Health Canada’s Research Ethics Board

ETHICS REVIEW OF RESEARCH INVOLVING HUMANS

Administrative Policy and Procedures Manual

January 2009
Health Canada is the federal department responsible for helping Canadians maintain and improve their health. We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.

Published by authority of the Minister of Health.

Également disponible en français sous le titre:
*Comité d’éthique de la recherche de Santé Canada – Guide de la politique et des procédures administratives - Évaluation des questions d’éthique entourant la recherche avec des humains*

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978-1-100-11733-1

Before you submit.....”

**REB Submission Checklist**

- Completed application form including all necessary signature
- Study protocol
- Completed independent science review
- Itemized response to science issues raised
- Consent and assent forms
- Previously approved by another REB (if applicable, a copy of all submitted documentation, including the letter of approval from the REB.)
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1. Introduction

1.1 About this Manual

Health Canada’s Research Ethics Board (REB) Policy and Procedures Manual provides guidance to Health Canada scientists and managers in regard to departmental research involving human participants. Since research ethics is a continually evolving participant, this manual may be modified from time to time. It is the responsibility of readers to ensure that they are using the most recent version.

1.2 The Tri-Council Policy Statement - Ethical Conduct for Research Involving Humans

The purpose of this policy is to promote and facilitate the conduct of human participant research in a manner consistent with the highest ethical standards. To this end, Health Canada is committed to adhering to the principles and articles stipulated in the Tri-Council Policy Statement Ethical Conduct For Research Involving Humans (TCPS). The guiding ethical principles, referenced in full under Appendix A, are respect for human dignity, respect for free and informed consent, respect for vulnerable persons, respect for privacy and confidentiality, respect for justice and inclusiveness, minimizing harm and maximizing benefit. The articles referenced in the TCPS are presented in full under Appendix C of this policy. Researchers are responsible for knowing about and adhering to the standards articulated therein.

The TCPS presents a model that has emerged in the international community in recent decades. This model generally involves the application of national norms by multidisciplinary, independent local REBs for reviewing the ethical standards of research projects developed within their institutions. The Health Canada REB has been established and is operating in accordance with the TCPS.

1.3 Authorities

1.3.1 Empowering Authority

The Deputy Minister (DM) of Health Canada empowered the REB to assure its legitimacy within Health Canada, while ensuring its independence, as the DM is not directly responsible for setting research priorities, developing research protocols or with funding decisions linked to the research. Independence will be strengthened by ensuring the following are public: the REB’s terms of reference, membership and operating procedures.

1.3.2 Appointing Authority

To protect the Crown's interests and its potential or actual liability arising from the acts or omissions of its servants, the DM of Health Canada is required to appoint all REB members and alternate members to the REB, including the Chair.
1.3.3 Reporting Authority

Under a Delegation of Authority, the DM of Health Canada may delegate his reporting authority functions to a senior official within Health Canada who will be referred to as the Reporting Authority throughout this document. For the moment, the DM will not be delegating his reporting authority functions.

The DM has delegated to the Chair of the REB of Health Canada, the authority to sign certificates of ethics approval for all research projects that receive approval from the REB, on ethical grounds, to proceed as submitted.

1.3.4 Authority of the REB

The REB, which was established by the Deputy Minister of Health Canada in 2002, will serve as an independent Board to help ensure that all research involving human participants carried out or funded by Health Canada meets the highest ethical standards and that safeguards are developed to provide the greatest protection to participants who serve as research participants. The REB, therefore, has both educational and review roles. The REB serves the research community as a consultative body, contributing to education in research ethics. It also has responsibility for independent, multidisciplinary review of the ethics of research to determine whether the research should be permitted to start or to continue. The REB is concerned solely with the protection of humans involved in research.

The REB may, on ethical grounds, approve, reject, make modifications to, or terminate any proposed or ongoing research involving humans, which is conducted by or on behalf of the Department. The REB reviews applications according to the considerations set forth in the *Tri-Council Policy Statement Ethical Conduct for Research involving Humans* (TCPS) as the minimum standard.

Health Canada and/or the Public Health Agency of Canada may not override any negative REB decisions reached on grounds of ethics without a formal appeal mechanism. The institutions may however disallow research despite the REB’s ethics approval, as the final decision to proceed with favorably REB reviewed research, remains an operational decision.

1.4 Responsibilities

1.4.1 Responsibilities of Reporting Authority of Health Canada

The Reporting Authority is responsible for the implementation of Health Canada’s research ethics policy. Specifically, the Reporting Authority is responsible for:

- Directing, in writing, that researchers submit their proposals to the REB if they have not done so;

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• Directing, in writing, that the research be suspended if it has not received an ethics review or if there is reason to believe it is proceeding contrary to the decisions of the REB;
• Promptly advising the Deputy Minister of Health Canada of serious adverse events, the suspension or termination of approved research project, as deemed appropriate by the REB, providing a statement of the reasons for the action taken; and
• Advising the Deputy Minister of Health Canada on the REB and its decisions on an annual basis.

1.4.2 Responsibilities of REB

The REB shall be responsible for advising the Reporting Authority on policies and procedures to be established or modified, in order to ensure that all research involving human participants conducted at or under the auspices of Health Canada is carried out in a manner consistent with the highest ethical standards. The REB will actively monitor the consistency of these policies and procedures with the Tri-Council Policy Statement - Ethical Conduct For Research Involving Humans, federal and provincial regulations, and all other applicable guidelines.

Each REB member is responsible for:
• Reviewing research projects involving human participants in a manner consistent with this policy.
• Conducting the continuing review of ongoing research projects.
• Promptly reporting the suspension or termination of approval of a research project on ethical grounds to the Principal Investigator, and other institutional officials as deemed appropriate by the REB, providing a statement of the reasons for the action taken.
• Reporting on REB activities to the Reporting Authority of Health Canada.
• Reporting any real, potential or apparent conflict of interest he/she may have, to the REB Chair before the beginning of the ethics review and excusing himself/herself from the decision process of the ethics review of his/her research project, if deemed necessary by the Chair.

1.4.3 Responsibilities of REB Chair

The REB Chair is responsible for the overall management of the REB and its ethics review process. The duties of the Chair include:
• Chairing the meetings;
• Determining if proposals are suitable for expedited review;
• Reaching a decision on whether to allow the proposed research to proceed on ethical grounds;
• Conveying in writing, the REB ethics decisions to the researchers and advising the Reporting Authority of Health Canada of all REB monthly activities;
• Promptly reporting to the Reporting Authority the suspension or termination of approved research project on grounds of ethics;
• Generally speaking and writing on behalf of the REB;
• Developing guidelines and procedures for implementing the requirements of this policy consistent with the needs of the relevant research disciplines served by the REB;
• Monitoring the REB’s ethics decisions for consistency and ensuring that these decisions
are recorded properly;

- ensuring that researchers are given written communication of the REB’s ethics decisions (with reasons for negative ethics decisions);
- Conducting the continuing review of ongoing research projects, amendments and any adverse events reported by the principal investigators;
- Promptly reporting any adverse events, suspension or termination of research project on grounds of ethics to the Reporting Authority and other institutional officials as deemed appropriate by the REB, providing a statement of the reasons for the action taken; and
- Providing an Annual Report on REB activities to the Reporting Authority of Health Canada.

### 1.4.4 Responsibilities of Researchers

Researchers have the primary responsibility to ensure that their research is carried out in an ethical manner. Investigators play a crucial role in protecting the rights and welfare of human participants and are responsible for carrying out sound ethical research consistent with research plans approved by the REB. Along with meeting the specific requirements of a particular research study, investigators are responsible for ongoing requirements in the conduct of approved research that include, in summary:

- Obtaining and documenting informed consent of participants or participants’ legally authorized representatives prior to the participants’ participation in the research;
- Obtaining prior ethics approval from the REB for any modifications of the previously approved research, including modifications to the informed consent process and document; and
- Ensuring that progress reports and requests for continuing review and approval are submitted to the REB in accordance with the REB policy and procedures. Investigators are also responsible for meeting the following requirements of:
  - Providing to the REB prompt reports of any unanticipated problems involving risks to participants or others;
  - Providing to the REB prompt reports of serious or continuing noncompliance with the requirements or determinations of the REB; and
  - Keeping certain records as required by the REB for at least three years after completion of the study or as specified in the research protocol.

- Investigators are also responsible for reporting to the research participants any significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation in the study.
- Investigators are responsible for reporting to the Health Canada REB any real, apparent or potential conflict of interest that they may have with their research. They should report it as soon as the conflict of interest emerges. The REB members will assess it and deal with the situation accordingly.

Researchers must be familiar with and comply with this policy and other ethical guidelines relevant to their research discipline. It is the responsibility of the researcher to obtain ethics approval as described in this policy for any project involving human participants before starting the research. If there is any uncertainty about whether the research needs ethics review and approval, the researcher should consult with the REB Secretariat for advice.
All members of a research team who conduct research under the supervision of others also bear personal responsibility for the ethical conduct of research with human participants. The Principal Investigator has the responsibility to ensure that the members of the research team comply with the provisions of this policy. Principal investigators should ensure that the members of the research team are aware of the contents of this policy and of other applicable ethical guidelines that are relevant to their responsibilities. Researchers must ensure that all individuals under their supervision have the training and competence needed to carry out their responsibilities in an ethical manner.

All Health Canada research involving humans must be reviewed and approved by the REB. A certificate of REB ethics approval must be obtained from the REB Chair before the research begins.

Note: A certificate of REB ethics approval from the REB Chair will not be provided after the fact for any research project that was undertaken by a researcher without prior REB approval. It should be noted that some Editors of medical journals require a REB certificate of ethics approval prior to publishing the results of any research in their journal.

1.4.5 Responsibilities of the REB Secretariat

The REB Secretariat manages all the administrative affairs of the REB and is responsible for:

- Organizing the REB meetings and meeting agendas;
- Managing all applications;
- Developing REB policies and procedures, and operational guidelines for REB and senior management approval;
- Communicating with principal investigators (PIs) on the required revisions to be made to the proposed research project as recommended by the REB;
- Seeking additional information from the PIs as required by the REB to conclude the ethics review of a proposed research project;
- Seeking in between meetings the REB’s approval on the additional information provided by the PIs in response to the comments raised by the REB members;
- Following-up with members of the REB that were present at an REB meeting to seek feedback and approval on outstanding research protocols;
- Summarizing all REB members’ comments and documenting this in a final email to the members for their feedback and approval;
- Consulting with another REB member that was not in attendance at an REB meeting and seeking the member’s expertise and comments on specific issues;
- In the absence of a REB member at an upcoming REB meeting, providing the members with the comments received from this individual on a specific research project under review by the REB;
- Receiving, in writing, confirmation from managers and researchers that the research will be carried out in accordance with the protocol as approved by the REB and conveying this information back to the Chair and the Reporting Authority;
- Producing the minutes of the REB meetings;
• Dealing with all communications regarding individual applications submitted to the REB;
• Developing and delivering Departmental training programs for the REB; and
• Maintaining the REB web site.

1.5 Mandate of Health Canada’s REB

The REB shall review all departmental research involving human participants in circumstances where the research is:
• Intra-mural (occurring within the limits of Health Canada);
• Carried out on Health Canada premises that involves technical or consultation support including equipment, laboratories, or other facilities;
• Undertaken in collaboration or partnership between Health Canada and external researchers;
• Funded by Health Canada through grants and contributions; and
• Carried out under contract with Health Canada.

It is important to note that within the REB scope of review, the REB Secretariat should be consulted in circumstances whether:
• The funding is internal or external;
• The participants are from inside or outside Health Canada;
• The participants are paid or unpaid;
• The research is conducted inside or outside Canada;
• The research is conducted inside or outside Health Canada;
• The research is conducted by staff or by students;
• The research is conducted in person or remotely (ex: by mail, electronic mail, fax or telephone);
• The information is collected directly from participants or from existing records not in the public domain;
• The research is to be published or not;
• The focus of the research is the participant;
• The research is observational, experimental, correlational or descriptive;
• A similar project has been approved elsewhere or not;
• The research is a pilot study or a fully developed project;
• The research is to acquire basic or applied knowledge; and
• The research is primarily for teaching or training purposes or whether the primary purpose is the acquisition of knowledge.

1.6 Membership of the REB

The REB membership is designed to meet the requirements of the TCPS and to ensure the expertise, independence and multidisciplinarity, essential for competent research ethics reviews by the REB. The REB reflects gender as well as Canada’s geographical and ethnic diversity. REB members are appointed by the Deputy Minister and can serve for up to two consecutive 3 year terms.
The REB consists of eight members including the Chair which provides the required expertise to make sound judgements on the ethics of research and they are:

- Three members with broad expertise in the methods of research conducted by Health Canada: 1) one from outside Health Canada, 2) one from Health Canada and 3) one from the Public Health Agency of Canada;
- Two members who are knowledgeable in ethics;
- One member is knowledgeable in the relevant law; and
- Two members who have no affiliation with Health Canada, one recruited from the community served by Health Canada and the other member as an Aboriginal representative.

The TCPS provides that institutions should also consider the nomination of substitute REB members so that the Board is not paralysed by illness or other unforeseen eventualities. The use of alternate members should not, however, alter the membership structure as outlined in the TCPS.

REB membership includes alternate members comprised of:

- Three alternate members with broad expertise in the methods of research conducted by Health Canada from:
  1) one from outside the Department;
  2) one from Health Canada;
  3) one from the Public Health Agency of Canada;
- One alternate member who is knowledgeable in ethics;
- One alternate member who is knowledgeable in the relevant law;
- One alternate member who is a representative of the Aboriginal Population; and
- Two alternate members who have no affiliation with Health Canada, one who is recruited from the community served by the Department and another member as an Aboriginal representative.

1.7 REB Meetings

The REB meets once a month or more frequently as needed with the exception of July and August. Researchers should be informed of the dates by which their projects must be received by the REB Secretariat, for consideration at the next scheduled REB meeting. Meeting dates are posted on the REB website at [http://www.hc-sc.gc.ca/sr-sr/advice-avis/reb-cer/applic-demande/even_e.html](http://www.hc-sc.gc.ca/sr-sr/advice-avis/reb-cer/applic-demande/even_e.html). Researchers are invited to attend the REB meeting to participate in the discussion of their proposals, but the researchers cannot be present when the REB makes its decisions.

The REB will consider Health Canada research to be ethically sound when:

- The research is scientifically sound;
- The potential benefits significantly outweigh the potential harms or other risks;
- There is adequate process for informed consent and where applicable, an assent to participate in the research; and
- There is justice and fairness in the selection of participants.
The REB Chair and/or Deputy Chair may appoint ad hoc members or seek outside advice when reviewing a project that requires specific expertise regarding methodology, community or research participant representation, or other matters.

In accordance with the TCPS, there is a need to obtain a quorum of at least five out of eight members that were in attendance at the REB meetings when a recommendation is to be made for a research project to proceed. The TCPS also provides for consensus decision making which may not always be unanimous. Only regular members (or their alternates when replacing the regular member) have a vote. However, the Chair and/or the Deputy Chair have the final authority to decide if the quorum present is adequate to properly conduct the meeting.

The REB Secretariat will produce minutes of every REB meetings, in sufficient detail to document members’ attendance, REB’s decisions, member’s dissents (when applicable), and a summary of the discussion of important issues.

The REB Secretariat will maintain all REB records for a minimum of fifteen years beyond the termination of a project.

1.8 Conflicts of Interest Involving Researchers

The burden of avoiding conflicts of interest first resides with the individual. Researchers should conduct themselves with respect of the highest ethical standards elaborated in the TCPS. The importance of managing conflicts of interest is in its proper identification and in the way it is dealt with.

“A conflict of interest may be actual, apparent, perceived or potential. A conflict of interest does not necessarily imply wrongdoing as a conflict of interest depends upon the circumstances, and not on the character of a researcher.”

