TRI-COUNCIL POLICY STATEMENT

Ethical Conduct for Research Involving Humans

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Canadian Institutes of Health Research
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Chapter 2

SCOPE AND APPROACH

Introduction

The purpose of this Policy, as set out in Chapter 1, is to establish principles to guide the design, ethical conduct and ethics review process of research involving humans. This chapter outlines the scope of application of the Policy and the approach to research ethics review that flows from the core principles – Respect for Persons, Concern for Welfare, and Justice. The preferred approach to research ethics review is a proportionate approach. The research ethics board (REB) tailors the level of scrutiny by an REB to the level of risk presented by the research, and assesses the ethical acceptability of the research through consideration of the foreseeable risks, the potential benefits and the ethical implications of the research, both at the stage of the initial REB review and throughout the life of the project (continuing ethics review). The establishment, governance, jurisdiction and composition of REBs, and operational issues related to their functioning are addressed in Chapter 6.

A. Scope of Research Ethics Review

Research Requiring REB Review

The following article defines the general categories of research that require REB review in accordance with this Policy, subject to the exceptions set out further on in this Policy. These exceptions are distinct from research that is exempt from REB review, as described in Articles 2.2 to 2.4.

Article 2.1 The following requires ethics review and approval by an REB before the research commences:

(a) research involving living human participants;

(b) research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

Application The scope of this Policy is restricted to the review of the ethical conduct of research involving humans. The scope of REB review is limited to those activities defined in this Policy as “research” involving “human participants.”

For the purposes of this Policy, “research” is defined as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.

A determination that research is the intended purpose of the undertaking is key for differentiating activities that require ethics review by an REB and those that do not.
For the purposes of this Policy, “human participants” (referred to as “participants”) are those individuals whose data, or responses to interventions, stimuli or questions by the researcher, are relevant to answering the research question.

Human participants are unique among the many parties involved in research, because they bear the primary risks of the research. These individuals are often referred to as “research subjects.” This Policy prefers the term “participant” because it better reflects the spirit behind the core principles: that individuals who choose to participate in research play a more active role than the term “subject” conveys. As well, it reflects the range of research covered by this Policy, and the varied degree of involvement by participants – including the use of their data or human biological materials – that different types of research offer. The core principles of this Policy – Respect for Persons, Concern for Welfare, and Justice – help to shape the relationship between researchers and participants.

Where researchers seek to collect, use, share and access different types of information or data about participants, they are expected to determine whether the information or data proposed in research may reasonably be expected to identify an individual. For the purposes of this Policy, researchers and REBs shall consider whether information is identifiable or non-identifiable. Information is identifiable if it, alone or when combined with other available information, may reasonably be expected to identify an individual. The term “personal information” generally denotes identifiable information about an individual. Guidance on the assessment of the potential for information to identify an individual is addressed in this Policy in Chapter 5, Section A.

In some cases, research may involve interaction with individuals who are not themselves the focus of the research in order to obtain information. For example, one may collect information from authorized personnel to release information or data in the ordinary course of their employment about organizations, policies, procedures, professional practices or statistical reports. Such individuals are not considered participants for the purposes of this Policy. This is distinct from situations where individuals are considered participants because they are themselves the focus of the research. For example, individuals who are asked for their personal opinions about organizations, or who are observed in their work setting for the purposes of research, are considered participants.

For the purposes of this Policy, human biological materials include tissues, organs, blood, plasma, serum, DNA, RNA, proteins, cells, skin, hair, nail clippings, urine, saliva and other body fluids. Materials related to human reproduction include embryos, fetuses, fetal tissues and human reproductive materials. Embryo means a human organism during the first 56 days of its development following fertilization or creation, excluding any time during which its development has been suspended, and includes any cell derived from such an organism that is used for the purpose of creating a human being. Fetus means a human organism during the period of its development beginning on the 57th day following fertilization or creation, excluding
any time during which its development has been suspended, and ending at birth. Fetal tissue includes membranes, placenta, umbilical cord, amniotic fluid and other tissue that contains genetic information about the fetus. Human reproductive materials mean a sperm, ovum or other human cell, or a human gene, as well as a part of any of them. The term “human biological materials” may be considered, for the purposes of this Policy, to include materials related to human reproduction. The last section of Chapter 12 discusses ethical issues specific to these materials.\(^1\)

When in doubt about the applicability of this Policy to a particular research project, the researcher shall seek the opinion of the REB. The REB makes the final decision on exemption from research ethics review.

**Research Exempt from REB Review**

Some research is exempt from REB review where protections are available by other means. This Policy allows the following exemptions from the requirement for REB review, as outlined below.

**Article 2.2** Research that relies exclusively on publicly available information does not require REB review when:

(a) the information is legally accessible to the public and appropriately protected by law; or

(b) the information is publicly accessible and there is no reasonable expectation of privacy.

**Application** For the purposes of this Policy, publicly available information is any existing stored documentary material, records or publications, which may or may not include identifiable information. Some types of information are legally accessible to the public in a certain form and for a certain purpose, as specified by law or regulations: registries of deaths, court judgments, or public archives and publicly available statistics (e.g., Statistics Canada public use files), for example. In Canada, all publicly available archives (national, provincial or municipal) have policies governing access to their records. An archival record or database that is subject to restrictions, such as those under access to information and privacy legislation or contractual restrictions imposed by the donor of the records, may also be considered publicly available for the purposes of this Policy.

Research that relies exclusively on information that is publicly available, or made accessible through legislation or regulation, does not require REB review. Exemption from REB review for research involving information that is legally accessible to the public is based on the presence of a legally designated custodian/steward who protects its privacy and proprietary interests (e.g., an access to information and privacy coordinator or a guardian of Canadian census data).

REB review is also not required where research uses exclusively publicly available information that may contain identifiable information, and for which there is no
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reasonable expectation of privacy. For example, identifiable information may be disseminated in the public domain through print or electronic publications; film, audio or digital recordings; press accounts; official publications of private or public institutions; artistic installations, exhibitions or literary events freely open to the public; or publications accessible in public libraries. Research that is non-intrusive, and does not involve direct interaction between the researcher and individuals through the Internet, also does not require REB review. Cyber-material such as documents, records, performances, online archival materials or published third party interviews to which the public is given uncontrolled access on the Internet for which there is no expectation of privacy is considered to be publicly available information.

Exemption from REB review is based on the information being accessible in the public domain, and that the individuals to whom the information refers have no reasonable expectation of privacy. Information contained in publicly accessible material may, however, be subject to copyright and/or intellectual property rights protections or dissemination restrictions imposed by the legal entity controlling the information.

However, there are situations where REB review is required.

There are publicly accessible digital sites where there is a reasonable expectation of privacy. When accessing identifiable information in publicly accessible digital sites, such as Internet chat rooms, and self-help groups with restricted membership, the privacy expectation of contributors of these sites is much higher. Researchers shall submit their proposal for REB review (see Article 10.3).

Where data linkage of different sources of publicly available information is involved, it could give rise to new forms of identifiable information that would raise issues of privacy and confidentiality when used in research, and would therefore require REB review (see Article 5.7).

When in doubt about the applicability of this article to their research, researchers should consult their REBs.

Article 2.3 REB review is not required for research involving the observation of people in public places where:

(a) it does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups;

(b) individuals or groups targeted for observation have no reasonable expectation of privacy; and

(c) any dissemination of research results does not allow identification of specific individuals.
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Application For the purposes of this article, observational research is used to study acts or behaviour in a natural environment. It does not refer to observational methods used in epidemiological studies.

When designing their research, researchers shall pay attention to the environment in which observation takes place, the expectation of privacy that individuals in public places might have, and the means of recording observations. Researchers shall also determine whether the use of this information in the dissemination of research results (e.g., through publications, photographs, audio recordings, or video footage of groups or particular individuals) will allow the identification of individuals observed in public places. When in doubt, researchers should consult the REB prior to the conduct of such research. Article 10.3 addresses observational studies in qualitative research.

Article 2.4 REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information.

Application Secondary use refers to the use in research of information or human biological materials originally collected for a purpose other than the current research purpose. Anonymous information and human biological materials are distinct from those that have been coded, and also from those that have been anonymized (see Section A of Chapters 5 and 12).

Rapid technological advances facilitate identification of information and make it harder to achieve anonymity. These activities may heighten risks of identification and possible stigmatization where a dataset contains information about or human biological materials from a population in a small geographical area, or information about individuals with unique characteristics (e.g., uncommon field of occupational specialization, diagnosis with a very rare disease). Where the researcher seeks data linkage of two or more anonymous sets of information or human biological materials and there is a reasonable prospect that this could generate identifiable information, then REB review is required.

Guidance related to other categories of identifiable and non-identifiable information and human biological materials and their possible secondary use is provided in Chapters 5 and 12.

Activities Not Requiring REB Review

The following distinguishes research requiring REB review from non-research activities that have traditionally employed methods and techniques similar to those employed in research. Such activities are not considered “research” as defined in this Policy, and do not require REB review. Activities outside the scope of research subject to REB review (see Articles 2.5 and 2.6), as defined in this Policy, may still raise ethical issues that would benefit from careful consideration by an individual or a body capable of providing some independent guidance, other than an REB. These
ethics resources may be based in professional or disciplinary associations, particularly where those associations have established best practices guidelines for such activities in their discipline.

**Article 2.5** Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this Policy, and do not fall within the scope of REB review.

**Application** Article 2.5 refers to assessments of the performance of an organization or its employees or students, within the mandate of the organization, or according to the terms and conditions of employment or training. Those activities are normally administered in the ordinary course of the operation of an organization where participation is required, for example, as a condition of employment in the case of staff performance reviews, or an evaluation in the course of academic or professional training. Other examples include student course evaluations, or data collection for internal or external organizational reports. Such activities do not normally follow the consent procedures outlined in this Policy.

If data are collected for the purposes of such activities but later proposed for research purposes, it would be considered secondary use of information not originally intended for research, and at that time may require REB review in accordance with this Policy. Refer to Section D of Chapter 5 for guidance concerning secondary use of identifiable information for research purposes.

**Article 2.6** Creative practice activities, in and of themselves, do not require REB review. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to REB review.

