established action thresholds for trace metals of health concern.
- 3.3 Health Canada (Principal Investigator Constantine Tikhonov) will assume primary interest and responsibility for laboratory hair samples' analysis for mercury concentrations and, reporting anonymous results to UNBC and U de M. Health Canada (Principal Investigator Constantine Tikhonov) will also be responsible for the preparation (in collaboration with other FNFNES investigators Research Team) of Health Canada publication of regional synthesis reports on all results of FNFNES in a given region, after two calendar years from the completion of work in that region (for example for Pacific Region, Health Canada report can be published not earlier than January 2012).
- 3.4 Health Canada (Principal Investigator Harold Schwartz) will assume primary interest and responsibility for surface water sample collection, and reporting of surface water analysis results to communities as well as the synthesis of data.
- 3.5 The U de M (Principal Investigator Olivier Receveur) will assume primary interest in and responsibility for dietary surveys, social, health and lifestyle surveys, data entry and statistical analysis of all FNFNES components, synthesis of dietary, nutritional and food security components of the study. Further, the U de M (Principal Investigator Olivier Receveur) will be responsible for the overall synthesis and reporting of results of the study.
- 3.6 AFN (Principal Investigator Don Sharp) will assume primary interest in the Drinking Water Component of the project and in the interaction with First Nation governments, communication activities, training, sample collection, analysis and synthesis of data and publication of research results on all components of the study. In addition, AFN (Principal Investigator Don Sharp) will assume the primary interest and responsibility for analysis and synthesis of pH and chlorine

results from drinking water samples and reporting this to communities in summary reports prepared by the Parties.

- 3.7 Health Canada (Principal Investigator Harold Schwartz) will assume primary interest and responsibility for the analysis and synthesis of trace metal results from drinking water samples and reporting to communities.
- 3.8 All Parties will work in collaboration as directed by the Steering Committee, ensuring the most productive analysis and synthesis of data and information and reporting of results to communities, who are primary beneficiaries of the study, as well as productive reporting to the scientific community at large through peer-reviewed publications (see section 7.4).

4. Steering Committee

- 4.1 For the purpose of implementing this study a Steering Committee is formed made up of three of the four Parties: the AFN, the UNBC and the U de M. On the Steering Committee Health Canada has observer status only.
- 4.2 The Steering Committee will appoint a secretariat , which will be responsible for day-to-day administrative work and will assist in planning and implementation.
- 4.3 The Steering Committee is responsible for overall project operations and implementation; the conduct of any meetings held in conjunction with this study, including the agenda of such meetings; development of protocols, forms and procedures; publication and production of reports and educational/communications materials; dissemination of results; and coordination of all in-kind contributions (both technical contributions and expertise) as dictated by the Steering Committee's Terms of Reference.
- 4.4 All decisions made by the Steering Committee will be by consensus.

5. Data Management

- 5.1 The Parties will protect the confidentiality and security of the collective research data during, as well as after completion of the study.
- 5.2 The U de M (Principal Investigator Olivier Receveur) and the UNBC (Principal Investigator Laurie Chan) will develop a SAS database infrastructure (and other databases when necessary) for data analysis, fundamental data, and distribution of data.
- 5.3 The Steering Committee appoints the AFN as the custodian to host the complete database during and after the completion of the study. The custodian will be responsible for the management of the data, and maintenance of the transparent data access policies and processes developed in consultation with the Parties. Other than to satisfy the reporting requirements of this project,

Health Canada researchers or any other interested party, may request specific data from AFN in writing with stated reasons. The same protocol will be followed by other researchers and/or other First Nations to use the data for further analysis under the stated objectives of the project.