Conflicts of interest or appearance of one should be avoided, but where it is unavoidable, there should be transparency with these interests. Investigators are responsible for reporting to the Health Canada REB any real, apparent or potential conflict of interest that they may have with their research. They should report it as soon as the conflict of interest emerges and as soon as possible. The REB will assess the situation by looking at the likelihood that the conflict of interest could or appear to influence the researcher’s judgment by other interests. The REB will then assess the harm potentially resulting from these conflicting interests.

The REB will deal with the situation accordingly and take the proportionate approach needed. The REB may ask the researcher to abandon the conflicting interests, to withdraw from this research if the conflict of interest is deemed too serious, or to leave the situation as is. The REB will continue reviewing periodically the conflict of interest for the researcher to verify that its management is still appropriate.

The existence or the appearance of a conflict of interest from the researcher should be mentioned in the informed consent forms, if deemed appropriate by the REB.
1.9 Conflicts of Interest for REB Members

REB members may have a variety of conflicts that may bias decision-making. Most obviously, a member may be part of the research team undertaking the study under review. As co-workers or academic colleagues, board members will commonly have personal relationships with those submitting protocols for review. Further, while it is helpful for an REB member to have research or clinical experience in the subject matter of the protocol under review, there may also be an element of conflict. If the member is familiar with the area of research, he or she may tend to be too lenient in review. However, if the Board member is an academic competitor in the area, the review may be too critical. An REB decision may impact a member’s own work within the institution or other responsibilities within the institution. For example, a member who also works as legal counsel, or in the research programs, may be faced with conflicting obligations.

2. When is an Ethics Review Required?

All Health Canada and/or the Public Health Agency of Canada (PHAC) research involving humans (which includes pre-testing of survey instruments, such as questionnaires and consent forms) requires an ethics review by the Health Canada Research Ethics Board (REB) and a REB certificate of ethics approval must be received from the REB Chair before the research begins.

2.1 Research

Definition of research: It is an activity designed to test a hypothesis, permit conclusions to be drawn and develop or contribute to generalizable knowledge.

- Generalizable knowledge consists of theories, principles or relationships, or the accumulation of information on which they are based, that can be corroborated by accepted scientific methods of observation and inference. In the present context "research" includes both medical and behavioural studies pertaining to human health. Usually "research" is modified by the adjective "biomedical" to indicate its relationship to health;
- The involvement of human participants is required where progress in medical care and disease prevention depends upon an understanding of physiological and pathological processes or epidemiological findings. The collection, analysis and interpretation of information obtained from research involving human beings contribute significantly to the improvement of human health;
- Uses scientific methods and standardized protocols.

The research involving humans as "research participants" includes the use of human remains, cadavers, tissues, biological fluids, embryos or foetuses. Research involving humans may also include the collection of information from or about humans, such as through surveys, and from records of nonliving humans that are not in the public domain.
2.2 Ethics Application

Researchers whose research projects involve human participants must complete an application form (Appendix A) and submit the required documentation to the REB Secretariat in order to obtain an ethics review by the Health Canada REB. A REB certificate of ethics approval must be obtained from the REB Chair before the research begins.

From time to time, researchers may be unsure as to whether or not their proposed work is research. The REB Secretariat should be consulted in all cases where there is such doubt.

2.3 Surveillance

Surveillance is often defined as the ongoing collection, analysis and interpretation of health data, essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of the data to those who need to know. The final link in the surveillance chain is the application of the data to prevention and control. A surveillance system includes a functional capacity for data collection, analysis and dissemination linked to public health programs. Sources of surveillance data can include disease outbreak reports and mortality and morbidity reports based on death records or laboratory diagnosis.

It is important to note that some surveillance activities may not need an ethics review by the Health Canada REB, such as surveillance activities for the purpose of improving programs in Health Canada and/or the PHAC.

Consequently, there is an ill-defined boundary between research and surveillance activities. Since this determination can only be made on a case-by-case basis, the advice of the REB should always be sought in such circumstances by contacting the REB Secretariat.

If an ethics review is required by the Health Canada REB, this could be considered by the REB Chair or the Deputy Chair to qualify for an expedited review. Researchers whose research involves human participants must complete Appendix B and submit the required documentation to the REB Secretariat in order to obtain an ethics review by the REB.

A REB certificate of ethics approval must be obtained from the REB Chair before the research begins.

2.4 Supplemental Services

Health Canada and PHAC officers, due to their highly specialized expertise, are often requested by a Principal Investigator (PI) from another institution to provide analytical services to a specific project, for example where a Health Canada and/or PHAC officer analyzes anonymous or anonymized human biological material samples without engaging in their collection.

The PI must obtain an ethics review from his/her institution’s REB, before the research begins. Once the PI has obtained the approval for the project to proceed by his/her institution’s REB, the Health Canada and/or PHAC officer is now required to obtain an ethics review by the Health
Canada REB. A Health Canada REB certificate of ethics approval must be obtained from the REB Chair before the Health Canada and/or PHAC official takes possession of the data or biological material and prior to analyzing the samples thereof.

A questionnaire (Appendix N) has been developed by the REB Secretariat to assist Health Canada and/or PHAC officers in obtaining an ethics review by the Health Canada REB. The purpose of this questionnaire is to screen the general parameters of the project that has received an approval by the outside REB.

The Health Canada and/or PHAC officer should submit the following documentation to the REB Secretariat:

- Completed Supplemental Services questionnaire
- Provide a copy of the PI’s application to his/her REB, and
- Copy of the PI’s REB letter of approval.

The REB Chair or the Deputy Chair will undertake an ethics review of the questionnaire, research protocol and Health Canada and/or PHAC’s component of the research to determine if the project in which Health Canada and/or PHAC is taking part can be considered as a supplemental service rather than research (a turnaround time of one (1) week is necessary).

1. Research component: The REB may consider this request to qualify for an expedited review by the Board and schedule this project for discussion at the upcoming REB meeting.

2. Exclusion criteria for Supplemental Services component: If, after submission of this questionnaire to the Board, the REB Chair or the Deputy Chair determines that:
   - the officer’s activities in the project consist solely of performing an analytical service;
   - Health Canada and/or PHAC is not involved in the collection of the data or biological material; and
   - Health Canada and/or PHAC does not plan to be acknowledged or be a partner/co-author in the publications resulting from the project;
   - the Board may inform the REB Secretariat that this component of the project does not require an ethics review/approval by the REB. The REB Secretariat will inform the Health Canada and/or PHAC officer in writing to proceed without an ethics review by the Health Canada REB.

The REB Secretariat should be consulted in all cases prior to the Health Canada and/or PHAC official agreeing to perform these analytical services and/or obtaining the samples in question.

2.5 Performance Reviews

Performance reviews or testing within normal educational requirements are generally not subject to a REB review. If it is clear that a study is related directly to assessing the performance of an organization or its employees within the mandate of the organization or according to the terms and conditions of employment or training, REB ethics review would not be required.
However, if a performance review or project contains an element of research in addition to an assessment, an ethics review by the Health Canada REB will be required. The application form ([Appendix B](#)) must be completed and the required documentation submitted to the REB Secretariat. *A REB certificate of ethics approval must be obtained from the REB Chair before the research begins.*

From time to time, researchers may be unsure as to whether or not their proposed work is research. The REB Secretariat should be consulted in all cases where there is such doubt.

### 2.6 Quality Assurance

Quality assurance studies are generally not subject to an ethics review by the REB. However, it is important to distinguish research from quality assurance for the purposes of a REB review.

Quality assurance aims to:
- Evaluate and review the quality of a service, or a product within a particular institution;
- Identify problems or deficiencies in delivery;
- Design activities and procedures to overcome these deficiencies; and
- Monitor the effectiveness of corrective measures.

Quality assurance does not require a REB ethics review when it:
- Is intended solely for internal use within an individual institution;
- Only measures the integrity of the functions delivered by the organization or performance of staff internal to the institution while carrying out their duties and responsibilities; and
- Is not intended through publishing, to contribute to generalizable scientific knowledge about treatments and procedures.

If the project has an element of research, an ethics review is required and this could be considered by the REB Chair or the Deputy Chair to qualify for an expedited review. Researchers whose research involves human participants must complete an application form ([Appendix B](#)) and submit the required documentation to the REB Secretariat in order to obtain an ethics review by the Health Canada REB. *A REB certificate of ethics approval must be obtained from the REB Chair before the research begins.*

The REB Secretariat should be consulted if there is uncertainty about whether or not the proposed project should receive an ethics review by the Health Canada REB.

### 2.7 Secondary Use of Data in Research

Secondary use of data refers to the use of stored information and/or human biological material, initially collected for a purpose involving a specified research project or for individual health care or education but subsequently proposed for use in a different research project.

Special ethical concerns are posed by such research when the data could be linked to an individual or community, who might then be identified in a published report and/or the participant has objected to their data or sample being used in a second or subsequent studies.
REB ethics review shall be sought for the ‘secondary use’ of data for research involving humans. To provide approval in such circumstances, the REB must ensure that:

- the potential to derive personally identifiable information is essential to the research;
- appropriate measures are in place to protect the privacy of the individual by ensuring the confidentiality of the data;
- potential harm to participants is minimized;
- participants have not objected to the secondary use of their data; and
- a proportionate approach is taken in addressing the sensitivity of these issues.

Mechanisms to be considered by the REB in providing an ethics approval for secondary use of data collected within a research study include:

- Assurance of reasonable informed consent, as reflected in the information and consent documentation in the primary protocol;
- The documentation should outline, at least in general terms, both the positive and negative implications of the linkage of research data to the participant personally;
- Dependent on the proportional risk associated with the data, the REB may require evidence of an appropriate strategy to obtain current consent from or inform the contributing participants, or their representatives, or to sample the opinion of a subset of the participating group, before initiating the secondary use of their data.

Researchers who wish to contact individuals to whom data refer to, shall seek an ethics review by the Health Canada REB prior to contacting these individuals.

The study must be brought to the REB for an ethics review whether or not it is impossible to identify individuals or communities from their records or biological material. When an ethics review is required, this could be considered by the REB Chair or the Deputy Chair to qualify for an expedited review. This can be obtained by completing Appendix B and submitting the required documentation to the REB Secretariat.

The REB will carefully appraise the possibility of identification, in particular with regard to the extent of the harm or stigma which might be attached to identification.

The REB Secretariat should be consulted if unsure as to whether or not the proposed project should receive an ethics review by the REB. A REB certificate of ethics approval must be obtained from the REB Chair before the research begins.

2.8 Data Linkage
Advances in the ability to link databases create both new research opportunities and new threats to privacy. These techniques may provide avenues for addressing previously unanswerable questions and for generating better social and health-related information.

The values underlying the ethical obligation to respect privacy oblige researchers and the REB to exercise caution in the creation and use of data linkage. The REB will also consider relevant statutory frameworks, and the criteria required by government for authorization of use of data in data banks.

Whether the data are to be used statistically or otherwise, confidentiality of the information must be maintained by all members of the research team. When a merged database identifies a person or a group who might be at significant risk of harm, it may be appropriate to contact those at risk or the appropriate authorities. In such circumstances, a REB certificate of ethics approval must be obtained prior to notifying the record holder.

For applications where data linkage might occur, making research participants identifiable, the researcher must submit an application form (Appendix B) and the required documentation to the REB Secretariat for an ethics review by the REB, to ensure that individuals, groups or communities do not become identifiable. A REB certificate of ethics approval must be obtained from the REB Chair before the research begins.

2.9 Use of Human Biological Material in Research

Human biological material, from which donors may be identifiable, can only be used with the consent of the donors or their legally authorized representative, at the time of its retrieval. Researchers who wish to contact these individuals shall seek an ethics review by the REB prior to contacting these individuals.

The REB must always be notified of the use of previously collected human biological material in research. The researcher must submit an application form (Appendix B) and the required documentation to the REB Secretariat for an ethics review by the Health Canada REB, prior to initiating the research. A REB certificate of ethics approval must be obtained from the REB Chair before the research begins.

The REB Secretariat should be consulted if unsure whether the proposed project should receive an ethics review by the REB.

2.10 Use of Biobanks (Biorepositories) in Research

Biobanks are an important resource for identifying the causes and mechanisms of a large number of diseases, including ones that are widespread among the population.

While biobanks hold out the prospect of significant breakthroughs in medical and pharmaceutical research, they also arouse anxiety and distrust. The main concern is donor protection. What is feared is the uncontrolled use of samples and data.
Prior to conducting a research project involving the use of biobank samples and/or data, researchers are required to seek an ethics review by the Health Canada REB. The researcher is to complete an application form (Appendix B) and submit the required documentation to the REB Secretariat. *A REB certificate of ethics approval must be obtained before the research begins.*

### 2.11 Use of Foetal Tissue in Research

Research involving the use of foetal tissue should be guided by respect for the woman's dignity and integrity. Researchers should obtain the free and informed consent of the individual whose foetal tissue is to be used for research.

Consent for such research can be obtained prospectively from women undergoing abortions. In such circumstances, the following consent clause should be appended to the consent to termination.

> “You are requested to consent to the use of foetal and placental tissues in scientific research. You may choose not to give consent. The decision on whether to consent will not affect your right to an abortion or your rights to any health care. All tissue information will remain anonymous and will not be identifiable in any way.”

Research that involves the use of foetal tissue must be submitted to the REB for review by completing an application form (Appendix B) and submitting the required documentation to the REB Secretariat. *A REB certificate of ethics approval must be obtained from the REB Chair before the research begins.*

### 2.12 Specific Research Projects

#### 2.12.1 Genetic Material in Research

The use of genetic material in research poses unique ethical issues. In seeking REB review for such research, the form included in Appendix H and the required documentation must be submitted to the REB Secretariat for an ethics review by the Health Canada REB.

#### 2.12.2 Grants and Contributions

Grants and Contributions funded research must be submitted to the REB for review. Before any funds are released, the researcher and/or manager of the funding unit must submit the form included in Appendix M and the required documentation to the REB Secretariat and receive an ethics review from the Health Canada REB.

#### 2.12.3 Focus Groups

A Focus Group is a selected set of people used to test and evaluate a concept or product. If you are collecting information from people (participants) with the use of surveys, questionnaires,
interviews in focus groups settings, the REB needs to review and approve the research project before any information is collected from the participants.

The Principal Investigator should put a procedure in place in which the researchers caution people that are participating in the Focus Group about the limit on confidentiality. The researcher must emphasize to all participants that comments made during the focus group session should be kept confidential, it is possible that some participants may repeat comments outside of the group at some time in the future. Therefore, the researcher must encourage the participants to be as honest and open as they can, but remain aware of the limits of the researcher in protecting confidentiality. The limit of confidentiality should also be included in the Information package that is to be sent to the individual. The REB Secretariat has developed focus groups guidelines for your ease of reference.

The researcher should complete Appendix A and submit this with a copy of the required documentation to the REB Secretariat.

2.13 Multicentred Research Projects

Research involving human participants conducted by Health Canada researchers in other institutions must be reviewed and approved by that institution as well as receiving a certificate of ethics approval from the Chair of the Health Canada REB before the research may begin.

Principles of institutional accountability require each local REB to be responsible for the ethical acceptability of research undertaken within its institution.

However, in multicentred research, when several REBs consider the same proposal from the perspectives of their respective institutions, they may reach different conclusions on one or more aspects of the proposed research. To facilitate coordination of ethics review, when submitting a proposal for multicentred research, the Principal Investigator may wish to distinguish between core elements of the research—which cannot be altered without invalidating the pooling of data from the participating institutions—and those elements that can be altered to comply with local requirements without invalidating the research project.

Health Canada and/or PHAC researchers are required to obtain an ethics review of their project by the Health Canada REB and this ethics review is required to be obtained after he/she has obtained an ethics review by the other REBs. The REB Secretariat may be contacted to assist in preparing an application for submission to the Health Canada REB. The process would be:

- The Principal Investigator should complete Appendix I and forward this with the required documentation to the REB Secretariat;
- The application should include a copy of the other REBs application for an ethics review; any exchange of correspondence with the other REBs; and their certificates of approval.
- A REB certificate of ethics approval must be obtained from the REB Chair before the research project begins.
2.14 Experimental Research

Experimental research (as opposed to observational research) involves the administration of a treatment, exposure or intervention under controlled conditions to a group of participants and comparing their responses to a similar group of participants (or the same participants) without the treatment. When experimental research is to be undertaken, an attempt by the researcher to maintain control over all factors that may affect the result of an experiment is required. In doing this, the research attempts to determine or predicts what may occur. Steps involved in conducting an experimental study:

The potential participants should be made aware of any and all potential risks and the researcher should include a statement in the consent form that there may be some unforeseeable risks. A risk is a potential harm (injury) associated with the research that a reasonable person, in the participant’s position, would be likely to consider important in deciding whether to participate in the research. Underlying the consideration of risk is the implicit moral guidelines that all investigators have a duty to *do no harm and minimize potential risk* to the greatest extent possible.