**Application** Creative practice is a process through which an artist makes or interprets a work or works of art. It may also include a study of the process of how a work of art is generated. Creative practice activities do not require REB review, but they may be governed by ethical practices established within the cultural sector.

**Relationship between Research Ethics Review and Scholarly Review**

**Article 2.7** As part of research ethics review, the REB shall review the ethical implications of the methods and design of the research.

**Application** The primary test to be used by REBs in evaluating a research project should be ethical acceptability and, where appropriate, relevant disciplinary scholarly standards.

Traditions for scholarly review vary among disciplines or fields of research, including the stage at which scholarly review occurs, and this needs to be taken into account by REBs. The extent of the scholarly review that is required for biomedical research that does not involve more than minimal risk will vary
according to the research being carried out. 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.

REBs should normally avoid duplicating previous professional peer-review assessments unless there is a good and defined reason to do so. It is to be noted that for specific types of research (e.g., clinical trials) REBs should respect the relevant guidelines that require REBs to evaluate the scientific aspects of the research as part of their research ethics review.

Researchers have a role to play in demonstrating to their REB whether, when and how appropriate scholarly review has been or will be undertaken for their research. REBs may request that the researcher provide them with the full documentation of scholarly reviews already completed.

Where scholarly review is required,

• an REB should consider what scholarly review has been applied to a particular research project (e.g., by a funder or sponsor, or for student research by the research supervisor or thesis committee, or by a permanent peer review committee where it exists);

• if scholarly review as indicated by the relevant disciplinary tradition has not yet been done, and there is no body available to do it, the REB should consider the following mechanisms in satisfying itself that scholarly review of the research is completed:

  - establish an ad hoc independent peer review committee;

  - if the REB has the necessary scholarly expertise, assume complete responsibility for the scholarly review. In assuming this responsibility, the REB should not be driven by factors such as personal biases or preferences, and should not reject proposals because they are controversial, challenge mainstream thought, or offend powerful or vocal interest groups.

**REB Review Shall Be Continuing**

**Article 2.8** Following initial REB review and approval, research ethics review shall continue throughout the life of the project in accordance with Article 6.14.

**Application** The primary goal of REB review is to ensure the ethical acceptability of research involving humans that falls within the scope of this Policy. Following the initial REB review and approval, the ethics review shall continue to ensure that all stages of a research project are ethically acceptable in accordance with the principles of this Policy.

Continuing ethics review by an REB provides those involved in the research process (in particular, researchers and REBs) with multiple opportunities to reflect
on the ethical issues surrounding the research. This reflection can show whether the stated risks, or other unknown risks, were incurred and how they affected the individual and collective welfare of participants. This reflective practice is intended to enable both researchers and REBs to be more effective in protecting participants in current and future research. This practice is especially important in new and emerging fields, where the ethical implications are not yet well understood. Here, reflection should involve an ongoing dialogue among REBs and researchers, as appropriate, to enable the practices surrounding research ethics to evolve as needed to comply with the principles of this Policy.

In the conduct of their approved research, should unanticipated issues arise that may increase the level of risk or have other ethical implications, researchers shall report them to their REB in a timely manner. Researchers shall also submit to their REBs in a timely manner requests for changes to their approved research. Further details are provided in Articles 6.14 to 6.16.

**B. Approach to REB Review**

This section introduces the concepts of risks and potential benefits of research (including a definition of minimal risk), as well as their balance in research ethics review and the conduct of research. It describes the proportionate approach to REB review: The REB tailors its level of scrutiny to the level of risk presented by the research, and assesses the ethical acceptability of the research through consideration of the foreseeable risks, the potential benefits and the ethical implications of the research, both at the stage of the initial review and throughout the life of the project (continuing ethics review).

**Concepts of Risks and Potential Benefits**

*Potential Benefits*

Research involving humans may produce benefits that positively affect the welfare of society as a whole through the advancement of knowledge for future generations, for participants themselves or for other individuals. However, much research offers little or no direct benefit to participants. In most research, the primary benefits produced are for society and for the advancement of knowledge.

*Risks*

Because research is a step into the unknown, its undertaking can involve harms to participants and to others. Harm is anything that has a negative effect on the welfare of participants, and the nature of the harm may be social, behavioural, psychological, physical or economic.

Risk is a function of the magnitude or seriousness of the harm, and the probability that it will occur, whether to participants or to third parties (as outlined below). A proper ethical analysis of research should consider both the foreseeable risk and the available methods of eliminating or mitigating the risk.
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- **The magnitude or seriousness of the harm**

Potential harms in research may span the spectrum from minimal (e.g., inconvenience of participation in research) to substantial (e.g., a major physical injury or an emotional trauma). Harms may be transient, such as a temporary emotional reaction to a survey question, while other types of harm may be longer lasting, such as the loss of reputation following a breach of confidentiality, or a traumatic experience. The perspective of the participants regarding harm may vary from that of researchers. Participants themselves may vary in their reaction to the research. Researchers and REBs should attempt to assess the harm from the perspective of the participants to the extent possible. Research in certain disciplines, such as epidemiology, genetics, sociology or cultural anthropology, may present risks that go beyond the individual and may involve the interests of communities, societies or other defined groups.

- **The probability of occurrence of the harm**

This refers to the likelihood of participants actually suffering the relevant harms. An assessment of such probability may be based on the researcher’s past experience conducting such studies, the review of existing publications that provide rates of the relevant harms in similar issues, or on other empirical evidence. And while researchers should attempt to estimate the occurrence of the relevant harms, this may be more difficult, or not possible, for new or emerging areas of research where no prior experience, comparable research or publications exist.

Certain accepted research paradigms bring inherent limitations to the prior identification of risk. For example, when research in the social sciences employs emergent design, the manner in which the research project will proceed and any associated risks may be known only as it unfolds (see Chapters 3 and 10).

**Minimal Risk**

Minimal risk research that falls within the scope of this Policy requires REB review. It is generally eligible for delegated review – described in Article 6.12.

For the purposes of this Policy, “minimal risk” research is defined as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.

In their assessment of the acceptable threshold of minimal risk, REBs have special ethical obligations to individuals or groups whose situation or circumstances make them vulnerable in the context of a specific research project, and to those who live with relatively high levels of risk on a daily basis. Their inclusion in research should not exacerbate their vulnerability (see Article 4.7).
Balancing Risks and Potential Benefits

The analysis, balance, and distribution of risks and potential benefits are critical to the ethics of research involving humans. The principle of Concern for Welfare imposes an ethical obligation to design, assess and conduct research in a way that protects participants from any unnecessary or avoidable risks. In their review, REBs should be concerned with an assessment that the potential research outcomes and potential benefits merit the risks.

Risks and potential benefits may be perceived differently by different individuals and groups in society. Researchers and REBs should take this into account in designing and reviewing research. They should also recognize that researchers and participants may not always see the risks and potential benefits of a research project in the same way. In assessing risks and potential benefits for specific populations, researchers and REBs should understand the role of the culture, values and beliefs of the populations to be studied. In this regard REBs may consult ad hoc advisors as needed. Researchers and REBs may also consult guidelines that exist for conducting research with these populations (see Chapters 8, 9 and 10). Researchers shall demonstrate to their REBs that they have a reasonable understanding of the culture, values and beliefs of the population to be studied, and the likely effects of their research upon them. This could be demonstrated, for example, by referring to previous experience with conducting research with a similar population, or by presenting feedback from a community advisory group.

Article 2.9  The REB shall adopt a proportionate approach to research ethics review such that, as a preliminary step, the level of review is determined by the level of risk presented by the research: the lower the level of risk, the lower the level of scrutiny (delegated review); the higher the level of risk, the higher the level of scrutiny (full board review). A proportionate approach to assessing the ethical acceptability of the research, at either level of review, involves consideration of the foreseeable risks, the potential benefits and the ethical implications of the research.

Application  The proportionate approach to REB review encompasses both the initial assessment of the level of risk to participants posed by a research project – used to determined the level of review (i.e., delegated or full REB review [see Articles 6.11 to 6.17]) – and the approach to the actual review of the research project itself. While all research shall be reviewed in light of the core principles of this Policy, the proportionate approach to REB review is intended to direct the most intensive scrutiny, time and resources, and correspondingly, the most protection, to the most ethically challenging research.

A proportionate approach to research ethics review starts with an assessment of the magnitude and probability of harms. Minimal risk research should normally receive delegated review and above-minimal risk research shall receive full REB review. Whether the review is delegated, full-board, initial or continuing, foreseeable risks and potential benefits should be considered as well as the ethical implications of the research. The proportionate approach to REB review requires that a project
have a favourable balance of risks and benefits in order to receive REB approval. The REB should make this assessment in light of the context of the research – that is, elements of the research that may produce benefits or harms, or otherwise have an impact on the ethics of research. Regardless of the level of review selected, the review should include the necessary expertise.

Both risks and potential benefits may span the spectrum from minimal to substantial. The concept of minimal risk (described above) provides a foundation for the proportionate approach to REB review. The various applications of the proportionate approach to REB review are addressed in Article 6.12.

**Risks to Researchers**

Risks in research are not limited to participants. In their conduct of research, researchers themselves may be exposed to risks that may take many forms (e.g., injury, incarceration). Risks to researchers may become a safety concern, especially for student researchers who are at a learning stage regarding the conduct of research, and who may be subject to pressures from supervisors to conduct research in unsafe situations.

While it is not a formal part of its responsibilities, an REB may raise concerns about the safety of student researchers as part of its communication to the student researchers, and to their supervisors. Based on the level of risk, the REB may consider referring these concerns for review by an appropriate body within the institution.

**Endnotes**


Chapter 6

GOVERNANCE OF RESEARCH ETHICS REVIEW

Introduction

This chapter sets out the elements of research ethics review including the procedures necessary to establish a research ethics board (REB), and operational guidelines for the REBs and research ethics review, both initially and throughout the course of the research project. It also includes guidelines for the conduct of research ethics review during publicly declared emergencies.

A key goal in establishing an appropriate governance structure for research ethics review is to ensure that REBs operate with a clear mandate, authority and accountability; and that roles and responsibilities are clearly defined. REBs need independence in their decision-making process to carry out their role effectively, and to properly apply the core principles of this Policy – Respect for Persons, Concern for Welfare and Justice – to their ethics review of research projects. These operational guidelines are meant to be flexible enough to apply in various contexts, at institutions of various sizes, and to the full range of research disciplines, fields and methodologies.