- 5.4 In order to maximize the use of de-identified project data, access will be made available through mechanisms developed allowing Parties to:
- find data through directories;
 - view data through GIS mapping applications;
 - download data for use on their own systems for analysis consistent with the original objectives of the study articulated in the study protocol and in accordance with the consent form signed by individual study participants.
- 5.5 The individual data or information provided or made available by one party to the other belongs to the various First Nation individuals, who participated in the study.
- 5.6 The Parties will develop and/or adopt common data standards, information sharing protocols and agree to strive for compatible data and system management practices and common data transfer protocols.
- 5.7 Raw data or draft information acquired by one party from the other under the document may not be disseminated or otherwise disclosed to any individual or organization other than the parties to the document without the written consent of the party that is a custodian of the data or produced the information.
- 5.8 Methods and models of data analysis according to type of variables will be developed further on the basis of Principal Investigator discussions and incorporating the expert advice of a statistician.
- 5.9 The Parties agree to develop an outline of the detailed data management process, policies, and the flow of information received from each participating community.

6. Access to Historical Data

- 6.1 The intention and purpose of archiving data is to ensure that data are available for other uses consistent with the original purpose of the research such as ongoing health monitoring, health and environmental assessments or as agreed by the data custodian and the Parties and in accordance with the consent form signed by individual study participants.
- 6.2 All archiving of data and other information must provide appropriate security and must ensure the continuing recoverability of archived data and must include metadata and/or other relevant supporting documentation to enable use of that data and other information.

- 6.3 For the purpose of satisfying the terms of this document as stated in sections 5 and 7, all archived data must be made available to the Parties for the duration of the FNFNES and for at least 5 years after FNFNES conclusion.
- 6.4 Archived data will be time stamped and version controlled and will not be changed, amended or altered unless this is necessary to correct an error that had occurred during the archiving process.

7. Dissemination of Results

- 7.1 Any future publication or dissemination of research results, beyond what is described in this document, shall not be undertaken without agreement among the Parties and consultation/accommodation with participating First Nation communities.
- 7.2 Each First Nation community will be the first to receive its community research results and the first invited to provide input and feedback on the results, except in the event of a drinking water sample where an exceedance of trace metals of health concern is confirmed. In the event of such exceedances, the Regional Environmental Health Manager, Chief and Council will also be informed of the results as outlined in the *Communication procedures for Drinking Water Analysis Results* of the Drinking Water Component. The results will be presented in a format and language appropriate and accessible to the First Nation community and communicated to the Chief and Council in a timely manner.
- 7.3 The Parties agree to participate in community meetings to discuss the results and their implications. The Parties will also request feedback from the community on the best manner to present these results in writing, particularly on matters related to risk communications, issues concerning risk management, and suggestions for follow-up action
- 7.4 The Parties shall release the findings of the study to the public at large in a joint research report, scientific journal or other publication after First Nations' consultations have been completed and First Nations concerns addressed. The authors of all reports, articles or other publications shall include the FNFNES investigators, who provided intellectual contribution to the research project and participated in the development of the publication, and any other author(s) the Steering Committee deems appropriate. All publications will acknowledge those involved including all First Nations contributions.

8. Dispute Resolution

- 8.1 In the event that a dispute arises out of this study, all Parties agree first to try in good faith to settle the dispute among themselves through discussion and

negotiation and then by mediation administered by an agreed upon neutral party before resorting to arbitration, litigation or some other dispute resolution procedure. A mediator will assist the parties in finding a resolution that is mutually acceptable. If a dispute cannot be resolved to the satisfaction of all parties, the study may be terminated.

9. General Provisions

9.4 The Parties acknowledge that Health Canada may be required or ordered to disclose information under the federal *Access to Information Act*, or otherwise, pursuant to any applicable legislative requirement or any order of a court or other tribunal having jurisdiction.

9.5 No research will be carried out in any First Nations community without a signed research agreement with that community and no samples will be collected without the signed agreement of the individuals from which the samples will be collected.

9.6. No amendment, supplement, modification or waiver of this document shall be binding unless approved by the FNFNES Steering Committee and agreed in writing by all Parties.