Prior to conducting any experimental research, researchers are required to seek an ethics review by the HC REB. The researcher is to complete an application form (Appendix A) and submit the required documentation to the REB Secretariat. *A REB certificate of ethics approval must be obtained from the REB Chair before the research begins.*

2.15 Analysis of Publicly Available Data

The REB members’ review is generally not required for research involving public policy issues or the writing of modern history even though all of these might well involve human participants.

The REB Secretariat should be consulted if unsure as to whether or not the project requires an ethics review by the Health Canada REB.

Note: In all circumstances where personal data is being collected, applicants must consider the requirements of the *Privacy Act* and applicable Treasury Board Directives and, if necessary, seek legal advice.
3. Special Care Required for Certain Populations

3.1 Definition

Special care is required to be undertaken by researchers when their research projects involve vulnerable populations. Vulnerable populations include women, single mothers, Aboriginals, visible minority populations, the homeless, immigrants with insecure status, and street youth. These populations may also include people with psychiatric, cognitive, or developmental disorders and substance abusers, persons who are mentally incompetent; persons who have been abused; persons with neuro-motor impairment; persons with low socio-economic status; elderly persons; and persons with similar histories which raise concern.

Children are considered a vulnerable population because they develop decision making skills and related competencies over time.

Other vulnerable populations include those who are institutionalized and may be not be free to choose without coercion or undue influence, e.g. prisoners.

Although the use of vulnerable persons as participants is not prohibited by any ethical codes, justification for involving vulnerable persons in research generally becomes more difficult as the degree of risk and vulnerability increases.

3.2 Ethics Application

Any research projects for which any of these individuals would be involved would require an ethics review by the Health Canada REB. The researcher must complete the application form and submit this form along with a copy of the consent and/or assent forms and the required documentation to the REB Secretariat.

A risk is a potential harm (injury) associated with the research that a reasonable person, in the participant’s position, would be likely to consider important in deciding whether to participate in the research. Underlying the consideration of risk is the implicit moral guidelines that all investigators have a duty to do no harm and minimize potential risk to the greatest extent possible.

3.3 REB Consideration

The REB considers both immediate and delayed risk. The estimated probability, severity, average duration, and reversibility of potential harm will be considered. Furthermore, since certain populations of vulnerable participants may be at greater risk than others, REB will take into consideration the potential risk characterization of participants. Victims of child abuse, spouse abuse or assault, for example, may be at increased risk in sociological or psychological studies. In such circumstances, the research should ameliorate or remediate.
• If the person has been adjudicated to lack capacity to give informed consent, the legally authorized representative (parent or parents with custody, etc.) may give consent in writing and should be witnessed.

• If the person has not been adjudicated to lack capacity to give informed consent, and the participant is or is expected to become incapable of consenting, but is capable of executing a power of attorney, the person may grant authority to the holder of power of attorney to grant informed consent in writing and should be witnessed.

• If the person has not been adjudicated to lack capacity to give informed consent but is judged by the investigator to 1) lack the capacity to give consent and 2) appoint the holder of power of attorney, then the participant may be enrolled in research offering an acceptable level of direct therapeutic benefit to the participant.

• When informed consent is obtained from the participant’s legally authorized representative, the assent of the participant to participate shall be a necessary condition unless the participant is incapable of assenting or an exception is made by the REB. Assent forms similar to those used for children and youth should be used.

3.4 Research Involving Those Incompetent to Consent for Themselves

Although ethical duties to vulnerable populations preclude the exploitation of those who are incompetent to consent for themselves for research purposes, there is, nonetheless, an obligation to conduct research involving such people because it is unjust to exclude them from the benefits that can be expected from research.

There is a need to recognize that research involving those who, though not competent to consent for themselves, are unique individuals who command all the respect, justice and inclusiveness accorded to competent individuals. The behaviour, psychology, biology and diseases of infants and children who are incompetent because of immaturity often differ markedly from those of adults; also, incompetence is often caused by disease, which cannot be studied only in those without the disease. However, the ethical imperative for research must be interpreted in the context of the safeguards expressed in the TCPS.

Subject to the provisions of the TCPS, those who are not competent to consent for themselves shall not be automatically excluded from research which is potentially beneficial to them as individuals, or to the group that they represent.

3.5 Consent Procedures

Persons who lack the capacity to give informed consent cannot participate as a participant unless proxy consent is obtained. “Legally authorized representative” is the parent or parents having custody of the person, the legal guardian, or any individual with power of attorney who is authorized to consent on behalf of a prospective participant. Consent forms similar to those used for children and youth should be used.

Before undertaking research involving individuals who by reason of mental or behavioural disorders are not capable of giving adequately informed consent, the investigator must ensure that:
• Such persons will not be participants of research that might equally well be carried out on persons in full possession of their mental faculties;
• The purpose of the research is to obtain knowledge relevant to the particular health needs of persons with mental or behavioural disorders;
• The consent of each participant has been obtained to the extent of that participant's capabilities, and a prospective participant's refusal to participate in non-clinical research is always respected;
• In the case of incompetent participants, informed consent is obtained from the legally authorized representative or other duly authorized person;
• The degree of risk attached to interventions that are not intended to benefit the individual is low and commensurate with the importance of the knowledge to be gained; and
• Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual as any alternative.

3.6 Research Involving Humans in Underdeveloped Communities

Before undertaking research involving humans in underdeveloped communities, whether in developed or developing countries, the investigator must ensure that:

• Persons in underdeveloped communities will not ordinarily be involved in research that could be carried out reasonably well in developed communities;
• The research is responsive to the health needs and the priorities of the community in which it is to be carried out;
• Every effort will be made to secure the ethical imperative that the consent of individual participants be informed; and
• The proposals for the research have been reviewed and approved by an ethics review committee that has among its members or consultants persons who are thoroughly familiar with the customs and traditions of the community.

3.7 Research Involving Women

Women have historically been excluded from participating in some research largely because of concerns about: damaging either the foetus or the woman's reproductive capacity; harming the newborn through breast-feeding; the influence of hormonal cycles; or failing to recognize that diseases and conditions might affect men and women differently, for example at different ages; and fear of liability by research sponsors. Such exclusions retard the advance of knowledge, deny potential benefits to women and may expose women to heightened risk. For example, the exclusion of women as research participants raises serious concerns regarding the generalizability and reliability of some research data; and research data on drug dosages, the effects of devices, treatments, cultural norms, moral development and social behaviour obtained from male-only studies likely will not be generalizable to women. As a result, data for women are lacking and often must be inferred, despite important differences that may render such inferences inaccurate, and treatments or interventions based thereon more harmful. The inclusion of women in research is essential if men and women are equally to benefit from research. It advances both the
commitment to justice and to rigorous scholarly or scientific analysis.

Women shall not automatically be excluded from research solely on the basis of sex or reproductive capacity.

3.8 Research involving Aboriginal People

There is growing recognition that some research involving Aboriginal individuals may also involve communities or groups to which they belong. The TCPS affirm that in developing ethical standards and practices, Aboriginal peoples have rights and interests which deserve recognition and respect by the research community.

The Guidelines for Health Research Involving Aboriginal People have been developed by the Ethics Office of the Canadian Institutes of Health Research (CIHR), in conjunction with its Institute of Aboriginal Peoples’ Health, to assist researchers and institutions in carrying out ethical and culturally competent research involving Aboriginal people. The intent is to promote health through research that is in keeping with Aboriginal values and traditions. The Guidelines will assist in developing research partnerships that will facilitate and encourage mutually beneficial and culturally competent research. The Guidelines will also promote ethics review that enables and facilitates rather than suppresses or obstructs research.

These Guidelines are applicable to researchers carrying out research to which Health Canada has made a financial contribution. The reader should note that these Guidelines are not regulations nor are they meant to be of general application. Rather, they are guidelines that should be followed by anyone who carries out research involving Aboriginal people in Canada if the research is carried out and/or funded by Health Canada.

The principles listed below should be applied whenever a research project involves Aboriginal people:

1. A researcher should understand and respect Aboriginal world views, including responsibilities to the people and culture that flow from being granted access to traditional or sacred knowledge. These should be incorporated into research agreements, to the extent possible.
2. A community’s jurisdiction over the conduct of research should be understood and respected.
3. Communities should be given the option of a participatory-research approach.
4. A researcher who proposes to carry out research that touches on traditional or sacred knowledge of an Aboriginal community, or on community members as Aboriginal people, should consult the community leaders to obtain their consent before approaching community members individually. Once community consent has been obtained, the researcher will still need the free, prior and informed consent of the individual participants.
5. Concerns of individual participants and their community regarding anonymity, privacy and confidentiality should be respected, and should be addressed in a research agreement.
6. The research agreement should, with the guidance of community knowledge holders, address the use of the community's cultural knowledge and sacred knowledge.

7. Aboriginal people and their communities retain their inherent rights to any cultural knowledge, sacred knowledge, and cultural practices and traditions, which are shared with the researcher. The researcher should also support mechanisms for the protection of such knowledge, practices and traditions.

8. Community and individual concerns over, and claims to, intellectual property should be explicitly acknowledged and addressed in the negotiation with the community prior to starting the research project. Expectations regarding intellectual property rights of all parties involved in the research should be stated in the research agreement.

9. Research should be of benefit to the community as well as to the researcher.

10. A researcher should support education and training of Aboriginal people in the community, including training in research methods and ethics.

11. A researcher has an obligation to learn about, and apply, Aboriginal cultural protocols relevant to the Aboriginal community involved in the research. A researcher should, to the extent reasonably possible, translate all publications, reports and other relevant documents into the language of the community. A researcher should ensure that there is ongoing, accessible and understandable communication with the community.

12. A researcher should recognize and respect the rights and proprietary interests of individuals and the community in data and biological samples generated or taken in the course of the research. Transfer of data and biological samples from one of the original parties to a research agreement, to a third party, requires consent of the other original party(ies). Secondary use of data or biological samples requires specific consent from the individual donor and, where appropriate, the community. However, if the research data or biological samples cannot be traced back to the individual donor, then consent for secondary use need not be obtained from the individual. Similarly, if research data or biological samples cannot be traced back to the community, then its consent for secondary use is not required. Where the data or biological samples are known to have originated with Aboriginal people, the researcher should consult with the appropriate Aboriginal organizations before initiating secondary use. Secondary use requires REB review.

13. Biological samples should be considered "on loan" to the researcher unless otherwise specified in the research agreement.

14. An Aboriginal community should have an opportunity to participate in the interpretation of data and the review of conclusions drawn from the research to ensure accuracy and cultural sensitivity of interpretation.

15. An Aboriginal community should, at its discretion, be able to decide how its contributions to the research project should be acknowledged. Community members are entitled to due credit and to participate in the dissemination of results. Publications should recognize the contribution of the community and its members as appropriate, and in conformity with confidentiality agreements.

As these guidelines primarily address the special considerations that arise when carrying out research involving Aboriginal people, researchers must also refer to, and comply with, the TCPS and departmental policies, as well as any applicable legislation and, for those to whom it applies, the Canadian Charter of Rights and Freedoms. Other agencies of government may impose additional regulatory or other requirements.
3.8.1. Responsibilities of the Principal Investigators

Prior to submitting an application to the Health Canada REB to obtain an ethics review, the Principal Investigator must ensure that:

- The involvement of Aboriginal communities in the development of the proposed research project has been undertaken.

The Principal Investigator, when submitting an application for an ethics review to the Health Canada REB, should include the following:

- The results of the consultation undertaken with the Aboriginal communities and a copy of the exchange of correspondence with these communities;
- The recruitment processes to be undertaken in these communities;
- The consent processes for obtaining informed consent from both these communities and the individuals;
- The communication of the report of findings to these communities and the individuals.

3.8.2 Consultation with Aboriginal Populations

There is a need for researchers to involve Aboriginal communities when doing research involving Aboriginal people. The REB Secretariat should be contacted when unsure as to whom to consult with when carrying out any research involving Aboriginal population. A sample of possible contacts is being provided for ease of reference:

The Assembly of First Nations (AFN) is the national organization representing First Nations citizens in Canada. The AFN represents all citizens regardless of age, gender or place of residence. They can be reached by mail at: Trebla Building, 473 Albert Street, Suite 810, Ottawa, ON K1R 5B4. Telephone: 613-241-6789, Toll-Free: 1-866-869-6789. Link: http://www.afn.ca/.

The Métis National Council informs citizens from throughout the Métis Nation Homeland on developments and initiatives being undertaken at the national and international level. Overall, the Métis National Council's central goal is to secure a healthy space for the Métis Nation's on-going existence within the Canadian federation. They can be reached by mail at: 350 Sparks St., Suite 201 Ottawa, ON K1R 7S8, by telephone: (613) 232 – 3216, Toll Free: (800) 928 – 6330, or by email: info@metisnation.ca. The link to their website is: http://www.metisnation.ca/.

The Inuit Tapiriit Kanatami (ITK) has been representing the interests of the Inuit of Canada at the national level since its incorporation in 1972. Working primarily as an advocacy organization, ITK has been actively involved in a wide range of issues some of which have proven to be of critical importance in enabling Inuit to pursue their aspirations and take control of their destinies. They can be reached by mail at: 170 Laurier Avenue West, Suite 510, Ottawa, ON K1P 5V5, by telephone (613) 238-8181, Toll Free 1-866-262-8181. The link to their website is: http://www.itk.ca/corporate/index.php.
The Pauktuutit Inuit Women of Canada’s vision is to be a dynamic, visible, influential organization, supporting Inuit women and providing leadership, voice and excellence for the betterment of Inuit women, their families and communities. They can be reached by mail: 56 Sparks Street, Suite 400, Ottawa and at 613-238-3977 or by email at: info@pauktuutit.ca. Their website link is: http://www.pauktuutit.ca/about_e.asp

The Native Women's Association of Canada (NWAC) is founded on the collective goal to enhance, promote, and foster the social, economic, cultural and political well-being of First Nations and Métis women within First Nation, Métis and Canadian societies. The Six Nations of the Grand River can be reached by mail: 1721 Chiefswood Road, Ohsweken, ON, and/or by telephone at 519-445-0990 or by email at: bhcobs@nwac-hq.org. Their website link is: http://www.nwac-hq.org/en/nwacstructure.html.

3.9 Research Involving Youth

It is essential that the individual has full information about the research in order to give their ‘informed consent’ to take part, and that consent is ‘freely volunteered’. The individual should also know that ‘she/he can withdraw at any time’.

Young people between 16-18 years of age with sufficient understanding are able to give their full consent to participate in research independently of their legally authorized representative. Children under 16 years of age are able to give their full consent providing they have been counselled and do not wish to involve their parents and they have sufficient maturity to understand the nature, purpose and likely outcome of the proposed research. In addition, participation in the research must always be in the individual’s best interests. However, the REB would regard it as unwise for an investigator to allow the participation of a child in a project where parental consent was not forthcoming or a competent child was not in agreement.

3.10 Research Involving Children

The child should provide his/her assent and may refuse to participate even if the parent has provided their consent. The age of consent to participate in research in the Province of Quebec is 18 years of age. Section 21 of the Quebec Civil Code should be referenced for additional information as to the involvement of children in research. The Assent form for the involvement of minors in research should be used for any individuals under the age of 18.