A. Establishment of Research Ethics Boards

Authority, Mandate and Accountability

Article 6.1 Institutions shall establish or appoint REB(s) to review the ethical acceptability of all research involving humans conducted within their jurisdiction or under their auspices, that is, by their faculty, staff or students, regardless of where the research is conducted, in accordance with this Policy.

Application Each institution is accountable for the research carried out in its own jurisdiction or under its auspices. In fulfilling this responsibility, where research involving humans takes place within the jurisdiction or under the auspices of an institution, that institution shall establish the necessary structure of an REB (or REBs) capable of reviewing the ethical acceptability of that research. In fulfilling this responsibility, institutions may opt to appoint an external REB in accordance with the Memorandum of Understanding between the Agencies and institutions. Any such appointment should be based on an official agreement clarifying the ultimate responsibility of the institution for the ethical acceptability of research undertaken within its jurisdiction or under its auspices. To demonstrate their accountability, institutions may wish to issue public reports summarizing the institution’s activities and initiatives relevant to the ethics review of research involving humans, its research ethics administration, and relevant research ethics education and training.

The number of REBs and the expertise of their members will depend on the range and volume of research for which that institution is responsible, in accordance with
Articles 6.4 and 6.5 relating to REB composition. Large institutions may find it necessary to create more than one REB to cover different areas of research or to accommodate a large volume of research. Small institutions may wish to explore regional cooperation or alliances for access to an REB based on formal agreements between the institutions (see Article 8.1).

Members of an institution (i.e., its faculty, staff and students) may be affiliated with other institutions, or may be engaged in consulting or other professional activities in a separate enterprise, or in student co-op work or field placements. If members of the institution make reference to their affiliation to the institution, or use any of its resources when engaging in research, they should submit their research proposal to their institutional REB for research ethics review in accordance with this Policy. Where student co-op work or field placements involve components of research that require research ethics review, institutions and organizations hosting co-op student researchers may consider specifying in advance (e.g., in policies, agreements or contracts for co-op student placements) the roles and responsibilities pertaining to the ethics review of research involving humans of the host organization versus those of the institution.

Should the institution determine that some situations warrant an exception to the requirement for REB review, the basis and conditions for case-by-case exceptions shall be clearly documented in the institutional policies. Case-by-case exceptions may be determined by such factors as the degree to which the members’ affiliation with the institution is their primary affiliation, or by how practical it is to distinguish the capacity in which the member is conducting the research, and the participants’ reasonable perceptions of this capacity. Other factors include the availability of other avenues through which the member may address the guidance in this Policy outside the institution, including the possibility of sharing responsibility for research ethics review, and the methods in place to address real, potential or perceived conflict of interest issues.

**Article 6.2**

The highest body within an institution shall: establish the REB or REBs, define an appropriate reporting relationship with the REBs, and ensure the REBs are provided with necessary and sufficient ongoing financial and administrative resources to fulfill their duties. REBs are independent in their decision making and are accountable to the highest body that established them for the process of research ethics review.

**Application**

The highest body of the institution that establishes the REB or REBs could be an individual, such as the president, rector or chief executive officer, or an equivalent body, such as a governing council, board of directors, or council of administration. Institutions shall have in place written procedures for the appointment, renewal and removal of REB members.

For the integrity of the research ethics review process, and to safeguard public trust in that process, institutions shall ensure that REBs are able to operate effectively and independently in their decision making. Disagreement between the researcher
and the REB over a decision that cannot be resolved through discussion and reconsideration can be resolved through the normal appeal process (see Articles 6.18 to 6.20).

Institutional policies and procedures shall also support and promote the independence of REBs in their decision making so that REBs may be free of inappropriate influence, including situations of real, potential or perceived conflicts of interest (see Chapter 7).

It is critical that institutions provide appropriate administrative resources to REBs (e.g., research ethics administration staff, a research ethics office) for the effective and efficient operation of the REB. The means by which this support may be provided will vary by institution, but may include REB coordination, support in policy development and interpretation, record keeping, and provision of research ethics training opportunities to REB members, researchers and students. The research ethics administration staff may provide important ethics expertise in support of the REB’s ethical analysis and discussion. Research ethics administration staff should also have the necessary qualifications, as well as initial and continuing training, to appropriately perform their roles and responsibilities. Institutions should recognize the integral role of research ethics administration staff and research ethics office(s), as applicable, in supporting the REB in fulfilling its mandate.

As an entity that draws its authority and resources from the institution, the REB remains accountable to the highest body of the institution that established it for the integrity of its processes.

**Article 6.3** The institution shall grant the REB the mandate to review the ethical acceptability of research on behalf of the institution, including approving, rejecting, proposing modifications to, or terminating any proposed or ongoing research involving humans. This mandate shall apply to research conducted under the auspices or within the jurisdiction of the institution, using the considerations set forth in this Policy.

**Application** The institution shall delegate to the REB the authority to review the ethical acceptability of research through its normal process of governance. In defining the scope of the REB’s mandate, the institution shall clearly define the jurisdiction of the REB to cover a range of research consistent with relevant disciplinary competence and a manageable workload. Where the institution requires more than one REB, it should establish a mechanism to coordinate the operations of all its REBs, and clarify their relationship with each other, and with other relevant bodies or authorities. Institutions shall have clear written policies describing the mandate of each REB. An institution may wish to use different models for the ethics review of research conducted under its auspices (see Chapter 8).

Institutions shall respect the authority delegated to the REB. An institution may not override an REB decision to reject a research proposal. An appeal of the REB decision to reject a research proposal can only be brought in accordance with Section C of this chapter.
An REB approval applies to the ethical acceptability of the research, and does not, in itself, constitute authorization for the research to proceed.

**REB Composition**

**Basic REB Membership Requirements**

The membership of the REB is designed to ensure competent independent research ethics review. Provisions respecting its size, composition, terms of appointment and quorum are set out below.

**Article 6.4** The REB shall consist of at least five members, including both men and women, of whom:

(a) at least two members have expertise in relevant research disciplines, fields and methodologies covered by the REB;

(b) at least one member is knowledgeable in ethics;

(c) at least one member is knowledgeable in the relevant law (but that member should not be the institution’s legal counsel or risk manager). This is mandatory for biomedical research and is advisable, but not mandatory, for other areas of research; and

(d) at least one community member who has no affiliation with the institution.

It is advisable that each member be appointed to formally fulfil the requirements of only one of the above categories.

To ensure the independence of REB decision making, institutional senior administrators shall not serve on the REB.

**Application**

This minimum requirement for REB membership brings to bear the necessary basic background, expertise and perspectives to allow informed independent reflection and decision making on the ethics of research involving humans. At a minimum, the REB shall have members appointed in one capacity only for each of the membership categories. Where the size of the REB exceeds the minimum requirements, additional members may fulfil more than one capacity. In any case, REB members can contribute to the review based on their experience, expertise or knowledge in more than one of the categories above (Article 6.4[a] to [d]).

As an entity created and supported by the institution, an REB is encouraged to build strong relationships with its host institution and senior administration. The involvement of administrative staff dedicated to research ethics functions (e.g., the research ethics office administrator or director) may be relevant and appropriate to support REB procedures. However, an institutional senior administrator (e.g., vice-president of research, director general or director of business development) should not serve on an REB, or directly or indirectly influence the REB decision-making process (see Articles 6.2 and 6.10). The mere presence of a non-voting institutional senior administrator at REB meetings may be a source of real, potential or perceived con-
Conflict of interest, and may therefore undermine the independence of the REB by unduly influencing REB deliberations and decisions (see Article 7.2).

The size of an REB may vary based on the diversity of disciplines, fields of research and methodologies to be covered by the REB, as well as on the needs of the institution. In appointing REB members, institutions should strive for appropriate diversity. Institutions may need to exceed the minimum REB membership requirements in order to ensure adequate and thorough reviews, reasonable workload for REB members, or to respond to other local, provincial/territorial, or federal legal or regulatory requirements. For example, in the case of REB review of clinical trials, provincial/territorial or federal regulations may outline specific membership requirements in addition to the requirements set out in this Policy. Where REBs mainly review student research, they may consider adding a student REB member. Additional community representation should be commensurate with the size of the REB. Institutions are encouraged to establish a pool of substitute members (see below). Where research ethics administration staff have the requisite experience, expertise and knowledge comparable to what is expected of REB members, institutions may appoint them (based on the written policies and procedures of the institution) to serve as non-voting members on the REB.

**Relevant Expertise in Research Content and Methodology**

At least two members should have the relevant knowledge and expertise to understand the content area and methodology of the proposed or ongoing research, and to assess the risks and potential benefits that may be associated with the research (Article 6.4[a]). For example, REBs reviewing oncology research, education or topics involving Aboriginal peoples, or research using qualitative methodologies, should have members that are knowledgeable and competent to address those fields of research, disciplines and methodologies.

**Knowledgeable in Ethics**

Knowledge of ethics of research involving humans is key within the REB membership as a whole. A member knowledgeable in ethics (Article 6.4[b]) needs to have sufficient knowledge to guide an REB in identifying and addressing ethics issues. A balance of ethics theory, practice and experience offers the most effective path to knowledge in ethics for REB membership. The kind and level of knowledge or expertise needed on the REB will be commensurate with the types and complexities of research the REB reviews. For example, a member knowledgeable in ethics serving on a social sciences and humanities REB may need to have different contextual and disciplinary knowledge in ethics than a member knowledgeable in ethics serving on a biomedical REB.

**Knowledgeable in the Law**

The role of the member knowledgeable in the law (Article 6.4[c]) is to alert REBs to legal issues and their implications (e.g., privacy issues), not to provide formal
legal opinions or to serve as legal counsel for the REB. To avoid undermining the independence and credibility of the REB, the institution’s legal counsel or risk manager should not be a member of the REB. In-house legal counsel might be seen to identify too closely with the institution’s financial interest in having research go forward or, conversely, may be unduly concerned with protecting the institution from potential liability. Any external legal counsel hired on a case-by-case basis by the institution should not serve as a member of that institution’s REBs while working for the institution.