There are three categories of research involving children. The categories are determined by the degree of risk and prospect of benefit to the participating child-participant. For any protocol involving children, the REB, in consultation with the Principal Investigator (PI), is responsible for determining in which of the three categories of research the study belongs and for documenting in the minutes the rationale for its choice.
Therefore, it is desirable for the PI to address these issues directly in the protocol in a section entitled “The ethical considerations concerning the involvement of children” in which he/she identifies which of the categories the study fits into and the rationale for this categorization.

The three categories of research which may be approved by REBs are:

- **Category 1**: research that involves minimal risk to children.
- **Category 2**: research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child-participant.
- **Category 3**: research involving greater than minimal risk and no prospect of benefit to the individual child-participant. In order to approve research in this category, the REB must determine that the risk of the research represents no more than a minor increase over minimal risk; that the intervention or procedure presents experiences to the child-participants that are reasonably commensurate with those inherent in their actual, or expected medical, dental, psychological, social, or educational situations; and the intervention or procedure is likely to yield generalizable knowledge about the participant's disorder or condition which is of vital importance for understanding or amelioration of the disorder or condition.

If you are not certain as to whether an ethics review should be undertaken by the REB, the PI should consult with the REB Secretariat.

**Parental Consent**

Parental consent is required where it is viewed that a child is incapable of understanding the implications of taking part in a study or where the child is regarded as incompetent to consent. Although the child’s assent is advisable, the power to consent, in law, is that of his/her legally authorized representatives. Those acting for a child are only acting legally if participation in the project is of benefit to the child. If it is not, the legally authorized representative could be said to be acting illegally.

Where there is parental disagreement as to whether an ‘incompetent’ child should be volunteered for research, the REB may, in such circumstances, advise the researcher that where there is disagreement, the child should not be included in the research.

The child should provide his/her assent and may refuse to participate even if the parent has provided their consent. The age of consent to participate in research in Quebec is 18 years of age, and the assent form for the involvement of minors in research should be used for any individuals under the age of 18.

**Confidentiality Issues**

Confidentiality and anonymity must be explained in a way that children can understand. The researcher present at the interview is rarely the only person to see the results. It must therefore be made very clear who will have access to the data and what will happen to the data when the research is complete. Anonymization in the form of removing names and other identifying information should be explained. The extent of the anonymity and any potential areas where the
confidentiality of the interview may be broken should be explained to the child at the outset of the interview. For example, the researcher has a duty to take steps to protect the child or other children, if they are considered to be ‘at risk of significant harm’. The child needs to know what action may be taken in the event that he/she discloses that they or others are at risk of ‘significant harm’, or where the researcher observes or receives information of incidents likely to cause harm. Arrangements need to be made in advance, following professional advice, on agreed procedures in these cases, and for support for the child.

3.11 Research Involving Prisoners

Research involving prisoners should only be done in specific conditions and according to relevant ethical guidelines.

Voluntariness Issues

It is essential that the individual has full information about the research in order to give their informed consent to take part, and that consent is freely volunteered. The ability of prisoners to consent freely and voluntarily to participation to research may be modified due to their incarceration. "The influence of power relationships on voluntary choice should be judged according to the particular context of prospective participants." Prisoners should not be offered large inducements for their participation in research, putting them under undue pressure. The salary they would otherwise get in prison should be considered as an example of the maximum amount offered for participation in research. The individual should also know that she or he can withdraw at any time and that their participation will not influence their parole. The risks from participating to research should be commensurate to those accepted by non-prisoner participants.

Confidentiality Issues

Participants should know "who will have access to identifying information, and to know about the nature of that information." Hence, the researcher needs to inform participants if the information gathered from their participation to research will be provided to authorities monitoring or not the research in question. REB members and the researcher should also consider the interests of prisoners and the possibility of stigmatization of this particular population. Gathered data should only be provided to administrative bodies for policy making purposes and if it is unlinked to any specific individual.
4. Research Consent and Assent Forms

4.1 Informed Consent

Informed consent is an ongoing process that starts with the researcher's first contact with the individual and continues until the study is complete or the participant withdraws. The informed consent and any other written information given to participants should provide adequate information for the participant to make an informed decision about his/her participation. Researchers should be aware of the consent requirements established by the Health Canada REB.

In certain cases, it is not necessary that the person actually sign the form. This includes cases where to sign would endanger the participant, as in research on stigmatized or illegal behaviour; and situations in which the participant can refuse behaviourally, such as by throwing out a survey. There is a need for the researcher to document that the individual has consented to participate in the research project.

There are also cases in which the individual is not legally competent to consent, such as children or persons with Alzheimer’s. In such cases, a qualified person such as a parent, or legally authorized third party, must provide his/her consent for participating in the research project, and be given the opportunity to observe the study as it progresses, so that they can judge if they want to withdraw the individual. It would be appropriate for the individual’s physician and/or principal caregiver to be involved in the consent process and its periodic review. The REB Secretariat has produced some templates of consent and assent forms and these have been posted on the REB website.

4.1.1 Assent Form

4.1.1.1 Children

It is also necessary to seek a child’s assent (seven (7) to fifteen (15) years of age) to participate in a particular study. While children may be legally incapable of giving informed consent, they nevertheless may possess the ability to assent to or dissent from participation. Out of respect for children as developing persons, children should be asked whether or not they wish to participate in the research, particularly if the research does not involve interventions likely to be of benefit to the participants and the children can comprehend and appreciate what it means to volunteer for the benefit of others.

Assent in children is understood as a method of expression significant for recognizing autonomy, and represents a child’s agreement to participate as a participant in research. The process provides the means for a child to communicate a negative preference on becoming a participant in research.

The REB has determined that the policy for obtaining assent will apply to children between the ages of 7 and 15 years of age. The age of consent to participate in research in Quebec is 18 years of age, and the REB members recommend that the assent form for the involvement of minors in research should be used for any individuals under the age of 18. Section 21 of the Quebec Civil
Code should be referenced for additional information as to the involvement of children in research.

From the age of 16 to 17 years of age, consent may be obtained from the participant alone or if required, the legally authorized representative may be asked to provide consent also. From the age of 18, the participant will provide his/her own consent to participate in research.

Researchers should review the consent requirements established by the REB to ensure adequate written informed consent or assent is provided to the participants and the general points are:

- Wording should be very simple.
- If the child is not able to read, procedures may be used to present the information verbally to obtain verbal assent.
- The Assent Form should be brief and study specific.
- Explain what will happen to the child while participating in the study.
- Explain what the research is about, risks and benefits in language that is appropriate to the child’s maturity.
- The assent form should have a simple format that is easy to read and when possible, should be limited to one to two pages.
- The use of larger type, simple schema, and pictures can facilitate the child’s understanding of the text.

The assent form does not replace a thoughtful discussion with the child regarding participation in the research. The assent process, or discussion with the child, is more important than the document. Investigators should remember that the assent process should take into account, in both oral and written communication, the child’s experience and level of understanding. Ultimately, the assent process should illustrate respect for the child and convey the essential information the child requires, in a manner the child can understand, in order to make a decision about participating in the research. The assent process should be well documented.

The REB Secretariat has produced an assent form template and this is to be used by investigators as a guide; however, use of this template is not required. Investigators are encouraged to develop assent forms that they feel will most effectively present information about the research to participants.

4.1.1.2 Mature minors

Mature or emancipated minors may also provide consent. A mature minor is a person who can demonstrate adequate understanding and decision-making capacity. Emancipated minors result from a variety of situations such as marriage, parenthood, self-support and military membership. With respect to obtaining consent, the REB agreed that for minors:

- If able to understand the nature and consequences of the study (the "mature minor" concept) - a standard consent form should be used.
• If able to only partially understand the nature of the study - a standard form should be used, phrased in 2nd/3rd person (you/your child) and signed by the legally authorized representative. The minor must sign an assent. It is implied that should the minor refuse to sign the assent, participation in the study would not be permitted regardless of the legally authorized representative signing a consent form.
• If unable to understand the nature and consequences of the study - standard form should be used, phrased in 2nd/3rd person (you/your child) and signed by the legally authorized representative. No assent is required.

The REB will determine for each protocol – depending on such factors as the nature of the research and the age, status, and condition of the proposed participants – whether all or some of the children are capable of assenting to participation.

When the REB determines that the assent of the child is required, it will also determine that the provisions for obtaining and documenting assent are adequate. The child should be given an explanation of the proposed research procedures in a language that is appropriate to the child’s age, experience, maturity and condition. This explanation should include a discussion of any discomfort and inconvenience the child may experience if he/she agrees to participate.

If in doubt about procedures or special considerations, please seek the advice of the REB Secretariat.

4.2 Consent Form

This is a tool to assist you in writing your consent form, but individual researchers hold the final responsibility for clarity and completeness. If you have questions please feel free to contact the REB Secretariat:

• The pages of the document should be numbered, i.e. 1 of 3, 2 of 3, 3 of 3 etc.
• Include a date as header or footer on every page. If you make changes in the consent form, you must change the date which then signifies the version number.
• All information required by the participant must be included in the consent form. Do not use attachments or additional information forms.
• The consent form submitted for review should be in its final form (as it will be seen by the participant), including letterhead if used. Photocopied letterhead is okay.
• Spelling and grammar must be corrected before submission for review.
• The consent form should be written in the second person (use "you" not "I").
• When submitting revised consent forms to the REB please highlight any changes, whether originating with the investigators or requested by the REB.
• Any changes to the application or consent form must be approved by the Research Ethics Board before the research begins or continues.

The following is a template and is not meant to be copied verbatim. There are sections that should be modified to suit your research project:
Introductory Information:

- The identity of the researcher(s);
- That the individual is invited to participate in research;
- The basis for inviting the individual to take part. (Include information on any criteria under which prospective participants would be excluded from participation);
- The alternative procedures or courses of treatment that may be available to the participant and their important potential benefits and risks;
- That the individual's participation in the research is voluntary and that the individual may refuse to participate or may withdraw from the study, at any time, without penalty or loss of benefits to which he/she is otherwise entitled;
- If they wish to participate, they will be asked to sign the consent form. If they do decide to take part in this study, they are still free to withdraw at any time and without giving any reasons for their decision;
- If they do not wish to participate, they do not have to provide any reason for their decision not to participate nor will they lose the benefit of any medical care to which they are entitled or are presently receiving;
- That the investigators may decide to discontinue the study at any time, or withdraw the participant from the study at any time, if they feel that it is in their best interests;
- The purpose of the research. Be sure that the description of the purpose provided in the consent documents is consistent with the purpose as described in the protocol;
- Where appropriate, the approximate number of participants involved in the study.

What Will The Participant Be Asked To Do?

- Describe the research procedures that the participant will be involved in;
- State the expected duration of the participant's participation in the research;
- Where relevant, provide information regarding audio or video taping;
- If a questionnaire is required to be completed, the individual must be informed that they have a choice of not answering any questions. A statement informing the individual as to how long it will take to complete the questionnaire.

Risks / Benefits:

- The reasonably foreseeable risks, harms, or inconveniences to the participant;
- If any sensitive questions, the impact of these on the individual;
- The reasonably expected benefits. When there is no direct benefit to the participant, the participant should be made aware of this;
- If blood is taken, a statement about the possibility of bruising or swelling while giving blood, or some other discomforts at the site where blood is drawn and that there may be minimal chance of infection, that these discomforts are brief and transient. The individuals should be informed in teaspoon measurements of the amount of blood that will be taken.

Compensation / Expenses:
• The anticipated payment (including any pro-rations) or reimbursements, if any, to the participant for participating in the research;
• The anticipated expenses, if any, to the individual for participating in the research.
• The individuals should be reimbursed for any out-of-pocket expenses, such as parking, baby sitting, etc.

Access to Research Information:

• Information regarding who will have access to the data
• Information regarding retention of data (including audio and video tapes) and schedules for their disposal
• How, if at all, participants will be informed of the results of the research.
• That the participant or the participant's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the participant's willingness to continue participation in the study.
• A statement indicating the sources of financial support for the study (if any).
• Where relevant, information regarding the possibility of commercialization of research findings and the presence of any apparent, actual, or potential conflict of interest on the part of the researcher, the researcher's institution, or sponsors.

Confidentiality / Publication of Results:

• The degree of confidentiality and/or anonymity that will be provided. Include information on the extent to which and the manner in which records identifying the participant will be kept confidential, including any limits on confidentiality (e.g., legal reporting requirements).
• If a Focus Group is being considered, the Principal Investigator should put a procedure in place in which the researchers caution people about the limit on confidentiality and make reference to the limits on confidentiality in the consent form.
• A statement indicating that the researchers intend to publish the research (e.g., in scholarly publications), or that the researchers intend to make public presentations based on the research. If the results of the study are published, whether the participant's identity will remain confidential.

Contact Information:

If you have any questions about this study, please contact:
• Name, area code and phone number of Investigator;
• Collect calls will be accepted.

If you have questions about your rights as a research participant, you may contact:
• Research Ethics Board Secretariat
  Holland Cross, Tower B  Postal Locator 3104A
  Ottawa, Ontario  K1A 0K9
4.3 Consent Requirements

Researchers should review the consent requirements established by the REB to ensure adequate written informed consent or assent is provided to the participants and the general points are:

- Information letters and consent forms must be presented on institutional / departmental letterhead.
- The level of language used should be appropriate to the age and comprehension / reading level of the participant population, generally at approximately a grade 6 - 8 reading level:
  - Avoid the use of legalistic phrases.
  - Volumes, weights, etc. should be expressed in meaningful scales as well as scientific measurements (e.g., blood draws in numbers of teaspoonfuls or proportion of a Canadian Blood Services donation).
- Where a legally authorized representative’s consent is necessary for a minor participant, the form should be appropriately expressed, the minor named, and the legally authorized representative's capacity given. If a minor's unwritten concurrence (assent) is to be sought, the form should reflect this fact, and a place should be given for the investigator to indicate whether it was or was not obtained. If the minor is assenting in writing, the assent form should be drafted in age-appropriate language.
- If blood is taken, a statement about the possibility of bruising or swelling while giving blood, or some other discomforts at the site where blood is drawn and that there may be minimal chance of infection, that these discomforts are brief and transient.
- If a Focus Group is being considered, the Principal Investigator is required to make reference to the limits on confidentiality in the consent form.
- The consent form should be dated, signed and the participant should receive a copy of the consent form for his or her own reference.

If there is any doubt about whether all or part of the consent form will be clear to potential participants, it should be pre-tested. The pre-testing will require that the researcher obtains an ethics review by the REB prior to initiating this process.

Note: When study interventions consist solely of administering a questionnaire, a separate consent form is not required. Rather, the process must include a cover introductory letter (or telephone script) outlining the salient issues, such as introduction of investigator(s) (and/or caller), how the person was selected, where the contact name was taken from, purpose of study, length of time to complete the questionnaire, confidentiality issues and any alternatives to participation. With the completion of the questionnaire, implied consent is inferred.

4.4 Confidentiality Statement for Focus Groups

The Principal Investigator should consider adding a statement of the potential harm that could exist if confidentiality is violated by someone participating in these focus groups. The
researchers are required to explain the two kinds of confidentiality that may apply in this situation: 1) the researchers are capable of promising confidentiality of information but 2) can’t promise that the other participants will observe each others privacy.

The Principal Investigator should put a procedure in place in which the researchers caution people about that limit on confidentiality. The limit of confidentiality should also be included in the Information package that is to be sent to the individuals. For more information on conducting interviews and focus groups, please see the documents pertaining to Focus Group Guidelines on the HC REB Website.
5. Guidelines for Human Participants Research Protocol

The purpose of the research protocol is to provide a clear and complete description of the purpose and benefits of the research, the methodology involved, the informed consent process, and any questionnaires, surveys, interview schedules, or other materials to be used. Be advised that some of the individuals reviewing your proposal may be entirely unfamiliar with the field of study involved. The protocol should be written in the tense (past, present, future) that is accurate at the time of submission of the protocol. Thus, future tense should be most common as the research should not have been initiated prior to obtaining the Health Canada’s REB ethics approval. It is very important for researchers to review carefully the REB Policy and Procedures’ Manual on research involving humans for clarification of items mentioned here (e.g., the use of informed consent, vulnerable groups) and to ensure that your practices are in keeping with those guidelines.

A summary of the present knowledge (Literature review) on the exposure, the outcome, the relation between exposure and outcome: systematic review, should be documented in the protocol. The PI should demonstrate how the project will improve the current knowledge: is this the first study? if not, how this study will correct biases present in previous studies, or their lack of precision. A concise summary of the need for your research, its potential benefits, and your hypotheses is requested by the REB.

5.1 The Research Protocol should contain the following:
- Title of the research
- Name and department/affiliation of the primary investigator(s)
- Statement of purpose, benefits, and hypotheses. (This section need not be lengthy. In most cases, one paragraph is likely to be sufficient.)

- Methods:
  - Participants: Source, selection and exclusion criteria (if applicable), approximate number, whether prospective participants are members of a vulnerable group or not (see Section #3 on Special Care Required for Certain Populations, for a discussion of vulnerable groups such as children and disabled persons), expected age range, other descriptors that might be relevant (e.g., gender, ethnicity)
  - Experimenter(s): Identity of individual(s) who will administer the study; relevant qualifications of experimenter(s) (such as medical training when conducting physical tests)
  - Materials and Procedures: Copies of any questionnaires, surveys or interview questions; description of other materials or apparatus that will be used; location of the study; chronological description of the procedures that will be followed in collecting the data; how participants will be debriefed.

Informed Consent Form**:
Include identification of the activity as research, purpose(s) of the study, expected duration of the individual's participation, summary of the procedures, notification of any experimental procedure(s) that may be used (meaning procedures not yet accepted as standard practice such as experimental drugs), foreseeable risks or discomforts (physical, psychological, social, or economic as described in Section #4 on Research Consent and Assent Forms), benefit(s) to participant or others, disclosure of alternative treatments (if applicable), how confidentiality will be protected, recourse if injury occurs (if the study is deemed of greater than minimal risk), referral for questions or to report harm or to obtain a summary of the study's results (e.g., the name and campus phone number of the faculty member conducting or supervising the project), indication that their participation is voluntary and that no penalty or loss of benefits will result from their refusal to participate or their discontinuing their participation once initiated, referral(s) to services that might assist them with any distress generated by their participation, offer of a copy of the consent form.

** A separate signed informed consent form may not be appropriate in studies in which the only link between the data and the participant's identity would be the signed consent form. In this case, the informed consent information should still be presented, though not on a signed form.
6. Awareness of Privacy Legislation

Researchers should be aware of their obligations as stipulated in the Privacy Act and other applicable regulations.

6.1 Privacy Legislation

The purpose of the Privacy Act is to provide citizens with the right to access personal information held by the government and protection of that information against unauthorized use and disclosure. For further information pertaining to the Privacy Act, please contact the Privacy Officer in the Access to Information and Privacy Division of Health Canada at (613) 954-8744.

6.2 Privacy Impact Assessment Policy

The Government of Canada is committed to protecting the personal information of Canadians. The Privacy Impact Assessment Policy, in conjunction with other relevant legislative and policy considerations, is integral to the design, implementation and evolution of all programs and services. Institutions are responsible for demonstrating that their collection, use and disclosure of personal information respect the Privacy Act and privacy principles throughout the initiation, analysis, design, development, implementation and post-implementation review phases of their program and service delivery activities. For further information on this subject, please contact the Director of the Privacy Policy Division, Health Canada, at (613) 946-3179.

6.3 Personal Information Banks

The Privacy legislation states that government institutions shall not collect personal information unless it relates directly to an operating program or activity. The policy requires that institutions have administrative controls in place to ensure that they do not collect any more personal information than is necessary for the related programs or activities. This means that institutions must have parliamentary authority for the relevant program or activity, and a demonstrable need for each piece of personal information collected in order to carry out the program or activity. For details on how to proceed with the registration of the personal information bank, please contact the Privacy Officer in the Access to Information and Privacy Division of Health Canada, at (613) 954-8744.

6.4 Personal Information Protection and Electronic Documents Act (PIPEDA)

The purpose of PIPEDA is to promote electronic commerce and adequate protection of the personal information collected, used or disclosed by any organization subjected to this Act, during commercial activities. PIPEDA also gives protection of personal information communicated or recorded by electronic means. A link to the PIPEDA is provided for your ease of reference.
6.5 Provincial and Territorial Privacy Legislation

Each province and territory possesses its own legislation concerning privacy for the collection, use and disclosure of personal information by government agencies. Some researchers funded or affiliated with Health Canada working in another research location may be subjected to this particular legislation in addition to the two Federal laws on privacy. In private sectors, some provincial legislation on privacy are deemed similar to the federal legislation thus, in certain circumstances, the researchers concerned can follow the provincial legislation. When it is unclear, a researcher may consult the REB Secretariat.

6.6 CIHR Best Practices for Protecting Privacy in Health Research

These Privacy Best Practices are intended to provide guidance for the health research community in Canada on the application of fair information principles to research involving the collection of personal information.

The Best Practices are organized into a series of elements that should be considered in the design, conduct and evaluation of health research to address privacy and confidentiality concerns. A link to these Best Practices is provided for your ease of reference.
7. Types of Ethics Review

7.1 Full Review

All Health Canada and/or Public Health Agency of Canada’s research projects involving humans shall be subject to a full review by the Health Canada REB wherein all REB members shall review the proposed research project. Researchers are required to complete Appendix A and forward a copy of the completed form and the required documentation to the REB Secretariat in order to obtain an ethics review by the REB.

7.2 Expedited Review

In particular circumstances, the REB may review applications as expedited reviews or as time sensitive reviews. The following criteria have been developed for ease of reference:

7.2.1 Criteria for Expedited Review

In order for an application to be subjected to an expedited review, the Principal Investigator must demonstrate how the research meets any of the following criteria:

Expedited review is intended for studies that:

- Are non-invasive. Harms cannot include: e.g. breaking of the skin, noxious procedures, and invasive questionnaires in vulnerable circumstances/ context or significant nuisance/inconvenience;
- Are retrospective, including chart reviews, and participants are to be contacted for additional information not found in the chart. However, ‘cold calling’ by the investigator is not permitted and, when a child is involved, at a minimum a caregiver familiar to the participant/parent must be included in the ‘request loop’.
- Involve no direct participant contact, may involve anonymous waste or leftover tissue, and only aggregate data is being reported. However, studies involving foetal waste tissue or genetic material must be submitted for a full review by the REB.
- Have minor revisions of a previously approved project;
- Involve substantive replication of a previously approved study where any changes to the study do not introduce any additional risks or raise any new ethical concerns;
- Involve secondary use of research data (as stated in Article 3.2 of the TCPS “secondary use of research” is understood to be “the use in research of data contained in records collected for a purpose other than the research itself”) which cannot be linked to individuals; (Note: no review is required for use of previously collected, publicly available, anonymized research data);
- Have already been approved by a Research Ethics Board of a Canadian university, Canadian hospital, where such REB is in compliance with the TCPS and any applicable legislation;
- Involve non-invasive product testing or quality assurance activities and publication is planned;
- Do not involve biomedical procedures.

The REB Chair or the Deputy Chair will determine if this application is meeting the requirements of an expedited review. If the Chair or the Deputy Chair does not agree that the research qualifies for an expedited review, the researcher will be informed that the application will receive a full review at the next monthly REB meeting.

### 7.2.2 Timeline

The time required to conduct an expedited review process will vary because it is dependent upon the workload and availability of the persons participating in this process, namely the REB Chair and the REB Secretariat. Hence, researchers should recognize that a decision to refer an Ethics application to an expedited review process may have occasional delays due to the availability of REB members participating in the review process and may necessitate that the researchers provide additional copies of the application. Typically, however, an expedited review by the REB should take approximately 3-4 weeks.

When requesting an expedited review, the Principal Investigator must complete Appendix B and submit the required documentation to the REB Secretariat. An original plus three copies should be provided, as well as an electronic version. Researchers are strongly encouraged to contact the REB Secretariat prior to submitting for advice on whether their application may be eligible for expedited review.

### 7.3 Time Sensitive Review

The Tri-Council Policy Statement (TCPS) provides that, “subject to all applicable legislation and regulatory requirements, research involving emergency health situations shall be conducted only if it addresses the emergency needs of individuals involved and then only in accordance with criteria established in advance of such research by the REB”. The REB may allow research that involves health emergencies to be carried out without the free and informed consent of the participant or the participant’s legally authorized representative if all of the following apply:

- A “serious threat to the prospective participant requires immediate intervention;
- Either no standard efficacious care exists or the research offers a real possibility of direct benefit to the participant in comparison with standard care;
- Either the risk of harm is not greater than that involved in standard efficacious care, or it is clearly justified by the direct benefits to the participant;
- The prospective participant is unconscious or lacks capability to understand risks, methods and purpose of the research;
- Third-party authorization cannot be secured in sufficient enough time, despite diligent and documented efforts to do so; and
- No relevant prior directive by the participant is known to exist.”
7.3.1 Criteria for Time Sensitive Review

In circumstances that are deemed emergency health situations, the REB established certain criteria that have to be met to qualify for a time-sensitive review. Researchers must ensure that their research project meets the following criteria prior to submitting an application for a time sensitive review:

- Epidemiological studies where incidences of the study target are limited, such as outbreak investigations of a new disease such as SARS;
- Studies of time limited events;
- Research whereby waiting for the next REB meeting would place individuals at risk;
- Approval by the REB is urgently required due to circumstances beyond the researchers’ control. Submission of the study for ethics review within required timelines is considered to be in his/her control and not subject to this type of review.

7.3.2 Process for Time Sensitive Review

Applications for time sensitive review by the REB must be submitted electronically to the REB Secretariat. Researchers should demonstrate clearly how the research meets the criteria for time sensitive review. It should be noted that circumstances might arise where the REB may not be able to review a time sensitive application despite its best efforts to do so.

The REB Chair or the Deputy Chair will determine if the application meets the criteria for time sensitive review. If the REB Chair or the Deputy Chair determines that the application does not meet the time sensitive review criteria, the application will not be reviewed until the next scheduled REB meeting.

However, if the REB Chair or the Deputy Chair determines that the application warrants time-sensitive review, it will be deemed a “high priority” review. The REB Secretariat will then schedule a time for a face-to-face or a teleconference meeting with REB members to review the application. *A REB certificate of ethics approval must be obtained from the REB Chair before the research begins.*

The REB established the procedures for time sensitive reviews in January 2004. The REB will review these procedures periodically to ensure their effectiveness and relevance.

7.4 Protocol Previously Approved by an Outside REB

A protocol that has been previously reviewed and approved by an outside REB that is guided by the ethical principles found in the *Tri-Council Policy Statement (TCPS)* must also be submitted to the Health Canada REB for review and approval. This is in keeping with Health Canada’s accountability for research carried out within the Department’s jurisdiction or under its auspices.
The researcher is required to complete Appendix I and forward a copy of the entire application approved by the other REB to the REB Secretariat, as well as a copy of the outside REB’s letter of approval. A REB certificate of ethics approval must be obtained from the Health Canada REB Chair before the research project begins.

7.5 Public Health Activities

The Health Canada REB will be collaborating with the Public Health Agency of Canada in the development of a template for expedited ethics review process of applied research protocols in the face of outbreaks and similar public health emergencies. This section of the Manual will be revised by the REB Secretariat when these criteria have been developed.
8. Preparing the Application

A complete REB application package has six (6) main components:

- Completed application form with all necessary signatures;
- Research protocol;
- Consent and assent forms;
- Completed science peer review and itemized response;
- Copy of the contract’s terms of references or statement of work (if applicable);
- All documentation submitted and approved by another REB (if applicable).

8.1 Application Form

The Application form for an ethics review (Appendix A) must be completed and submitted to the REB Secretariat. If the proposed research meets the criteria for an expedited review, the application form (Appendix B) must be submitted.

The following provides explanatory information about some of the questions on the application form for a full ethics review:

#1 - Project Title
Full title of the research project must be provided. The title must be the same as the title found on the research protocol. The same title and assigned REB file number must be used consistently in all future REB correspondence.

#2 - Principal Investigators
The Principal Investigator (PI) will assume full responsibility for the study as detailed in the research protocol and must sign the application.

Address of Principal Investigator
The Principal Investigator’s name, address and telephone number, must be provided as a contact on the REB application form. Do not leave this blank.

#3 - Co-Investigators
A listing of all co-investigators is required to be provided to the REB Secretariat.

#4 – Departmental Official
The name of the contact in Health Canada or in the Public Health Agency of Canada must be provided if the principal investigator is not an employee of these institutions.

#5 - Departmental Approval
The research must be authorized by the relevant Branch(es) and/or Directorate Head(s) in Health Canada and in the PHAC. The Branch/Directorate Head’s signature confirms the scientific integrity of the research, the feasibility of conducting the research at Health Canada and/or
PHAC, that sufficient funds are available to complete the study and that appropriate monitoring will occur.

The REB Secretariat must ensure that all signatures are obtained before the application can be processed and reviewed by the Health Canada REB. If signatures are missing, the application will not be processed until these are received by the REB Secretariat.

#6 - Scientific Peer Review
In order for research to be ethically acceptable, it must be scientifically sound. If research does not have sufficient scientific merit, generalizable knowledge cannot be anticipated and the reason for undertaking the research vanishes. Even a negligible risk of harm resulting from research that may not yield meaningful results is inherently unethical. Therefore, before the research can be reviewed by the Health Canada REB, it should be independently reviewed to ensure scientific validity. The REB Secretariat has developed a Scientific Peer Review form to assist the researcher in ensuring that his/her research is scientifically sound.

If not applicable, the researcher must provide a rationale as to why a scientific peer review has not been undertaken and obtain his/her Director General or Assistant Deputy Minister’s signature.

#7 – Funding
The research requires to be properly funded and the need for the researcher to include the study budget information.

#8.e - Recruitment
Special care must be taken when recruiting students, post doctoral fellows, colleagues, employees, family or friends as research participants. A staff member may feel obligated to participate to please his/her employer, or be concerned that refusal to participate may threaten his/her position. Alternatively, the investigator, by reason of the relationship, may feel unable to fully inform the person of an unexpected or negative finding of the study. This is particularly problematic when the findings could affect their present or future employment relationship.

#8.i-j. - Potential Harms and Potential Benefits
The potential for harm and benefit of the research must be described in simple lay terms, at a grade six (6) to eight (8) reading level.

There is always a potential for harm (if only as an inconvenience to the participant) with participation in research. This must be stated in this section. If there are no potential benefits, this must also be stated.

The Tri-Council Policy Statement (TCPS) states:
"Potential harms are usually understood in relation to risks, which are defined in terms of the magnitude of the harm and the probability of its occurrence. Both potential harms and benefits may span the spectrum from minimal through significant to substantial. A proportionate approach to ethics review thus starts with an assessment, primarily from the viewpoint of the potential participants, of character, magnitude and probability of potential harms in the research."
#10 - Privacy Legislation
The researchers must demonstrate that they are aware of their obligations as stipulated in the Privacy Act and other regulations.

#11 - Third Party Implications
The researcher will need to identify if there is any potential for identifying third parties.

#13 – Contract Information (if applicable)
If there is a contract for this study/project it must be reviewed and approved by the Director of the Division to whom the researcher reports; and be included with the application to be submitted to the REB Secretariat for obtaining an ethics approval by the REB. Conflict of interest disclosure information must be provided, e.g. commercial interests, consultative relationships.

Certification
The Principal Investigator (PI) will assume full responsibility for the study as detailed in the research protocol and must sign the application.

8.2 Research Protocol
A research protocol is a separate document that clearly describes the science and the ethics of the research.

The scientific component should include a discussion of:

- The research problem, background analysis, question(s) and/or hypothesis;
- The relevant literature;
- The study objectives;
- The research design and methodology (inclusion/exclusion criteria, sample size, justification and analytical methods for assessing results);
- The budget and available resources;
- The contract information (where applicable).
- The ethics of the research may also include a discussion of the following:
  - The potential benefit to participants and others;
  - The potential harm or costs to participants and others;
  - The alternative treatments or procedures available in place of study procedure;
  - How potential for harm/costs will be minimized - including the risk of breach of privacy and confidentiality;
  - The process for obtaining informed, voluntary, consent and assent.