An understanding of relevant legal issues and contexts is advisable for all REBs, although for non-biomedical research such insights may be sought from an ad hoc advisor whom the REB consults only for specific research projects. Where REBs review research on complex topics that regularly requires advice on legal issues, they should appoint a member knowledgeable in the relevant law. In some instances, the legal issues that may be identified by the REB will necessitate further scrutiny and even formal legal advice by the legal counsel to the institution. Legal liability is a separate issue for institutions to handle through mechanisms other than the REB.

**Community Member**

The community member shall not be affiliated with the institution. The community member requirement (Article 6.4[d]) is essential to help broaden the perspective and value base of the REB, and thus advances dialogue with, and accountability to, relevant communities. In addition to a broad-based representation from the community, it is highly desirable that institutions seek to appoint former participants on REBs. Their experience as participants provides the REB with a vital perspective and an important contribution to the research ethics review process. It is advisable that members are not currently engaged in research or legal work as their principal activities.

The role of community members on REBs during the ethics review process is unique and at arm’s length from the institution. Their primary role is to reflect the perspective of the participant. This is particularly important when participants are vulnerable and/or risks to participants are high.

To maintain effective community representation, the number of community members should be commensurate with the size of an REB and should increase as the size of an REB increases. Institutions should provide training opportunities to community members (see Article 6.7).

**Substitute Members**

Institutions should consider the nomination of substitute REB members so that REBs can continue to function when regular members are unable to attend due to illness or other unforeseen eventualities. The appointment of substitute members
should not, however, alter the REB membership composition as set out in this article. Substitute members should have the appropriate knowledge, expertise and training to contribute to the research ethics review process.

**Ad Hoc Advisors**

**Article 6.5** The REB should have provisions for consulting ad hoc advisors in the event that it lacks the specific expertise or knowledge to review the ethical acceptability of a research proposal competently.

**Application** In the event that the REB is reviewing a project that requires particular community or participant representation or specific disciplinary or methodological expertise not available from its members, it should have provisions for consulting ad hoc advisors. Consultation with an ad hoc advisor shall not alter the composition and representation of the REB as outlined in Article 6.4.

Ad hoc advisors are consulted for a specific research ethics review and for the duration of that review. Should this occur regularly, the membership of the REB should be modified to ensure appropriate expertise on the REB. For example, in cases where ethics review of research on topics related to Aboriginal peoples is regularly required, the REB membership should be modified to ensure that relevant and competent knowledge and expertise of Aboriginal cultures are captured within its regular membership.

While ad hoc advisors may complement the REB through their experience, knowledge or expertise, their input is a form of consultation that may or may not be considered in the final decision of an REB. They are not REB members and, as such, do not necessarily have the knowledge and experience gained from reviewing research proposals as members. Ad hoc advisors should not be counted in the quorum for an REB, nor be allowed to vote on REB decisions.

**Terms of Appointment of REB Members**

**Article 6.6** In appointing REB members, institutions shall establish their terms to allow for continuity of the research ethics review process.

**Application** In appointing REB members, institutions should arrange the terms of members and their rotation to balance the need to maintain continuity with the need to ensure diversity of opinion, and the opportunity to spread knowledge and experience gained from REB membership throughout the institution and community. The REB membership selection process should be fair and impartial. Institutions should have written policies that define the process of appointing REB members.

**Article 6.7** In appointing and renewing REB members, institutions should consider the qualifications and expertise their REBs need. Institutions should provide REB members with necessary training opportunities to effectively review the ethical issues raised by research proposals that fall within the mandate of their REB.
Application

An REB should have adequate expertise, experience and training to understand the research disciplines, methodologies and approaches of the research that it considers for research ethics review. Although an REB possesses the necessary expertise globally, each REB member brings specialized and complementary expertise and knowledge, or relevant experience to the ethics review of research involving humans.

Institutions should ensure that all REB members receive appropriate education and training in ethics review of research involving humans, to enable them to fulfil their duties. This includes providing training opportunities for all members in core principles and understanding of this Policy, basic ethics standards, applicable institutional policies, and legal or regulatory requirements. It includes an understanding of the role and mandate of REBs and responsibilities of REB members. Training should be tailored to the types and complexities of the research the REB reviews. This training should be offered both upon the appointment of new members, and periodically throughout a member’s tenure.

Institutions should promote and recognize the contribution of REB members to the research ethics review process, as a valued and essential component of the research enterprise.

REB Chair

Article 6.8

The REB Chair is responsible for ensuring that the REB review process conforms to the requirements of this Policy.

Application

The role of the REB Chair is to provide overall leadership for the REB and to facilitate the REB review process, based on institutional policies and procedures and this Policy. The Chair should monitor the REB’s decisions for consistency and ensure that these decisions are recorded accurately and communicated clearly to researchers in writing as soon as possible by the Chair or his or her designate. Institutions shall provide the necessary resources and adequate administrative support to enable the REB Chair to fulfill his or her responsibilities.

REB Quorum

Article 6.9

Institutions shall establish quorum rules for REBs that meet the minimum requirements of membership representation outlined in Article 6.4. When there is less than full attendance, decisions requiring full review should be adopted only when the members in attendance at that meeting have the specific expertise, relevant competence and knowledge necessary to provide an adequate research ethics review of the proposals under consideration.
Application

Institutions shall establish REB quorum rules subject to the range of competence and knowledge required by this Policy to ensure the soundness and integrity of the research ethics review process. To maintain quorum when REB members are geographically dispersed or in unexpected circumstances (e.g., emergencies), input from member(s) is allowed by other means, such as the use of technology (see Article 6.10).

Ad hoc advisors, observers, research ethics administration staff and others attending REB meetings should not be counted in the quorum for an REB. Nor should they be allowed to vote on REB decisions (see Article 6.5). Decisions without a quorum are not valid or binding.

REB Meetings and Attendance

Article 6.10

REBs shall have regular meetings to discharge their responsibilities, and shall normally meet face to face to review proposed research that is not assigned to delegated review.

Application

Face-to-face meetings are essential for adequate discussion of, and effective REB decision making on, research proposals, and for the collective education of the REB. The face-to-face medium provides interactive dynamics that tend to heighten the quality and effectiveness of communications and decisions.

Planning regular meetings is essential to fulfilling REB responsibilities. Where a member is frequently absent, the REB should have some mechanism for reviewing whether that member should continue to serve on the REB. Unexpected circumstances such as emergencies may prevent individual member(s) from attending the REB meeting. In these exceptional cases, input from member(s) by the use of technology (e.g., phone or video link) would be acceptable.

Videoconferencing, teleconferencing or use of other technologies may be regarded as necessary for meetings when REB members are geographically dispersed and there is no other way of holding an effective REB meeting, or when exceptional or exigent circumstances significantly disrupt or limit the feasibility of face-to-face REB meetings (e.g., during a public emergency). All efforts should be made to ensure that technical difficulties do not prevent the maintenance of quorum throughout the meeting. Use of such technologies requires the Chair to ensure active participation of members not physically present. Institutions should consider developing written procedures for the occasional use of videoconferences or other technologies by an REB.

In the design phase of their research prior to the formal ethics review process, researchers may consult informally with REBs. Such dialogue can establish the stage at which REB review and approval would be required, or facilitate the review. Such
informal meetings cannot, however, substitute for the formal review process. A schedule of REB meetings should be communicated to researchers for the planning of ethics review of their research.

On occasion REBs may need to consult other resources within or outside the institution for advice, and may invite experts to attend their meetings. REBs should consider whether the institutional functions of other individuals attending their meetings could exercise undue influence, or provide elements of power imbalances or coercion that would affect REB review, deliberations and decisions (see Articles 6.4 and 6.5 and Chapter 7).

REBs should establish a process for the basis of arriving at decisions requiring full REB review. For example, they may arrive at decisions by consensus, and where this is not possible resort to a vote. REBs should hold general meetings, retreats and workshops to enhance educational opportunities that may benefit the overall operation of the REB, discuss any general issues arising out of the REB’s activities or revise relevant policies.

**B. Procedures for REB Review**

**Initial Research Ethics Review**

**Article 6.11** Researchers shall submit their research proposals, including proposals for pilot studies, for REB review and approval of its ethical acceptability prior to the start of recruitment of participants, access to data, or collection of human biological materials. REB review is not required for the initial exploratory phase, which may involve contact with individuals or communities intended to establish research partnerships or to inform the design of a research proposal.

**Application** REB review and approval of the ethical acceptability of research is required before recruitment, formal data collection involving participants, access to data, or collection of human biological materials. Similarly, as an integral component of their research design, researchers may undertake pilot studies involving participants. For the conduct of pilot studies, researchers shall seek consent from prospective participants and obtain REB approval before recruitment or the formal data collection involving participants, or access to data, or collection of human biological materials in accordance with the provisions in this Policy.

Researchers shall submit sufficient details to enable the REB to make an informed review of the ethical acceptability of the research.

Some types of research using quantitative, qualitative research, or a combination of these methods, as well as collaborative or community-based research (see Chapters 9 and 10) may entail prior contact and dialogue with individuals or
communities as a normal and integral component to establish research collaborations or partnerships prior to the actual design of the research. Other research may, at their initial stages, not involve humans, but require engaging the research team, setting up equipment and other preparatory stages. These activities may precede REB review.

**Determining the Level of Research Ethics Review**

**Article 6.12**  In keeping with a proportionate approach to research ethics review, the selection of the level of REB review shall be determined by the level of foreseeable risks to participants: the lower the level of risk, the lower the level of scrutiny (delegated review); the higher the level of risk, the higher the level of scrutiny (full board review).

**Application**  REBs shall assess the level of risk that the research under review poses to participants to determine the appropriate level of research ethics review (delegated or full REB review). (For a full discussion of the proportionate approach to research ethics review, see Chapter 1, Section C, and Article 2.9). This applies to both initial research ethics review (see Article 6.11) and continuing research ethics review (see Article 6.14).

With the support of their institutions, REBs may develop their own mechanisms under which delegation of the conduct of research ethics review, decision making and the associated reporting processes will occur. Those mechanisms and procedures should be made public. It is the REB, based on its established procedures and through its Chair, that decides on the level of review for each research proposal.

Two levels of research ethics review may apply:

1) Full REB review

   Research ethics review by the full REB should be the default requirement for research involving humans.