8.3 Scientific Peer Review
Independent scientific peer review should occur prior to submission for ethics review and approval by the Health Canada Research Ethics Board (REB). In addition to including a copy of
the completed Report on Scientific Peer Review, an itemized response to issues raised and research director signoff is also required prior to submission to the REB Secretariat. For Health Canada funded research, the Principal Investigator (PI) must obtain the required delegated authority for the research to proceed. The research must be authorized by the relevant Branch and/or Directorate Head whose signature confirms:

- The scientific integrity of the research,
- The feasibility of conducting the research at Health Canada,
- That funding is available to complete the study, and
- That appropriate monitoring will occur.

In some instances, where external scientific review has been undertaken and funding granted (ex.: CIHR, CRTI, NIH), Health Canada scientific review may be waived. In these situations, a copy of the completed scientific review must be included with the application. A waiver of the Health Canada science review will be decided on a case-by-case basis by the REB Chair or the Deputy Chair.

### 8.4 Submission Process

This process is for all types of submissions for example

- Full or expedited review
- Review of protocol previously reviewed by an outside REB
- Time sensitive

For an ethics review by the Health Canada REB, please submit one (1) original hard copy, twelve (12) photocopies and one (1) electronic version to the REB Secretariat of the:

- Completed application form;
- Research protocol (see Section #5 of this manual);
- Scientific peer review;
- Signoff by a Director General for those projects reviewed;
- Information sheet and consent/assent forms on the required letterhead;
- Documentation for the recruitment of potential participants;
- Contract information (if applicable).

### 8.4.1 Application Deadline

As REB members are volunteers, the REB Secretariat established a two (2) week deadline for the submissions of applications to the REB. This deadline is to provide the members with sufficient time to review the protocols submitted to the REB Secretariat, prior to the scheduled REB meeting.

The REB Secretariat will:

- Review applications for completeness; and
• Assign a REB file number to the application. All subsequent correspondence with the REB Secretariat should quote the file number and the title of the research protocol.

Once the application is complete, it will be included on the agenda for the upcoming REB meeting, if received by the REB Secretariat prior or on the deadline for submission otherwise it will be scheduled for the following REB meeting.

The Principal Investigator will be informed by the REB Secretariat via email of the need to make a 5-10 minute presentation to the Board summarizing the project, informing the Board of any ethical issues considered and be present to answer any questions raised by the members. The REB Secretariat will provide the time and location for which his/her research project will be heard by the Board.
9. REB Ethics Review and Approval Process

9.1 REB Ethics Review

The REB will consider Health Canada research to be ethically sound when:

- The research is scientifically sound,
- The potential benefits significantly outweigh the potential for harm or other risks,
- There is adequate process for informed consent and where applicable, an assent to participate in the research, and
- There is justice and fairness in selection of participants.

The REB meets monthly (except during the summer) and face-to-face to consider applications except in exceptional circumstances for time sensitive reviews. Principal Investigators (PI) may be invited to give short presentations on their research. The REB Secretariat should be contacted for assistance in preparing the presentation.

REB ethics decisions will be communicated to the PI within fifteen (15) days of the meeting at which a decision was reached.

9.2 REB Ethics Decisions

Research must not commence until a certificate of ethics approval is received from the REB Chair. The research under review will receive one of the following approvals from the REB:

9.2.1 Approval

The REB may, on ethical grounds, approve a research project to proceed as submitted to the Health Canada REB. A REB certificate of ethics approval will be sent by the REB Chair to the PI which will provide him/her with the needed approval for the study to proceed as reviewed by the REB. A REB ethics approval is granted for a maximum of one (1) year. Research must be renewed annually or earlier if requested by the REB and until the project is completed.

9.2.2 Approval with Revisions

The REB may, on ethical grounds, provide a conditional approval for a research project to proceed as it is ethically sound but requires certain revisions to be made. The conditions will be summarized in an email from the REB Secretariat to the PI and included in the REB certificate of ethics approval signed by the REB Chair. It is the responsibility of the investigator to promptly respond to the REB concerns. The principal investigator must then submit a revised copy of the documentation to the REB Secretariat, making clear the revisions (e.g. by underlining or tracking changes).
9.2.3 Deferral of Approval

The REB may indicate to the Principal Investigator the need to defer the approval for this project to proceed as the following action is required:

- receipt of additional information from the PI, or
- major revisions are required to the application being reviewed.

The REB Secretariat will provide an email to the PI in which a copy of the summary of the members’ discussions is provided for his/her action and this within five (5) days of the meeting. The PI will be requested to review and implement the necessary modifications to the documentation. It is the responsibility of the investigator to promptly respond to the REB’s concerns. The additional information or the required revisions must be re-submitted to the REB Secretariat for final REB review.

The REB will review the additional information or the proposed revisions and make decisions as appropriate. Upon finding them acceptable, a REB certificate of ethics approval will be issued by the REB Chair to the PI, giving ethics approval for the study to proceed. Research may only start when the PI has received this certificate of ethics approval from the Chair of the Health Canada REB.

9.2.4 Not Approved

If, in the opinion of the REB, the proposed research is unethical, the REB Chair will inform the Reporting Authority that the project is not ethically sound and should not proceed. The Reporting Authority or any other departmental or agency official shall not override the advice of the REB on the ethics of a research project. Should a PI decide to appeal a negative review, the proposed research will not proceed unless the appeal has been successful and the PI has been granted permission to proceed in writing from the REB Chair.

9.2.5 Operational requirements

Where the REB has advised that the proposed research is ethically sound and the REB Chair has informed the PI in writing that the research may proceed, Health Canada or the Public Health Agency of Canada could still refuse to allow the research to proceed for operational reasons.
10. Appeal of REB Review

The following sets out an appeal procedure that can be exercised by the Principal Investigators (PIs) in the event of a negative review by Health Canada’s REB or the imposition of conditions that the PI disagrees with. It is intended to ensure the utmost fairness in the REB’s procedures.

10.1 Reconsideration of the Negative Ethics Review by the REB

In accordance with Article 1.10 of the Tri-Council Policy Statement Ethical Conduct For Research Involving Humans (TCPS), if a negative ethics decision has been received from the REB, researchers have the right to request, and the REB has an obligation to provide, reconsideration of the review affecting a research project.

Any PI, who disagrees with the results of an ethics review by the REB, must provide a clear, detailed basis for the disagreement and relevant documentation that will support his/her request for reconsideration by the REB. This information must be sent by email to the REB Secretariat within ten (10) days of receiving the transcript from the REB Secretariat providing the results of the ethics review. The REB Secretariat will forward the e-mail or letter to the REB for their action/review.

A meeting between the REB and the PI will be scheduled at the earliest possible REB monthly meeting. The PI will be invited to further discuss the project with the Board members in order to reach a final consensus on the issues that are still subject to disagreement. The PI may not be present for the final deliberations of the REB. The PI will receive an email from the REB Secretariat within two (2) weeks of the meeting providing him/her with the results of the reconsideration.

If agreement is reached between the PI and the REB, the REB Chair will advise the Authority of the outcome of the reconsideration. The REB ethics approval will be sent by the REB Chair to the PI informing him/her that the research project may proceed as submitted to the REB.

10.2 Appeal of a Negative Ethics Review Following Reconsideration

Article 1.11 of the TCPS provides that, in cases where researchers and the REB cannot reach agreement through discussion and reconsideration, an institution should permit review of a REB recommendation by another REB, provided that the board’s membership and procedures meet the requirements of the TCPS.

If a consensus was not reached between the REB and the PI during the reconsideration of the REB’s earlier recommendation, the PI can initiate an appeal process within Health Canada.

Appeals are not allowed on the grounds that the PI disagrees with the REB on the ethics of the research project. An appeal will only be considered if the PI can show evidence of a:

- Perception of bias;
- Lack of due process;
To initiate an appeal process, the PI must send an appeal letter to the Reporting Authority and the REB Secretariat, setting out the basis for the appeal and providing supporting evidence. Upon receipt of the appeal letter, the Reporting Authority will enter into a contractual arrangement with another REB (Appeal Board) to review the evidence submitted by the PI. The Appeal Board will advise the Reporting Authority as to whether a failure occurred in the REB’s ethics review process for the project under appeal.

The Appeal Board composition will reflect the expertise profile of Health Canada’s REB. Members of the REB will not sit on the Appeal Board. The Appeal Board can seek assistance from other experts in fields relevant to the appeal.

The Appeal Board will meet within two (2) months of receiving the letter from the PI. The PI and the REB Chair will be invited to present their evidence to the Appeal Board. The REB Secretariat may also be asked to appear before the Appeal Board. The Appeal Board will consider all relevant evidence before reporting its decision to the Reporting Authority.

The Reporting Authority will consider the advice of the Appeal Board in deciding the appropriate action to take in regard to the project. If the Reporting Authority finds that a failure in the review process conducted by the REB has occurred, the project will be referred back to the REB for review.

If the Reporting Authority does not find that a failure occurred in the Health Canada REB ethics review process, the decision made by the REB will stand.

The Reporting Authority will inform the Deputy Minister of Health Canada of the findings of the Appeal Board.
11. Continuing Ethics Review

11.1 Adverse Effects/Unexpected Events

Adverse effects or unexpected events resulting from the research must be reported to the REB Secretariat immediately by submitting the form Appendix J. For some protocols, the REB may require that a monitoring committee be established.

The REB considers *unanticipated problems*, in general, to include any incident, experience, or outcome that meets all of the following criteria:

- Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the REB-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

The REB recognizes that it may be difficult to determine whether a particular incident, experience, or outcome is unexpected and whether it is related or possibly related to participation in the research. The REB notes that an incident, experience, or outcome that meets the three criteria above generally will warrant consideration of substantive changes in the research protocol or informed consent process/document or other corrective actions in order to protect the safety, welfare, or rights of participants or others. Examples of corrective actions or substantive changes that might need to be considered in response to an unanticipated problem include:

- Changes to the research protocol initiated by the investigator prior to obtaining REB approval to eliminate apparent immediate hazards to participants;
- Modification of inclusion or exclusion criteria to mitigate the newly identified risks;
- Implementation of additional procedures for monitoring participants;
- Suspension of enrolment of new participants;
- Suspension of research procedures in currently enrolled participants;
- Modification of informed consent documents to include a description of newly recognized risks; and
- Provision of additional information about newly recognized risks to previously enrolled participants.

The REB Chair will report immediately to the Reporting Authority any serious instances of adverse and/or unexpected events pertaining to research projects involving humans.
11.2 Modification of an Approved Project

Researchers proposing any changes to the research project must obtain the approval of the REB before proceeding with these changes, except when necessary to eliminate an immediate hazard to a participant. The REB must then be immediately notified and the modification submitted for consideration immediately thereafter. Such modifications may include, but are not limited to, changes in research design, participant population, or consent procedures. Prior to making any study amendments or modifications, the form Appendix D must be submitted to the REB Secretariat.

At the discretion of the REB Chair, these modifications may be reviewed via an expedited process. However, significant revisions will require that the proposal be reviewed by the REB at an upcoming REB meeting.

11.3 REB Continuing Ethics Review (REB Annual Approval Process)

Ongoing research shall be subject to continuing ethics review based on the associated risks to the participants. Normally, REBs will require an annual report on the status of all ongoing research projects.

The greater the risk to the participant, the greater the scrutiny of the continuing review process will be for the REB and this may require a review to be undertaken by the REB on a semi-annual basis. The design of this process will depend upon the particular circumstances of the project and might include but is not limited to:

- Requiring the researcher to submit status reports at various intervals as determined by the REB;
- Requiring the researcher to propose an appropriate monitoring mechanism;
- Requiring reports from an independent data and safety monitoring board.

The REB ethics approvals are valid for a maximum of one (1) year. The research must be reviewed at least annually and until it is completed. The annual approval process involves the following steps.

- Six (6) to eight (8) weeks prior to the REB meeting of the anniversary month of the initial approval, the REB Secretariat will send the annual renewal form Appendix K to the Principal Investigator (PI).
- This form must be completed, and returned to the REB Secretariat with supporting documents, as appropriate.
- The REB will review the submission and the results of the review will be provided to the PI by the REB Secretariat. The REB Chair will send a letter of ethics approval to the PI for him/her to proceed for another year.
Projects that are at least five (5) years old must include an updated science review at the time of annual renewal. This ensures that the study can still be justified in view of new information found in the literature. The PI is responsible for soliciting the review and ensuring the completed form Appendix C is submitted to the REB Secretariat.

*A REB certificate of ethics approval must be obtained from the REB Chair before the expiry date referenced on the initial certificate of approval received from the REB Chair.*

### 11.4 Non-Compliance

Instances of non-compliance with the REB policies or procedures for research involving human participants should be brought to the attention of the REB Chair for review and resolution. When deemed appropriate, the REB Chair will report any serious instances of non-compliance to the Reporting Authority and/or the appropriate institution officials for disposition.

Non-compliance can include, but is not limited to, failure to obtain prior REB ethics approval before starting a research project, inadequate supervision of the research, failure to report adverse events or protocol changes to the REB, failure to provide ongoing progress reports, or significant deviation from the approved protocol.

Actions taken by the REB may include, but are not limited to, education measures, compliance audits, terminating or suspending the REB approval of active studies; the REB may recommend to the Reporting Authority the restrictions on the ability to serve as an investigator on research projects involving human participants and of freezing of research funds. Any action taken by the REB will be reported promptly, in writing, to the investigator and the appropriate institution official.

### 11.5 Completion/Termination Reports

Upon completion of the research, the Principal Investigator must submit to the REB Secretariat, the Completion/Termination form Appendix L, and provide:

- A brief description of the outcome/results; and
- If there were any deviation to the REB approved protocol.

This instructs the REB Secretariat to close the file.

If participants undergo continued, periodic assessment after completion of a study intervention, or if continued correspondence about the research is anticipated (e.g. adverse event reports) the research must be designated as ongoing. Participant follow-up should be complete before the form Appendix L is submitted.

Note: All continuing correspondence must contain the REB File Number and the title of the research used in the original application.
12. Record Keeping

The REB Secretariat in accordance with this policy will be maintaining all original data submitted to the REB for an ethics review by the members, for a period of at least 15 years from the date of the last action taken on the file.

The REB Secretariat will be responsible to maintain:
- Copies of all research proposals reviewed by the REB
- Scientific evaluations, if any that accompanied the proposals
- Approved consent documents
- Progress reports submitted by the principal investigators
- Reports of injuries to participants
- Amendments, if any, to the research protocols, consent forms
- Minutes of the REB meetings with sufficient detail to show attendance at the meetings, actions taken by the REB, a written summary of the discussion of issues and their resolution
- Records of continuing review activities
- Copies of all correspondence between the REB, REB Secretariat, Office of the Assistant Deputy Minister and the principal investigators
- Up-to-date listing of all the REB membership
- Revise policy of the REB processes, as required.

Researchers are responsible for ensuring that all data is maintained in accordance with the confidentiality and security promised to the study participants. Researchers are responsible for being aware of any specific data retention requirements applicable to their particular research (e.g. funding agencies, Health Canada).

The REB Secretariat will maintain these records as specified above and will destroy these in accordance with the Library and Archives Canada’s Retention and Disposal Schedule.
Appendix A

The Guiding Principles of the *Tri-Council Policy Statement – Ethical Conduct for Research Involving Humans*

“*Respect for Human Dignity*: The cardinal principle of modern research ethics is respect for human dignity. This principle aspires to protecting the multiple and interdependent interests of the person — from bodily to psychological to cultural integrity. This principle forms the basis of the ethical obligations in research that are listed below.

In certain situations, conflicts may arise from application of these principles in isolation from one another. Researchers and Research Ethics Boards must carefully weigh all the principles and circumstances involved to reach a reasoned and defensible conclusion.

*Respect for Free and Informed Consent*: Individuals are generally presumed to have the capacity and right to make free and informed decisions. Respect for persons thus means respecting the exercise of individual consent. In practical terms within the ethics review process, the principle of respect for persons translates into the dialogue, process, rights, duties and requirements for free and informed consent by the research participant.

*Respect for Vulnerable Persons*: Respect for human dignity entails high ethical obligations towards vulnerable persons — to those whose diminished competence and/or decision-making capacity make them vulnerable. Children, institutionalized persons or others who are vulnerable are entitled, on grounds of human dignity, caring, solidarity and fairness, to special protection against abuse, exploitation or discrimination. Ethical obligations to vulnerable individuals in the research enterprise will often translate into special procedures to protect their interests.

*Respect for Privacy and Confidentiality*: Respect for human dignity also implies the principles of respect for privacy and confidentiality. In many cultures, privacy and confidentiality are considered fundamental to human dignity. Thus, standards of privacy and confidentiality protect the access, control and dissemination of personal information. In doing so, such standards help to protect mental or psychological integrity. They are thus consonant with values underlying privacy, confidentiality and anonymity.

*Respect for Justice and Inclusiveness*: Justice connotes fairness and equity. Procedural justice requires that the ethics review process have fair methods, standards and procedures for reviewing research protocols, and that the process be effectively independent. Justice also concerns the distribution of benefits and burdens of research. On the one hand, distributive justice means that no segment of the population should be unfairly burdened with the harms of research. It thus imposes particular obligations toward individuals who are vulnerable and unable to protect their own interests in order to ensure that they are not exploited for the advancement of knowledge. History has many chapters of such exploitation. On the other hand, distributive justice also imposes duties neither to neglect nor discriminate against individuals and groups who may benefit from advances in research.
Balancing Harms and Benefits: The analysis, balance and distribution of harms and benefits are critical to the ethics of human research. Modern research ethics, for instance, require a favourable harms-benefit balance — that is, that the foreseeable harms should not outweigh anticipated benefits. Harms-benefits analysis thus affects the welfare and rights of research participants, the informed assumption of harms and benefits, and the ethical justifications for competing research paths. Because research involves advancing the frontiers of knowledge, its undertaking often involves uncertainty about the precise magnitude and kind of benefits or harms that attend proposed research. These realities and the principle of respect for human dignity impose ethical obligations on the prerequisites, scientific validity, design and conduct of research. These concerns are particularly evident in biomedical and health research; in research they need to be tempered in areas such as political science, economics or modern history (including biographies), areas in which research may ethically result in the harming of the reputations of organizations or individuals in public life.

Minimizing Harm: A principle directly related to harms-benefits analysis is non-maleficence, or the duty to avoid, prevent or minimize harms to others. Research participants must not be subjected to unnecessary risks of harm, and their participation in research must be essential to achieving scientifically and socially important aims that cannot be realized without the participation of human participants. In addition, it should be kept in mind that the principle of minimizing harm requires that the research involve the smallest number of human participants and the smallest number of tests on these participants that will ensure scientifically valid data.

Maximizing Benefit: Another principle related to the harms and benefits of research is beneficence. The principle of beneficence imposes a duty to benefit others and, in research ethics, a duty to maximize net benefits. The principle has particular relevance for researchers in professions such as social work, education, health care and applied psychology. As noted earlier, human research is intended to produce benefits for participants themselves, for other individuals or society as a whole, or for the advancement of knowledge. In most research, the primary benefits produced are for society and for the advancement of knowledge.”
Appendix B

Articles included in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*

These articles outline the standards and procedures to be used by REBs for ethics review.

**Article 1.1**

a. All research that involves living human participants requires review and approval by an REB in accordance with this Policy Statement, before the research is started, except as stipulated below.

b. Research involving human remains, cadavers, tissues, biological fluids, embryos or foetuses should also be reviewed by the REB.

c. Research about a living individual involved in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, archival materials or third-party interviews, is not required to undergo ethics review. Such research only requires ethics review if the participant is approached directly for interviews or for access to private papers, and then only to ensure that such approaches are conducted according to professional protocols and to Article 2.3 of this Policy.

d. Quality assurance studies, performance reviews or testing within normal educational requirements should also not be subject to REB review.

**Article 1.2**

The institution in which research involving human participants is carried out shall mandate the REB to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human participants that is conducted within, or by members of, the institution, using the considerations set forth in this Policy as the minimum standard.

**Article 1.3**

The REB shall consist of at least five members, including both men and women, of whom:

a. At least two members have broad expertise in the methods or in the areas of research that are covered by the REB;

b. At least one member is knowledgeable in ethics;

c. For biomedical research, at least one member is knowledgeable in the relevant law; this is advisable but not mandatory for other areas of research; and

d. At least one member has no affiliation with the institution, but is recruited from the community served by the institution.
Article 1.4

a. REBs shall be established by the highest levels of the institution, and cover as broad a range of research as is consistent with manageable workloads. Departmental REBs normally are not acceptable (except as discussed below for review of undergraduate research within course requirements). A multiplicity of REBs with small workloads within the same institution should be avoided.

b. Large institutions may find it necessary to create more than one REB, usually to cover different areas of research. The jurisdiction of each REB should be clearly defined by the normal processes of governance within the institution, and a mechanism should be established to coordinate the practices of all REBs within the institution.

c. Small institutions may wish to explore regional cooperation or alliances, including the sharing of REBs.

Article 1.5

a. The REB shall satisfy itself that the design of a research project that poses more than minimal risk is capable of addressing the questions being asked in the research.

b. The extent of the review for scholarly standards that is required for biomedical research that does not involve more than minimal risk will vary according to the research being carried out.

c. Research in the humanities and the social sciences that poses, at most, minimal risk shall not normally be required by the REB to be peer reviewed.

d. Certain types of research, particularly in the social sciences and the humanities, may legitimately have a negative effect on public figures in politics, business, labour, the arts or other walks of life, or on organisations. Such research should not be blocked through the use of harms-benefits analysis or because of the potentially negative nature of the findings. The safeguard for those in the public arena is through public debate and discourse and, in extremis, through action in the courts for libel.

Article 1.6

The REB should adopt a proportionate approach based on the general principle that the more invasive the research, the greater should be the care in assessing the research.

Article 1.7

REBs shall meet regularly to discharge their responsibilities.
Article 1.8

Minutes of all REB meetings shall be prepared and maintained by the REB. The minutes shall clearly document the REB's decisions and any dissents, and the reasons for them. In order to assist internal and external audits or research monitoring, and to facilitate reconsideration or appeals, the minutes must be accessible to authorized representatives of the institution, researchers and funding agencies.

Article 1.9

REBs shall meet face-to-face to review proposed research that is not delegated to expedited review. REB review shall be based upon fully detailed research proposals or, where applicable, progress reports. The REB shall function impartially, provide a fair hearing to those involved and provide reasoned and appropriately documented opinions and decisions. The REB shall accommodate reasonable requests from researchers to participate in discussions about their proposals, but those researchers may not be present when the REB is making its decision. When an REB is considering a negative decision, it shall provide the researcher with all the reasons for doing so and give the researcher an opportunity to reply before making a final decision.

Article 1.10

Researchers have the right to request, and REBs have an obligation to provide, reconsideration of decisions affecting a research project.

Article 1.11

(a) In cases when researchers and REBs can not reach agreement through discussion and reconsideration, an institution should permit review of an REB decision by an appeal board, provided that the board's membership and procedures meet the requirements of this Policy. No ad hoc appeal boards are permitted.

(b) Small institutions may wish to explore regional cooperation or alliances, including the sharing of appeal boards. If two institutions decide to use each other's REB as an appeal board, a formal letter of agreement is required.

(c) The Agencies will not entertain any appeals of REB decisions.

Article 1.12

If an REB is reviewing research in which a member of the REB has a personal interest in the research under review (e.g., as a researcher or as an entrepreneur), conflict of interest principles require that the member not be present when the REB is discussing or making its decision. The REB member may disclose and explain the conflict of interest and offer evidence to the REB, provided the conflict is fully explained to the REB, and the proposer of the research has the right
to hear the evidence and to offer a rebuttal.

Article 1.13

a. Ongoing research shall be subject to continuing ethics review. The rigour of the review should be in accordance with a proportionate approach to ethics assessment.

b. As part of each research proposal submitted for REB review, the researcher shall propose to the REB the continuing review process deemed appropriate for that project.

c. Normally, continuing review shall consist of at least the submission of a succinct annual status report to the REB. The REB shall be promptly notified when the project concludes.

Article 1.14

Research to be performed outside the jurisdiction or country of the institution that employs the researcher shall undergo prospective ethics review both (a) by the REB within the researcher's institution; and (b) by the appropriate REB, where such exists, which has authority in the country or jurisdiction where the research is to be done.

Article 2.1

a. Research governed by this Policy (see Article 1.1) may begin only if (1) prospective participants, or authorized third parties, have been given the opportunity to give free and informed consent about participation, and (2) their free and informed consent has been given and is maintained throughout their participation in the research. Articles 2.1(c), 2.3 and 2.8 provide exceptions to Article 2.1(a).

b. Evidence of free and informed consent by the participant or authorized third party should ordinarily be obtained in writing. Where written consent is culturally unacceptable, or where there are good reasons for not recording consent in writing, the procedures used to seek free and informed consent shall be documented.

c. The REB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided that the REB finds and documents that:

   i. The research involves no more than minimal risk to the participants;

   ii. The waiver or alteration is unlikely to adversely affect the rights and welfare of the participants;

   iii. The research could not practicably be carried out without the waiver or alteration;

   iv. Whenever possible and appropriate, the participants will be provided with additional pertinent information after participation; and
v. The waived or altered consent does not involve a therapeutic intervention.

d. In studies including randomization and blinding in clinical trials, neither the research participants nor those responsible for their care know which treatment the participants are receiving before the project commences. Such research is not regarded as a waiver or alteration of the requirements for consent if participants are informed of the probability of being randomly assigned to one arm of the study or another.

Article 2.2

Free and informed consent must be voluntarily given, without manipulation, undue influence or coercion.

Article 2.3

REB review is normally required for research involving naturalistic observation. However, research involving observation of participants in, for example, political rallies, demonstrations or public meetings, should not require REB review since it can be expected that the participants are seeking public visibility.

Article 2.4

Researchers shall provide, to prospective participants or authorized third parties, full and frank disclosure of all information relevant to free and informed consent. Throughout the process of free and informed consent, the researcher must ensure that prospective participants are given adequate opportunities to discuss and contemplate their participation. Subject to the exception in Article 2.1(c), at the commencement of the process of free and informed consent, researchers or their qualified designated representatives shall provide prospective participants with the following:

a. Information that the individual is being invited to participate in a research project;

b. A comprehensible statement of the research purpose, the identity of the researcher, the expected duration and nature of participation, and a description of research procedures;

c. A comprehensible description of reasonably foreseeable harms and benefits that may arise from research participation, as well as the likely consequences of non-action, particularly in research related to treatment, or where invasive methodologies are involved, or where there is a potential for physical or psychological harm;

d. An assurance that prospective participants are free not to participate, have the right to withdraw at any time without prejudice to pre-existing entitlements, and will be given continuing and meaningful opportunities for deciding whether or not to continue to participate; and
e. The possibility of commercialization of research findings, and the presence of any apparent or actual or potential conflict of interest on the part of researchers, their institutions or sponsors.

In light of (b) and (c), REBs may require researchers to provide below:

| Table 1 |
|-----------------|------------------------------------------------------------------------------------------------|
| **Additional information that may be required for some projects** |
| 1. | An assurance that new information will be provided to the participants in a timely manner whenever such information is relevant to a participant's decision to continue or withdraw from participation; |
| 2. | The identity of the qualified designated representative who can explain scientific or scholarly aspects of the research; |
| 3. | Information on the appropriate resources outside the research team to contact regarding possible ethical issues in the research; |
| 4. | An indication of who will have access to information collected on the identity of participants, and descriptions of how confidentiality will be protected, and anticipated uses of data; |
| 5. | An explanation of the responsibilities of the participant; |
| 6. | Information on the circumstances under which the researcher may terminate the participant's participation in the research; |
| 7. | Information on any costs, payments, reimbursement for expenses or compensation for injury; |
| 8. | In the case of randomized trials, the probability of assignment to each option; |
| 9. | For research on biomedical procedures, including health care interventions; information about (a) foregoing alternative procedures that might be advantageous to the participant, (b) which aspects of the research involve the use of procedures that are not generally recognized or accepted; and, (c) particularly in trials of therapeutic interventions, the care provided if the potential participant decides not to consent to participation in the study; |
| 10. | The ways in which the research results will be published, and how the participants will be informed of the results of the research. |
Article 2.5

Subject to applicable legal requirements, individuals who are not legally competent shall only be asked to become research participants when:

a. the research question can only be addressed using the identified group(s); and
b. free and informed consent will be sought from their authorized representative(s); and
c. the research does not expose them to more than minimal risk without the potential for direct benefits for them.

Article 2.6

For research involving incompetent individuals, the REB shall ensure that, as a minimum, the following conditions are met:

a. The researcher shall show how the free and informed consent will be sought from the authorized third party, and how the participants' best interests will be protected.

b. The authorized third party may not be the researcher or any other member of the research team.

c. The continued free and informed consent of an appropriately authorized third party will be required to continue the participation of a legally incompetent participant in research, so long as the participant remains incompetent.

d. When a participant who was entered into a research project through third-party authorization becomes competent during the project, his or her informed consent shall be sought as a condition of continuing participation.

Article 2.7

Where free and informed consent has been obtained from an authorized third party, and in those circumstances where the legally incompetent individual understands the nature and consequences of the research, the researcher shall seek to ascertain the wishes of the individual concerning participation. The potential participant's dissent will preclude his or her participation.

Article 2.8

Subject to all applicable legislative and regulatory requirements, research involving emergency health situations shall be conducted only if it addresses the emergency needs of individuals involved, and then only in accordance with criteria established in advance of such research by the REB. The REB may allow research that involves health emergencies to be carried out without the free and informed consent of the participant or of his or her authorized third party if ALL of the following apply:
a. A serious threat to the prospective participant requires immediate intervention; and

b. Either no standard efficacious care exists or the research offers a real possibility of direct benefit to the participant in comparison with standard care; and

c. Either the risk of harm is not greater than that involved in standard efficacious care, or it is clearly justified by the direct benefits to the participant; and

d. The prospective participant is unconscious or lacks capacity to understand risks, methods and purposes of the research; and

e. Third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and

f. No relevant prior directive by the participant is known to exist.

When a previously incapacitated participant regains capacity, or when an authorized third party is found, free and informed consent shall be sought promptly for continuation in the project and for subsequent examinations or tests related to the study.

Article 3.1

Subject to the exceptions in Article 1.1(c), researchers who intend to interview a human participant to secure identifiable personal information shall secure REB approval for the interview procedure used and shall ensure the free and informed consent of the interviewee as required in Article 2.4. As indicated in Article 1.1c, REB approval is not required for access to publicly available information or materials, including archival documents and records of public interviews or performances.

Article 3.2

Subject to Article 3.1 above, researchers shall secure REB approval for obtaining identifiable personal information about participants. Approval for such research shall include such considerations as:

a. The type of data to be collected;

b. The purpose for which the data will be used;

c. Limits on the use, disclosure, and retention of the data;

d. Appropriate safeguards for security and confidentiality;

e. Any modes of observation (e.g., photographs or videos) or access to information (e.g., sound recordings) in the research that allow identification of particular participants;

f. Any anticipated secondary uses of identifiable data from the research;
g. Any anticipated linkage of data gathered in the research with other data about participants, whether those data are contained in public or personal records; and

h. Provisions for confidentiality of data resulting from the research.

**Article 3.3**

If identifying information is involved, REB approval shall be sought for secondary uses of data. Researchers may gain access to identifying information if they have demonstrated to the satisfaction of the REB that:

a. Identifying information is essential to the research;

b. They will take appropriate measures to protect the privacy of the individuals, to ensure the confidentiality of the data, and to minimize harms to participants; and

c. Individuals to whom the data refer have not objected to secondary use.

**Article 3.4**

The REB may also require that a researcher's access to secondary use of data involving identifiable information be dependent on:

a. The informed consent of those who contributed data or of authorized third parties; or

b. An appropriate strategy for informing the participants; or

c. Consultation with representatives of those who contributed data.