2) Delegated REB review of minimal risk research

   The REB delegates research ethics review to an individual or individuals. Delegates shall be selected from among the REB membership with the exception of the ethics review of student course-based research. This can be delegated to the department, faculty or equivalent level as indicated below.

   Where it is determined that the research is of minimal risk (defined in Chapter 2 of this Policy), an REB may authorize a delegated research ethics review in accordance with its institutional policies and written procedures. Delegated reviewer(s) shall be selected from the REB membership: the REB Chair or another member
(see Article 6.4 on the appointment of research ethics administration staff to the REB as non-voting members). Research ethics review may also be undertaken by non-REB members for student course-based research as outlined below. Delegated reviewers who are non-members or non-voting members of the REB must have experience, expertise and knowledge comparable to what is expected of an REB member.

The REB may decide that its Chair or other REB member(s) may review and approve categories of research that are confidently expected to involve minimal risk. Delegated reviewers may call on other reviewers within the REB or refer projects back to the full REB if they determine that full board review is required. Where delegates consider a negative decision (i.e., one that would refuse ethics approval), this decision shall be referred to the full REB for review and endorsement before communicating the decision to the researcher.

An institution may decide that ethics review of course-based research activities intended solely for pedagogical purposes can be delegated to non-REB members at the institution’s department, faculty or equivalent level. Such pedagogical activities are normally required of students (at all levels) with the objective of providing them with exposure to research methods in their field of study. If these activities are used for the purposes of research (e.g., as part of a researcher’s own research program), they should be reviewed by the regular institutional REB procedures. The REB should establish written procedures and set out criteria for determining which categories of research proposals may be eligible for this type of review, and specify who is responsible for implementing and overseeing the approval mechanisms.

In delegating research ethics review, the REB should carefully select delegated reviewer(s) and ensure that all delegated reviewers who are not members of the REB have the appropriate experience, expertise, training and resources required to review the ethical acceptability of all aspects of the proposal in accordance with this Policy. In the selection of delegated reviewers, special attention should be given to the assessment of real, potential or perceived conflicts of interest (see Article 7.3).

Examples of categories that may be delegated for research ethics review include:

- research that is confidently expected to involve minimal risk;
- minimal-risk changes to approved research;
- annual renewals of approved minimal risk research;
- annual renewals of more than minimal risk research where the research will no longer involve new interventions to current participants, renewal does not involve the recruitment of new participants, and the remaining research activities are limited to data analysis.
An REB that implements a delegated review process shall require that the actions and decisions of the delegated reviewer(s) be well documented and formally reported to the full REB, in a timely and appropriate manner. Where the delegated review is conducted by non-voting members or non-members of the REB, this formal report shall be made through the Chair. This will permit the REB to maintain oversight over the decisions made on its behalf so as to protect the interests of participants. Accountability requires that, regardless of the review strategy, the REB continues to be responsible for the ethics of all research involving humans within its jurisdiction.

Decision Making

**Article 6.13** REBs shall function impartially, provide a fair hearing to the researchers involved, and provide reasoned and appropriately documented opinions and decisions. REBs should make their decisions on the ethical acceptability of research in an efficient and timely manner, and shall communicate all approvals and refusals to researchers in writing, in print or by electronic means, in accordance with their procedures.

**Application** The REB shall accommodate reasonable requests from researchers to participate in discussions about their proposals. The REB may also invite researchers to attend an REB meeting to provide further information about their proposal. In either case, the researchers shall 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 (see Article 6.18).

In the event that a minority within the REB membership considers a research project unethical, even though it is acceptable to a majority of members, an effort should be made to reach consensus. Consultation with the researcher, external advice or further reflection by the REB may be helpful. If disagreement persists, a decision should be made in accordance with the process agreed upon, and documented by the REB. In such instances, the minority position may be communicated to the researcher.

Participation by the researcher in REB discussions is often very helpful to both REBs and researchers. It may result in a deferral of the REB’s decision until the researcher has considered the discussions and possibly modified the proposal. Such discussions are an essential part of the educational role of the REB.

**Continuing Research Ethics Review**

**Article 6.14** The REB shall make the final determination as to the nature and frequency of continuing research ethics review in accordance with a proportionate approach to research ethics review. At minimum, continuing research ethics review shall consist of an annual status report (for multi-year research projects), and an end-of-study report (projects lasting less than one year).
Application

Research is subject to continuing research ethics review from the date of initial REB approval throughout the life of the project (see Article 2.8). At the time of the initial review, the REB has the authority to determine the term of approval, and the level at which continuing ethics review occurs in accordance with a proportionate approach to research ethics review. As with initial review, continuing ethics review could be full board review or delegated review based on the level of risk of the research (see Article 6.12). The level of research ethics review may be adjusted over the life of the project based on the level of risk.

For research projects lasting longer than one year, researchers shall submit, at minimum, an annual report with sufficient details to enable the REB to make an informed judgment about the continued ethical acceptability of the research. For research lasting less than one year, an end-of-study report may suffice.

For some types of research (e.g., qualitative research or longitudinal research), there may be some difficulty in establishing start or end dates. In these cases, the REB should work with researchers to determine a reasonable timeline for continuing ethics review, and for determining the completion date dependent on the discipline and method of research. The reporting schedule for continuing ethics review may be adjusted throughout the life of the project. This would be necessary, for example, if the risk level of the research increases as a result of the addition of new procedures, or is re-assessed in light of changes to the approved research (see Articles 6.15 and 6.16).

Research that involves minimal or no risk to participants should be held to the minimum requirements for continuing ethics review, that is, an annual report. Consistent with a proportionate approach, an REB has the option of requesting more frequent and/or more substantive reports if necessary. Research that poses greater-than-minimal risk may require more extensive continuing ethics review. This may include more frequent reporting to the REB, monitoring and review of the consent process, review of participant records, and site visits. Other reporting mechanisms for continuing ethics review may be required by funders, sponsors or regulators.

Continuing research ethics review should be understood as a collective responsibility, to be carried out with a common interest in maintaining the highest ethical standards:

- Institutions have a responsibility to provide necessary resources to REBs to assist them in fulfilling their continuing ethics review responsibilities;
- REBs make the final decision about the nature and frequency of continuing ethics review;
- Researchers’ responsibilities include monitoring their research to ensure that it is conducted in an ethical manner, reporting unanticipated issues
(see Article 6.15) or changes to the research (see Article 6.16), supervising all team members in the application of the research procedures, and ensuring that they are properly qualified and versed in the conduct of ethical research.

Reports of Unanticipated Issues

**Article 6.15** Researchers shall report to the REB any unanticipated issue or event that may increase the level of risk to participants, or has other ethical implications that may affect participants’ welfare.

**Application** Over the course of the implementation of the approved research project, issues may arise that the researcher did not anticipate when originally submitting the research for ethics review. Unanticipated issues include unexpected reactions by participants to a research intervention (e.g., unintended stimulation of traumatic memories, unforeseen side-effects of a medication or natural health product), as well as unavoidable single incidents (e.g., a translator not available for a day, or a failure to follow correct research procedure for one participant on one occasion). They may be minor or serious in magnitude, with short- or long-term implications.

Any unanticipated issue that increases the level of risk to participants or has other ethical implications should be reported to the REB without delay. Changes that are necessary to eliminate an immediate risk(s) to the participants may be implemented as needed, but must be reported to the REB at the earliest opportunity. For clinical trials, reporting requirements for safety data or unanticipated issues are also addressed in Chapter 11 (Articles 11.7 and 11.8). If the incident or issue has immediate implications for the safety of participants, the REB may withdraw ethics approval, which would require that the research be halted or modified until the matter can be addressed (see Article 6.3 and Articles 11.8 and 11.9). It may require submission of a revised research proposal for REB review.

Minor deviations from the research (e.g., a slight increase or decrease of testing time, a wording adjustment on a question) should not require immediate reporting to the REB, but may be summarized in annual status reports (see Article 6.14). In some types of qualitative research, for example, emergent design (see Article 10.5), the research design evolves over time, so adjustments to the research are to be expected and need not be reported to the REB, unless they alter the level of risk or have other ethical implications for participants (see Article 6.16).

The report to the REB should include a description of the unanticipated issue or incident, including details of how the researcher(s) dealt with the situation. Reports may be submitted by researchers, or in some cases by data safety monitoring boards (see Article 11.7 and 11.8). The point in reporting is to enable the REB and the researcher to better protect participants. Depending on the nature of the issue, and in consultation with researchers, REBs may require that researchers adjust their procedures to prevent its recurrence during the research project.
Requests for Changes to Approved Research

Article 6.16  Researchers shall submit to their REBs in a timely manner requests for substantive changes to their originally approved research. REBs shall decide on the ethical acceptability of those changes to the research in accordance with a proportionate approach to research ethics review.

Application  In general, it is not the size of the change that dictates the ethics review process, but rather the ethical implications and risk associated with the proposed change. In case of doubt on the potential impact of the change to approved research on the level of risk to participants, researchers should consult with their REBs. Changes that substantially alter the nature of the approved research may be assessed as a new research project and require a new REB review.

In the conduct of their approved research, researchers should be aware of the requirement to report to their REB, in a timely manner, proposed changes from approved research that affect participants at any stage of the process including, but not limited to, changes to the consent form, changes to the tasks or interventions involved in the research, or changes to measures to protect privacy and confidentiality. Any substantive change to the research should not be implemented without documented approval by the REB, except when necessary to eliminate an immediate risk(s) to the participants.

Requests for changes to approved research may receive delegated or full REB review depending on the level of risk to participants that the changes represent. REB evaluation of these requests can result in a change to the assessed risk of the research and a corresponding change in the level of continuing ethics review.

REBs should give special attention to circumstances that may necessitate change in long-term research such as new knowledge, equipment or instruments, or new or revised applicable policies and laws that may develop over the lifetime of a research project.

Record Keeping of REB Documents

Article 6.17  REBs shall prepare and maintain comprehensive records, including all documentation related to the projects submitted to the REB for review, attendance at all REB meetings, and accurate minutes reflecting REB decisions. Where the REB denies ethics approval for a research proposal, the minutes shall include the reasons for this decision.

Application  REBs need to act, and to be seen to be acting, fairly and reasonably. Institutions shall provide REBs with the necessary resources to enable them to maintain complete study files, including the original research proposal, as well as annual and end-of-study reports. When deciding the retention period of their files, REBs should be guided by their institutional record-keeping policies and other relevant legal or
regulatory requirements. Files, minutes and other relevant documentation shall be accessible to authorized representatives of the institution, researchers, sponsors and funders when necessary to assist internal and external audits, or research monitoring, and to facilitate reconsideration or appeals.

The minutes of REB meetings shall clearly document the REB’s decisions, any dissents and the reasons for them. REB decisions should be supported by clear references (e.g., date of decision, title of project), documentary basis for decision (i.e., documents or progress reports received and reviewed), the plan for continuing ethics review and timelines, reasons for decisions, and any conditions or limitations attached to the approval. Providing reasons for REB decisions is optional when ethics approval is granted.

REBs should have written procedures for its management of record keeping and other submitted reports. REBs shall maintain reports and decisions on unanticipated issues or changes to approved research, including details of how the researcher dealt with or is proposing to deal with the situation and the REB’s response or decision (see Articles 6.15 and 6.16).

The research ethics administration should also maintain general records related to REB membership and qualifications of members (e.g., copies of curriculum vitae, participation in relevant research ethics training).

C. Reconsideration and Appeals

Where researchers do not receive ethics approval, or receive approval conditional on revisions that they find compromise the feasibility or integrity of the proposed research, they are entitled to reconsideration by the REB. If that is not successful, they may appeal using the established appeal mechanism in accordance with the institution’s procedures.

Reconsideration of REB Decisions

Article 6.18 Researchers have the right to request, and REBs have an obligation to provide, prompt reconsideration of decisions affecting a research project.

Application Researchers and REBs should make every effort to resolve disagreements they may have through deliberation, consultation or advice. If a disagreement between the researcher and the REB cannot be resolved through reconsideration, the researcher shall have the option of appealing the REB decisions through the established appeal mechanism (see Article 6.19). REBs should establish timelines to promptly conduct reconsiderations and issue their decision.

The onus is on researchers to justify the grounds on which they request reconsideration by the REB and to indicate any alleged breaches to the established research ethics review process, or any elements of the REB decision that are not supported by this Policy.
Appeal of REB Decisions

Article 6.19 Institutions shall have an established mechanism and a procedure in place for promptly handling appeals from researchers when, after reconsideration, the REB has refused ethics approval of the research.

Application In cases when researchers and REBs cannot reach agreement through reconsideration, the institution shall provide access to an established appeal process for the review of an REB decision. The researcher and the REB must have fully exhausted the reconsideration process, and the REB must have issued a final decision before the researcher initiates an appeal.

Based on its written institutional policies, the same authority that established the REB shall establish or appoint an appeal committee that reflects a range of expertise and knowledge similar to that of the REB, and that meets the procedural requirements of this Policy. An appeal committee may be an ad hoc or a permanent committee. Members of the REB whose decision is under appeal shall not serve on that appeal committee.

It should be stressed that the appeal process is not a substitute for REBs and researchers working closely together to ensure high-quality ethical research, nor is it a forum to merely seek a second opinion.

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 between institutions is required (see Chapter 8).

It is not the role of the three federal research Agencies that are responsible for this Policy to consider any appeals of REB decisions.

Article 6.20 The appeal committee shall have the authority to review negative decisions made by an REB. In so doing, it may approve, reject or request modifications to the research proposal. Its decision on behalf of the institution shall be final.

Application Researchers have the right to request an appeal of an REB decision. An appeal can be launched for procedural or substantive reasons. The onus is on the researchers to justify the grounds on which they request an appeal and to indicate any breaches to the research ethics review process or any elements of the REB decision that are not supported by this Policy.

The appeal committee shall function impartially, provide a fair hearing to those involved, and provide reasoned and appropriately documented opinions and decisions. Both the researcher and a representative of the REB shall be granted the opportunity to address the appeal committee, but neither shall be present when the
appeal committee deliberates and makes a decision. Appeal committee decisions on behalf of the institution shall be final, and should be communicated in writing (in print or by electronic means) to researchers and to the REB whose decision was appealed. Recourse to judicial review may be available to the researcher.

D. Research Ethics Review during Publicly Declared Emergencies

This section addresses research ethics review within the context of the official declaration of public emergencies. For the purposes of this Policy, a publicly declared emergency is an emergency situation that, due to the extraordinary risks it presents, has been proclaimed as such by an authorized public official (in accordance with legislation and/or public policy).

Publicly declared emergencies are extraordinary events that arise suddenly or unexpectedly, and require urgent or quick responses to minimize devastation. Examples include hurricanes and other natural disasters, large communicable disease outbreaks, catastrophic civil disorders, bio-hazardous releases, environmental disasters, and humanitarian emergencies. They tend to be time-limited. They may severely disrupt or may destroy normal functioning of institutions and communities, as well as individual lives. Once an emergency has been designated a publicly declared emergency, authorities may exercise special responsibilities and powers to deal with the situation, and the exercise of those responsibilities may temporarily modify normal procedures or practices. This section therefore applies to narrow, limited and exceptional circumstances.

There is a growing awareness of the need for institutional planning to respond to publicly declared emergencies, and the associated potential challenges for research ethics review. Given the extraordinary circumstances that participants are potentially subjected to in publicly declared emergencies, special attention and effort should be given to upholding the core principles of Respect for Persons, Concern for Welfare, and Justice when reviewing the ethics of research to be conducted in emergencies. It should be noted that the following articles and the requirement for consent will not apply to public health activities undertaken by federal, provincial and territorial public health officials operating under statutory powers during publicly declared health emergencies.

Preparedness Plans for Research Ethics Review during Publicly Declared Emergencies

Article 6.21 In collaboration with their researchers, institutions and their REBs should develop preparedness plans for emergency research ethics review. Research ethics review during publicly declared emergencies may follow modified procedures and practices.

Application Preparedness plans should outline policies and procedures for addressing research ethics review during public health outbreaks, natural disasters and other publicly declared emergencies. Research ethics policies and procedures, and their implementation, should adhere rigorously to a rule of reasonable, fair, and principled design and use during publicly declared emergencies.
Through their emergency preparedness plans, institutions, researchers and their REBs need to anticipate the pressures, time constraints, priorities and logistical challenges that may arise to ensure quality, timely, proportionate and appropriate research ethics review. The plan and its policies should proactively address basic operational questions. Examples include, but are not limited to, how emergencies may affect research and research ethics review in institutions; how REBs conduct business or meetings; what research needs should be planned in advance of, or addressed after, an emergency; what research, if any, needs to be done during an emergency; what qualifies as time-sensitive or “essential” research; what procedures govern the research ethics review process in emergency circumstances; and what evaluation methods need to be developed for post-response evaluations to inform any revisions to the institution’s emergency procedures. It is important to pilot test the emergency procedures and plans in advance.

Policies should try to anticipate the extraordinary circumstances or demands occasioned by emergencies and set priorities among them. For example, REBs should try to work collaboratively with researchers who would likely be involved in emergency research (e.g., relevant biomedical, environmental and social science researchers), and determine what special consent provisions may be made (see Chapter 3). Institutions might consider the use of an instrument to identify and triage the kinds of research that should be designed before, undertaken during or conducted after officially declared public emergencies. Likewise, a plan to help prioritize REB reviews during emergencies should take into account the following:

- what research is “essential” research during the emergency;
- the initial ethics review process of new research projects arising from the emergency (e.g., research involving interviews with first responders and victims to understand human response during a disaster, such as a tornado or earthquake);
- continuing ethics review of research undertaken prior to the occurrence of the emergency; and
- the ethics review process for changes to approved research, because new information may become available and require action very rapidly during emergencies (see Articles 6.15 and 6.16).

REB procedures may warrant reasonable adjustments to address the timing, locale, expertise, form and scope of research ethics review, and the holding of REB meetings during emergency situations (see Article 6.10). Special attention could be given to REB procedures to review and approve research (e.g., full or delegated research ethics reviews, quorum rules, or special agreements with other institutions), while considering the impact of the emergency on participants, researchers, REB members, institutional staff, and others. It is also important to coordinate research efforts
and research ethics review processes within and across institutions. REB members may become unavailable (e.g., due to illness, relocation, or quarantine by public authorities). Institutions and REBs should explore the nomination of substitute REB members and consultation with ad hoc advisors with relevant expertise (see Articles 6.4 and 6.5), negotiate reciprocity agreements with other institutions for REB reviews (see Article 8.1), and revisit how scholarly review (see Article 2.7) would be applied in emergency situations.

Research ethics review should be commensurate with the necessities occasioned by the emergency because of the critical interplay between public urgencies, essential research and a continuing commitment to the core principles even in the face of acute public necessity. Indeed, research ethics review during publicly declared emergencies is even more important than under normal circumstances, and may require even greater care, since everyone (participants, researchers and REB members themselves) may be rendered more vulnerable by the nature of the emergency.

**Research Ethics Review Policy and Procedures during Publicly Declared Emergencies**

**Article 6.22** Research ethics policies and procedures for emergencies take effect once an emergency has been publicly declared. They should cease to apply as soon as is feasible after the end of the publicly declared emergency.

**Application** Because emergencies present extraordinary public risks that warrant special responses, legislation or public policies usually require that they be officially proclaimed or declared. Research ethics review procedures that have been established for use during publicly declared emergencies should be applied only after an authorized public official declares a public emergency. These procedures therefore apply to very narrow, limited and exceptional circumstances. Institutions and REBs must endeavour to return to normal operating procedures as soon as possible after public officials have declared that the emergency is over.

**Respecting Core Principles: Limiting Exceptions**

**Article 6.23** REBs should give special care to requests for exceptions to the principles and procedures outlined in this Policy during publicly declared emergencies.

**Application** Especially during times of emergency, researchers, REBs and institutions need to be vigilant and exercise due diligence in respecting ethical principles, procedures and the law in effect during the emergency to preserve the values, purpose and protection that the principles of this Policy advance.