**Article 3.5**

Researchers who wish to contact individuals to whom data refer shall seek the authorization of the REB prior to contact.

**Article 3.6**

The implications of approved data linkage in which research participants may be identifiable shall be approved by the REB.

**Article 4.1**

Researchers and REB members shall disclose actual, perceived or potential conflicts of interest to the REB. REBs should develop mechanisms to address and resolve conflicts of interest.
Article 5.1

a. Where research is designed to survey a number of living research participants because of their involvement in generic activities (e.g., in many areas of health research, or in some social science research such as studies of child poverty or of access to legal clinics) that are not specific to particular identifiable groups, researchers shall not exclude prospective or actual research participants on the basis of such attributes as culture, religion, race, mental or physical disability, sexual orientation, ethnicity, sex or age, unless there is a valid reason for doing so.

b. This article is not intended to preclude research focused on a single living individual (such as in a biography) or on a group of individuals who share a specific characteristic (as in a study of an identifiable group of painters who happen to be all of one sex, colour or religion, or of a religious order that is restricted to one sex).

Article 5.2

Women shall not automatically be excluded from research solely on the basis of sex or reproductive capacity.

Article 5.3

Subject to the provisions in Articles 2.6 to 2.8, those who are not competent to consent for themselves shall not be automatically excluded from research that is potentially beneficial to them as individuals, or to the group that they represent.

Article 6

(None)

Article 7.1

Phase I non-therapeutic clinical trials shall undergo both stringent review and continuous monitoring by an REB independent of the clinical trials sponsor.

Article 7.2

In combined Phase I/II clinical trials, researchers and REBs shall carefully examine the integrity of the process of free and informed consent. Where appropriate, the REB may require an independent monitoring process.

Article 7.3

REBs shall examine the budgets of clinical trials to assure that ethical duties concerning conflict of interest are respected.
Article 7.4

The use of placebo controls in clinical trials is generally unacceptable when standard therapies or interventions are available for a particular participant population.

Article 8.1

The genetics researcher shall seek free and informed consent from the individual and report results to that individual if the individual so desires.

Article 8.2

The researcher and the REB shall ensure that the results of genetic testing and genetic counselling records are protected from access by third parties, unless free and informed consent is given by the participant. Family information in databanks shall be coded so as to remove the possibility of identification of participants within the bank itself.

Article 8.3

Researchers and genetic counsellors involving families and groups in genetic research studies shall reveal potential harms to the REB and outline how such harms will be dealt with as part of the research project.

Article 8.4

Genetics researchers and the REB shall ensure that the research protocol makes provision for access to genetic counselling for the participants, where appropriate.

Article 8.5

Gene alteration (including "gene therapy") that involves human germ-line cells or human embryos is not ethically acceptable. Gene alteration for therapeutic purposes and involving human somatic cells may be considered for approval.

Article 8.6

Though the banking of genetic material is expected to yield benefits, it may also pose potential harms to individuals, their families and the groups to which they may belong. Accordingly, researchers who propose research involving the banking of genetic material have a duty to satisfy the REB and prospective research participants that they have addressed the associated ethical issues, including confidentiality, privacy, storage, use of the data and results, withdrawal by the participant, and future contact of participants, families and groups.

Article 8.7
At the outset of a research project, the researcher shall discuss with the REB and the research participant the possibility and/or probability that the genetic material and the information derived from its use may have potential commercial uses.

**Article 9.1**

Researchers shall obtain free and informed consent from the individual whose gametes are to be used in research.

**Article 9.2**

In research, it is not ethical to use in research ova or sperm that have been obtained through commercial transactions, including exchange for service.

**Article 9.3**

It is not ethically acceptable to create, or intend to create, hybrid individuals by such means as mixing human and animal gametes, or transferring somatic or germ cell nuclei between cells of humans and other species.

**Article 9.4**

It is not ethically acceptable to create human embryos specifically for research purposes. However, in those cases where human embryos are created for reproductive purposes, and subsequently are no longer required for such purposes, research involving human embryos may be considered to be ethically acceptable, but only if all of the following apply:

a. The ova and sperm from which they were formed are obtained in accordance with Articles 9.1 and 9.2;

b. The research does not involve the genetic alteration of human gametes or embryos;

c. Embryos exposed to manipulations not directed specifically to their ongoing normal development will not be transferred for continuing pregnancy; and

d. Research involving human embryos takes place only during the first 14 days after their formation by combination of the gametes.

**Article 9.5**

It is not ethically acceptable to undertake research that involves ectogenesis, cloning human beings by any means including somatic cell nuclear transfer, formation of animal/human hybrids, or the transfer of embryos between humans and other species.

**Article 10.1**
Research proposing the collection and use of human tissues requires ethics review by an REB. Among other things, the researcher shall demonstrate the following to the REB:

a. That the collection and use of human tissues for research purposes shall be undertaken with the free and informed consent of competent donors;

b. In the case of incompetent donors, free and informed consent shall be by an authorized third party;

c. In the case of deceased donors, free and informed consent shall be expressed in a prior directive or through the exercise of free and informed consent by an authorized third party.

Article 10.2

For the purpose of obtaining free and informed consent, researchers who seek to collect human tissue for research shall, as a minimum, provide potential donors or authorized third parties information about:

a. The purpose of the research;

b. The type and amount of tissue to be taken, as well as the location where the tissue is to be taken;

c. The manner in which tissue will be taken, the safety and invasiveness of acquisition, and the duration and conditions of preservation;

d. The potential uses for the tissue including any commercial uses;

e. The safeguards to protect the individual's privacy and confidentiality;

f. Identifying information attached to specific tissue, and its potential traceability; and

g. How the use of the tissue could affect privacy.

Article 10.3

a. When identification is possible, researchers shall seek to obtain free and informed consent from individuals, or from their authorized third parties, for the use of their previously collected tissue. The provisions of Article 10.2 also apply here.

b. When collected tissue has been provided by persons who are not individually identifiable (anonymous and anonymized tissue), and when there are no potential harms to them, there is no need to seek donors' permission to use their tissue for research purposes, unless applicable law so requires.
Summary of Articles from the Canadian Institutes of Health Research (CIHR) - Guidelines for Health Research involving Aboriginal People

Ethical principles of Aboriginal health research and the CIHR Guidelines on Aboriginal people need to be understood in the context of Aboriginal concepts such as sacred space, sacred knowledge and traditional knowledge, as described below. This may mean that ethical principles familiar to the researcher, such as autonomy, beneficence and justice, would need to be adjusted to harmonize with the values and beliefs of the Aboriginal Community involved.

Protecting Aboriginal ethical space involves a series of stages of dialogue beginning with the conversations prior to the design of the research, through to the dissemination of results and perhaps even afterward. This requires a dialogue about intentions, values and assumptions throughout the research process.

A summary of these articles are provided for ease of reference:

**Article 1**
A researcher should understand and respect Aboriginal world views, including responsibilities to the people and culture that flow from being granted access to traditional or sacred knowledge. These should be incorporated into research agreements, to the extent possible.

The first principle of these Guidelines is premised on a need for researchers to understand and respect Aboriginal world views, particularly when engaging in the sphere of traditional and sacred knowledge, and the corresponding responsibility that possession of such knowledge entails. Researchers should understand the broader senses of accountability in order to understand the responsibility they have when entering into a research relationship with Aboriginal people.

**Article 2**
A community's jurisdiction over the conduct of research should be understood and respected. This article should be read in the context of the discussion in Section 1.5, which addresses the application of this document.

Some Aboriginal communities manage and control matters dealing with health. Where this is the case, a researcher should comply with any by-laws, policies, rules or procedures adopted by the community. For example, an Aboriginal community may have its own Research Ethics Board and/or community research protocols.

**Article 3**
Communities should be given the option of a participatory-research approach.

Genuine research collaboration is developed between researchers and Aboriginal communities when it promotes partnership within a framework of mutual trust and cooperation. Participatory research enables a range of levels and types of community participation while ensuring shared power and decision-making. Such partnerships will help to ensure that research proceeds in a manner that is culturally sensitive, relevant, respectful, responsive, equitable and reciprocal,
with regard to the understandings and benefits shared between the research partner(s) and Aboriginal community(ies).

**Article 4**

A researcher who proposes to carry out research that touches on traditional or sacred knowledge of an Aboriginal community, or on community members as Aboriginal people, should consult the community leaders to obtain their consent before approaching community members individually. Once community consent has been obtained, the researcher will still need the free, prior and informed consent of the individual participants.

A process to obtain the free, prior and informed consents from both the community affected and its individual participants should be undertaken sufficiently in advance of the proposed start of research activities and should take into account the community's own legitimate decision-making processes, regarding all the phases of planning, implementation, monitoring, assessment, evaluation and wind-up of a research project. The requirement for community consent is distinct from the obligation of researchers to obtain individual consent from research participants.

**Article 5**

Concerns of individual participants and their community regarding anonymity, privacy and confidentiality should be respected, and should be addressed in a research agreement.

The researcher, the individual participants and the community should have a clear prior understanding as to their expectations with regard to the anonymity of the community and of the individuals participating in the research project, and the extent to which research data and results will remain confidential to the researcher. If anonymity is not possible, or if there are necessary limitations to anonymity or confidentiality, these should be clearly communicated.

**Article 6**

The research agreement should, with the guidance of community knowledge holders, address the use of the community's cultural knowledge and sacred knowledge.

**Article 7**

Aboriginal people and their communities retain their inherent rights to any cultural knowledge, sacred knowledge, and cultural practices and traditions, which are shared with the researcher. The researcher should also support mechanisms for the protection of such knowledge, practices and traditions.

Any research involving Aboriginal people will involve the sharing of some cultural knowledge, practices and/or traditions even when these are not the participants of the study, as they provide necessary context. The recording of knowledge, practices and traditions in any form (written notes, audio, video, or otherwise) should only be done with explicit permission and under mutually-agreed terms that are set out in advance of the research with the guidance of appropriate Elders and knowledge holders. All uses and wider dissemination of cultural knowledge, practices and traditions should also be by permission.

**Article 8**

Community and individual concerns over, and claims to, intellectual property should be explicitly acknowledged and addressed in the negotiation with the community prior to starting the research project. Expectations regarding intellectual property rights of all parties involved in
the research should be stated in the research agreement.

Not all information and knowledge can be protected by existing intellectual property laws, given the strict eligibility criteria defining these legal rights. Understanding and communicating what does and does not qualify as intellectual property under current Canadian and international laws is the joint responsibility of the researcher and communities involved. Research with explicit commercial objectives and/or direct or indirect links to the commercial sector should be clearly communicated to all research partners.

Article 9  
Research should be of benefit to the community as well as to the researcher.

A research project should lead to outcomes that are beneficial to the participating Aboriginal community and/or individual community members. Benefit sharing vis-à-vis a community should be interpreted from the community's perspective. This may include tangible and intangible benefits, including those arising from altruism.

Article 10  
A researcher should support education and training of Aboriginal people in the community, including training in research methods and ethics.

Researchers should work to foster capacity building among Aboriginal people to enhance their participation in research projects and improve the overall interactions between Aboriginal governance mechanisms and public educational institutions.

Article 11.1  
A researcher has an obligation to learn about, and apply, Aboriginal cultural protocols relevant to the Aboriginal community involved in the research.

Article 11.2  
A researcher should, to the extent reasonably possible, translate all publications, reports and other relevant documents into the language of the community.

Article 11.3  
A researcher should ensure that there is ongoing, accessible and understandable communication with the community.

Aboriginal communities often have cultural protocols involving interactions within the community. It is important that researchers learn about these and respect them. When providing a research project report to the community, the researcher should, at a minimum, provide an executive summary in the language of the community unless the community has expressly waived this. The reports or other communications of results should use language and terminology that are readily understood by the community.

Article 12.1  
A researcher should recognize and respect the rights and proprietary interests of individuals and the community in data and biological samples generated or taken in the course of the research.

Article 12.2  
Transfer of data and biological samples from one of the original parties to a research agreement, to a third party, requires consent of the other original party(ies).

Article 12.3  
Secondary use of data or biological samples requires specific consent from the individual donor and, where appropriate, the community. However, if
the research data or biological samples cannot be traced back to the individual donor, then consent for secondary use need not be obtained from the individual. Similarly, if research data or biological samples cannot be traced back to the community, then its consent for secondary use is not required.

Article 12.4 Where the data or biological samples are known to have originated with Aboriginal people, the researcher should consult with the appropriate Aboriginal organizations before initiating secondary use.

Article 12.5 Secondary use requires REB review.

These guidelines set out basic principles for the collection, disclosure, use and transfer of data and biological samples. The details of safeguards protecting the privacy and confidentiality of data and biological samples should be negotiated as part of the research process and specified in a research agreement. Subject to the community's views on traditional or sacred knowledge, co-ownership of data between researchers and communities is recommended because the Aboriginal community and the researcher are both integral to the production of data.

If there is to be transfer of data or biological samples to a third party, this should be done only with the consent of the researcher, the individual participants and the community. If the third party is to engage in secondary use of the transferred data or biological samples, then a further consent to that use must be obtained. The consent should address how confidentiality and privacy will be respected.

In any case, secondary use of data or biological samples requires new consent unless such use is specifically agreed to in the research agreement. Notwithstanding the above, individuals retain the right to access data about themselves.

In cases where the research is a governmental activity, other standards for protecting privacy may apply, flowing, for example, from the Canadian Charter of Rights and Freedoms or privacy legislation.

Article 13 Biological samples should be considered "on loan" to the researcher unless otherwise specified in the research agreement.

Subject to the terms of the research agreement with their community, biological samples from Aboriginal participants should be considered "on loan" to the researcher, analogous to a licensing arrangement, and this should be detailed in the research agreement.

Article 14 An Aboriginal community should have an opportunity to participate in the interpretation of data and the review of conclusions drawn from the research to ensure accuracy and cultural sensitivity of interpretation.

Research involving Aboriginal people is susceptible to misinterpretation or misrepresentation when information about the group is analyzed without sufficient consideration of other cultural characteristics that make the group distinct.

The opportunity for review of research results by the Aboriginal community should be provided before the submission of research findings for publication, to ensure that sensitive information is not inappropriately divulged to the public and that errors are corrected prior to
wider dissemination.
This should not be construed as the right to block the publication of legitimate findings; rather, it refers to the community’s opportunity to contextualize the findings and correct any cultural inaccuracies.

**Article 15** An Aboriginal community should, at its discretion, be able to decide how its contributions to the research project should be acknowledged. Community members are entitled to due credit and to participate in the dissemination of results. Publications should recognize the contribution of the community and its members as appropriate, and in conformity with confidentiality agreements.

A sample research agreement and charts describing the step-by-step procedures of the research process are included as preliminary guides in Section III and in the Appendix.
Appendix D

Definitions

**Coded samples:** Sometimes termed “linked” or “identifiable,” these samples are supplied by repositories to investigators from identified specimens with a code rather than with personal identifiable information, such as a name or Social Insurance Number (SIN).

**Genetic material:** any human biological material containing functional units of heredity.

**Identified samples:** These samples are supplied by repositories from identified specimens with a personal identifier (such as a name or participant number) that would allow the researcher to link the biological information derived from the research directly to the individual from whom the material was obtained.

**Unidentified samples:** Sometime termed “anonymous”, these samples are supplied by repositories to investigators from a collection of unidentified human biological specimens.

**Unlinked samples:** Sometime termed “anonymized”, these samples lack identifiers or codes that can link a particular sample to an identified specimen or a particular human being.

**Human biological material:** consists of the human body and its parts – tissue and fluids of the human body – obtained from living and nonliving participants, with the exception of human gametes, human embryos, foetuses and foetal tissue.

**Prisoner:** an individual confined or detained in a penal institution.

**Third party:** a person, group or company besides the two primarily involved in the research project. If a third party is mentioned in the protocol, there is a need for the Principal Investigator to inform the REB that a third party is being identified in the research project.
Aboriginal Guidelines

The Canadian Institutes of Health Research Guidelines for Health Research Involving Aboriginal People