To guide fair and reasonable implementation of these principles in emergency circumstances, any exception to, or infringement of, ethics principles and REB procedures must be demonstrably justified by those urging the exception or infringement.
Where exceptions to or infringements of ethics principles and REB procedures are justified, they should be narrowly tailored to address the necessities occasioned by the publicly declared emergency, such that they rely on the most restrictive or least intrusive means necessary to achieve the Policy goal: the promotion and guidance of ethical conduct in research. This approach – consistent with international bioethics and human rights norms – maximizes respect for ethical principles and helps to ensure that exceptions and the means to implement them are not unduly broad, overreaching or unjustifiably invasive.

Recognizing and respecting the principle of Justice means that research ethics review policies and procedures for publicly declared emergencies shall be used in a manner that is not discriminatory or arbitrary. The commitment to justice advances a fair and balanced distribution of risks and potential benefits even in the face of public emergencies.

REBs and researchers should be aware that individuals, prospective participants, researchers, and institutions may not normally be considered vulnerable, but may become so by the very nature of public emergencies. Those already vulnerable may become acutely so (see Article 4.7). The increased public risks and devastation that cause public emergencies to be declared can threaten autonomy and physical, emotional, institutional and social welfare or safety. They also bring inherent tensions and pressures that may impact deliberative decision making. Taking all of this into consideration, REBs and researchers should ensure that the risks and potential benefits posed by any proposed research are appropriately evaluated, including provisions for greater-than-normal attention to risk, where applicable.

Endnote

(d) a research project conducted by a researcher who has multiple institutional affiliations (e.g., two universities, a university and a college, or a university and a hospital. See Application of Article 6.1);

(e) a research project conducted by a researcher at one institution that requires the limited collaboration of individuals affiliated with different institutions or organizations (e.g., statisticians, lab or X-ray technicians, social workers and school teachers); or

(f) a research project that researcher(s) working under the auspices of a Canadian research institution conduct in another province, territory or country.

Adoption of Alternative Review Models – An Institutional Responsibility

Article 8.1 An institution that has established an REB may approve alternative review models for research involving multiple REBs and/or institutions, in accordance with this Policy. The institution remains responsible for the ethical acceptability and ethical conduct of research undertaken within its jurisdiction or under its auspices irrespective of where the research is conducted.

Application As described in Chapter 6, institutions are accountable for research conducted under their auspices, irrespective of the location where it takes place. Where research involving humans requires the involvement of multiple institutions and/or multiple REBs, an institution may establish one or more, or a mix of models for research ethics review as described below. Institutions may also establish other models or arrangements that are appropriate for the research under review within their jurisdiction or under their auspices. The ultimate responsibility for approving alternative research ethics review models for potential use by REBs and researchers remains with their individual institutions.

In consultation with its REB(s), an institution may authorize its REB to accept reviews undertaken by an external REB of the ethical acceptability of research. This authorization should be based on an official agreement that includes, but is not limited to, the following minimum components:

• all institutions or equivalent organization(s) involved agree to (1) adhere to the requirements of this Policy, (2) formalize the cross-institutional agreement, and (3) document the existence of this agreement in their institutional policies;

• the highest institutional level, the body that originally defined the jurisdiction of the REB and its relationship to other relevant bodies or authorities within the institution, makes the decision to allow an REB to recognize research ethics review decisions made by another REB (in accordance with Article 6.2); and

• approvals based on cross-institutional agreement should be documented and reported to the full REB, through the REB Chair, in each institution. The point in reporting is informational. It should not necessarily trigger a duplicate research ethics review.
Researchers and REBs should use the research ethics review models defined by their institution (see Article 8.2) and facilitate coordination of the research ethics review process. Whatever model is chosen, roles and responsibilities of all involved in the process should be defined and agreed to at the outset. Continuing ethics review of research involving multiple institutions and/or multiple REBs should follow the same process outlined in Article 6.14.

**Research Ethics Review Models**

The following models for the ethics review of research involving multiple REBs and/or multiple institutions are intended to provide flexibility and efficiency, and avoid unnecessary duplication of review without compromising the protection of participants. All other provisions of this Policy remain applicable.

1) **Independent Ethics Review by Several REBs**

This model follows the same research ethics review process as when the research only involves a single REB review. The REBs involved at each participating institution conduct an independent research ethics review and provide their separate decisions, either concurrently or sequentially. The level of ethics review for research that involves multiple REBs and/or institutions shall be proportionate to the risk involved in the research (see Article 6.12).

Ethics review of the proposed research at each collaborating institution helps to ensure that local issues and values are taken into consideration. This approach may be particularly important, though often more challenging, when there are relevant social or cultural differences between the participating institutions. When several REBs consider the same proposal from their own institutional perspectives, they may reach different conclusions on one or more aspects of the proposed research, that reflect local issues and values. REBs may therefore wish to coordinate their ethics review of research projects requiring multiple REB involvement, including conducting their research ethics reviews in a timely manner, and communicating any concerns that they may have with other REBs reviewing the same project. When multiple REBs are involved, the principal investigators should work with their REBs to formulate a strategy to address procedural inconsistencies or substantive disagreements that may arise among the participating REBs.

Where possible, researchers should provide their REB with the name and contact information of the other REBs that will also review the project to facilitate direct communication between the REBs, and help resolve disagreements that may arise.

2) **Research Ethics Review Delegated to an External, Specialized or Multi-Institutional REB**

Institutions may allow research on specialized content or research methods to be reviewed by an external, specialized or multi-institutional REB, where such a body exists. External, specialized or multi-institutional REBs may be established regionally, provincially/territorially or nationally, as necessary. Two or more institutions may choose to create a single joint REB, or to appoint an external REB, to which they delegate research ethics review. This delegation of review may be based on geographical proximity or other considerations such as resources, volume of reviews or shared expertise.
Some provinces have introduced legislation or policies that designate one or more REBs for the review of certain types of research within the province (see References at the end of this chapter).

In the official agreement between the selected REB and the institutions submitting research for ethics review, the external, specialized, or multi-institutional REB shall agree to adhere to this Policy. Roles and responsibilities should be clearly defined in the official agreement between the institution(s) delegating the review, and the institution or equivalent organization of the REB that will review the ethical acceptability of the research, or in the relevant legislation or policies. The external, specialized or multi-institutional REB may act as the responsible REB for any given review, if formally mandated as such by the institutions in question. Where relevant, agreements should specify how the external, specialized or multi-institutional REB will assure familiarity with particular populations that may be involved in the research. Review by an external, specialized or multi-institutional REB need not be preceded or followed by local REB review unless warranted to help ensure that local issues and values are taken into account.

3) Reciprocal REB Review

Multiple institutions may enter into official agreements under which they will accept, with an agreed level of oversight, the research ethics reviews of each other’s REBs. This might involve specific agreements between institutions for sharing their workload. Alternatively, institutions may decide that reciprocity agreements should be established for the ethics review of each relevant research proposal on a case-by-case basis.

In either case, researchers shall ensure that the reviewing REB is provided with any relevant information about the local populations and circumstances that would ordinarily be available to the local REB, and that may have a bearing on its review. The reviewing REB might call upon local REBs to provide information in addition to that provided by the researchers.

Selection of a Research Ethics Review Model Relevant to the Research Project

**Article 8.2** When planning a research project involving multiple institutions and/or multiple REBs, researchers and REBs should select the most appropriate research ethics review model from among those authorized by their institution.

**Application** Sensitivity to context is a key issue in the application of the core principles of this Policy to the ethics review of research involving multiple institutions and/or REBs. Researchers should consider the alternative research ethics review models at the planning and design stage of their research, and should consult with their REB to facilitate the selection and coordination of the appropriate review model. In choosing the appropriate research ethics review model, the researcher and the REB should pay attention to the research context, and the characteristics of the populations targeted by the research. The final decision regarding the selection of the appropriate model is the responsibility of the principal REB.

When selecting from among research ethics review models authorized by their institution, researchers and REBs should consider the following:
the discipline and content area of the research, and the availability of appropriate experience and expertise within, or available to, the reviewing REB;

- the scope of the project to be reviewed and appropriateness of the proposed research ethics review model;

- the vulnerability of the study population overall and/or the particular characteristics of the local population at individual sites, differences in values and cultural norms, and the level of risk associated with the research under review;

- any relevant differences in laws and/or guidelines pertaining to the research in question if the institutions are in different provinces, territories and/or countries;

- relationships between institutions and REBs, and conflict resolution mechanisms related to REB decisions;

- the potential for conflicts of interest and undue influence, including those that may arise from funding sources;

- any differences in the standard of care normally followed, or access to services at the participating institutions that might be relevant to the conduct of the research; and

- any operational issues that might affect the research.

B. Ethics Review of Research Conducted outside the Institution

Researchers affiliated with Canadian institutions are undertaking research at numerous sites within Canada and in countries around the world. Such research may be carried out with or without any collaboration with host institutions and local researchers. Most middle-income countries, and many low-income countries, have laws, policies or guidelines governing the ethical conduct of research involving humans, but some parts of the world do not have developed or widespread research ethics infrastructure.

National and international standards for research involving humans are evolving continually, but methods for comparing the precise levels of protection afforded participants in different countries or jurisdictions, and by different institutions within those countries and jurisdictions, have not yet been developed. In exercising its responsibilities for the initial and continuing ethics review of research conducted under its auspices, the Canadian REB shall satisfy itself that the requirements of this Policy are met, both within the Canadian institution, and within the other country or research site. The Canadian REB shall take appropriate steps to ensure researchers are responsive to ethically relevant aspects of the research context.

Article 8.3  (a) Where research conducted under the auspices of a Canadian research institution and performed in whole or in part outside of Canada has been approved under a research ethics review model involving multiple institutions and/or REBs consistent with this Policy, the terms of that model apply.
(b) Subject to Article 8.3(a), research conducted under the auspices of a Canadian research institution and conducted outside its jurisdiction, whether elsewhere in Canada, or outside Canada, shall undergo prior research ethics review by both:

i. the REB at the Canadian institution under the auspices of which the research is being conducted; and

ii. the REB or other responsible review body or bodies, if any, at the research site.

Application

An institution is responsible for the ethical conduct and ethical acceptability of research undertaken by its faculty, staff or students regardless of where the research is conducted (see Article 6.1). Thus, for a Canadian research institution, review of the ethical acceptability of the research by the institution’s REB is required, in addition to ethics review by an REB or other appropriately constituted review body with jurisdiction at the research site elsewhere in Canada, or outside Canada, if any. Approval of a research proposal by an REB at the research site does not constitute sufficient authorization to conduct the research without the approval of the relevant Canadian REB(s). Conversely, approval by the Canadian REB(s) is not sufficient authorization to begin the research without the approval of the REB or other appropriately constituted review body at the research site. Researchers shall obtain necessary approvals of the ethical acceptability of their research prior to the start of recruitment of participants, access to data, or collection of human biological materials, in accordance with Article 6.11.

Researchers may undertake research in Canada or abroad without formal collaboration with other academic institutions. In these cases, in addition to the REB review at their own institution, researchers may need to obtain access to the site and prospective participants from a responsible agency, where one exists. They shall inform the REB whether, or how, they will seek permission to proceed with the research at that site and with the target participants. Some organizations or groups have established mechanisms or guidelines (e.g., school boards, Aboriginal communities [see Chapter 9], correctional services, service agencies and community groups) to review requests for research prior to allowing access to their members, or access to data about them that are under their authority. When designing their research, researchers should consider these provisions. This article does not apply to research involving critical inquiry about organizations or institutions (see Article 3.6).

Researchers shall inform the REB of the absence of established ethics review mechanisms at the research site, and report their efforts to identify any other suitable review mechanisms in the other country.¹ When no appropriate mechanisms for research ethics review exist at the research site, researchers and REBs shall apply the core principles outlined in this Policy (see Chapter 1).
REBs should not prevent research from proceeding solely because the research cannot be reviewed and approved through a formal REB review process in another country or other jurisdiction. Under these circumstances, researchers should be aware of relevant cultural practices, such as those normally followed to seek entry into the relevant communities, and be respectful of them. Researchers shall inform the REB of their strategies to familiarize themselves with the relevant norms and cultural practices, and to minimize risks to individuals and communities participating in, or potentially affected by, the research.

Researchers and REBs should afford prospective participants in other countries no less protection and respect than what this Policy requires. Respect for Persons, Concern for Welfare, and Justice considered in the context of the particular research project and setting should guide researchers in the design of their research, and REBs in their research ethics review.

**Article 8.4**

(a) The information to be provided to the researcher’s home REB will be determined by the provisions of the research ethics review model.

(b) When conducting research outside the jurisdiction of their home institution, whether at a site abroad, or in Canada, researchers shall provide their home REBs with:

- the relevant information about the rules governing research involving humans and the ethics review requirements at the research site, where any exist;

- the names and contact information for the relevant REBs or comparable ethics bodies, if known, that will review the proposal at the research site; and

- relevant information about the target populations and circumstances that might have a bearing on the research ethics review by the researchers’ home REB.

**Application**

Researchers and REBs should be aware of the research ethics requirements and the types of protections for research involving humans, including legal protection, afforded to participants at proposed research locations. Researchers and REBs should consult relevant reliable resources for details about governing laws or policies, and for information regarding appropriate REBs at the proposed research site in Canada or another country (see References at the end of this chapter). Applicable policies at the proposed site may differ considerably from this Policy, and therefore it is the responsibility of the researchers and REB(s) to ensure that, at a minimum, the provisions of this Policy, are followed.

Disagreements may arise when one of the REBs or equivalent review body (Canadian or foreign) grants ethics approval while the other does not. Such disagreements require open communication among the researchers and the REBs, or equivalent review bodies involved (see also Section A of this chapter). In keeping with the
context-sensitive approach to research ethics review embodied in this Policy, the
Canadian REB should ensure that it has a clear understanding of the differing ra-
tionale that might underlie divergent REB positions or decisions on a given
proposal. Where the REB is uncertain about the appropriate course of action in a
given research proposal, it should make contact with its counterpart REB in the re-
search site or country. In the absence of formal reciprocity agreements between
countries or institutions with respect to initial and continuing research ethics review,
the REBs should engage in dialogue and may establish a specific mechanism, such
as a joint subcommittee of the two REBs (e.g., for situations in which institutions
collaborate regularly), to facilitate appropriate deliberation in order to reach a
thoughtful and well-informed judgment on the ethical acceptability of a given re-
search proposal (see Article 8.1).

Endnote

1 See for example the United States Office for Human Research Protections (OHRP) registry of REBs
(see References below), mainly in the area of health and biomedical research. It can serve as one re-
source for identifying research ethics review bodies around the world.

References

• Council for International Organizations of Medical Sciences (CIOMS). International Ethical
  H-1.2. http://assembly.nl.ca/Legislation/sr/statutes/h01-2.htm
• Québec. Ministère de la Santé et des Services sociaux. Direction générale adjointe de l’évaluation,
de la recherche et de l’innovation. Unité de l’éthique. Mécanisme encadrant l’examen éthique et le
suivi continu des projets multicentriques. In effect since April 1, 2008.
  www.ethique.msss.gouv.qc.ca/site/fr_mecanismemulticentrique.phtml
  www.hhs.gov/ohrp/international/HSPCompilation.pdf
• ———. Federal-Wide Assurances Registry for Registered Organizations Operating Institutional
  Review Boards (IRBs) or Registered IRBs. ohrp.cit.nih.gov/search
• World Medical Association. Declaration of Helsinki – Ethical Principles for Medical Research
policies. Where divergences exist, they should be addressed and resolved prior to the commencement of the research, or as they arise over the course of the research.

First Nations, Inuit and Métis scholars attached to academic institutions as faculty members, students or research associates are increasingly engaged in research involving their own communities, and sometimes their own family members. They are generally exempt from restrictions on physical access to territory or personal access to community members. However, as members of institutions that adhere to this Policy, they are subject to the ethical duty to respect community customs and codes of research practice when conducting research in their own local or cultural communities, and to engage the relevant community as required by this Policy. In these cases, institutional REBs may be concerned about researchers being in a conflict of interest and should manage the conflict of interest in accordance with Articles 7.2 and 7.4.

Life history and language research are examples of research areas where insider relationships and cultural competencies provide unique opportunities to extend the boundaries of knowledge. Although it can be argued that recording the life history of an elderly relative is a family matter rather than a community matter, when undertaken as research, community engagement is important to ensure that the following considerations are reviewed: the potential impact of such research on the wider community; conflicts between the individualist norms of the academic environment and the norms of the community; and the possibility of unclear or mistaken assumptions on the part of participant and researcher. During the consent process, researchers should give the participant the opportunity to identify the relevant form of community engagement, and at what stage such engagement should occur. This may include engaging with extended family members, peers of the participant with whom the researcher’s interpretations can be validated, or Elders knowledgeable about cultural rules governing disclosure of privileged information.

**Institutional Research Ethics Review Required**

**Article 9.9** Research ethics review by community REBs or other responsible bodies at the research site will not be a substitute for research ethics review by institutional REBs, and will not exempt researchers affiliated with an institution from seeking REB approval at their institution, subject to Article 8.1. Prospective research and secondary use of data and human biological materials for research purposes is subject to research ethics review.

**Application** Applying this Policy in a way that accommodates the diversity of First Nations, Inuit and Métis cultures, and mixed Aboriginal communities in urban centres is complex. For example, the fit between institutional policies and community customs and codes of research practice may be unclear, requiring researchers to adapt conventional practice or negotiate a resolution.
Consistent with Article 8.3(b), research conducted outside the jurisdiction of the researcher’s institution shall undergo prior research ethics review by both “(i) the REB at the Canadian institution under the auspices of which the research is being conducted, and (ii) the REB or other responsible review body or bodies, if any, at the research site.”

Article 8.1 permits review models for multi-site research that do not require separate research ethics review by each site involved in a research project. In cases where the community is the direct recipient of funding and has constituted a local REB that is party to an agreement with the researcher’s institution, review by the institution’s REB may not be required.

In accordance with Article 8.4, communication between the institutional REB and the responsible agency in the community may assist in resolving inconsistencies between institutional policy and community customs and codes of research practice. Where a community research ethics review is required in addition to the mandatory institutional REB review, reconciling differences may require resubmission to one or both review bodies.

Researchers and REBs should recognize that research ethics review by community bodies will often pursue purposes and apply criteria that differ from the provisions of this Policy. The express purpose of most Aboriginal community codes of research practice is to ensure the relevance of research undertakings to community needs and priorities, and respect for First Nations, Inuit and Métis identities, cultures and knowledge systems. While community codes of practice and research agreements typically share many of the goals of institutional policies, the approaches to achieving those goals may differ significantly. It is therefore inappropriate to insist on uniformity between community practices and institutional policies. For example, when researchers seek to interview Elders willing to share their knowledge according to traditional customs of consent, REBs should not impose language and processes that may be experienced as culturally inappropriate or awkward (see Article 3.12).

In cases where REB review of research on topics related to Aboriginal peoples or affecting Aboriginal communities is regularly required, the REB membership should be modified to ensure that relevant and competent knowledge and expertise in Aboriginal cultures are available within its regular complement. Aboriginal scholars or members drawn from First Nations, Inuit or Métis communities may fill this role (see Article 6.4). For occasional review of Aboriginal research that is likely to affect the welfare of a community or communities, consultation with ad hoc advisors or delegation to a specialized or multi-institutional REB may be appropriate (see Articles 6.5 and Article 8.1).

The membership of community review bodies of First Nations, Inuit or Métis communities will not necessarily duplicate the membership criteria set out in this Policy. In the context of scarce resources in community organizations, the same
personnel may be involved in reviewing the ethics of a proposal and co-managing the research project. An expectation that conflicts of interest will be managed by separating research ethics review and project management functions may impose unsupportable demands on small communities. In these circumstances, researchers and participating Aboriginal communities should address the ethical safeguards of the community and its members that can be best achieved in circumstances when multiple roles are assumed by the same person (see Chapter 7 and, in particular, Article 7.2).

**Requirement to Advise the REB on a Plan for Community Engagement**

**Article 9.10** When proposing research expected to involve First Nations, Inuit or Métis participants, researchers shall advise their REB how they have engaged, or intend to engage, the relevant community. Alternatively, researchers may seek REB approval for an exception to the requirement for community engagement, on the basis of an acceptable rationale.

**Application** In order for REBs to consider whether the form of community engagement chosen by the researcher is appropriate, they will require evidence in the form of one or more of the following: (a) a preliminary or formal research agreement between the researcher and the responsible body at the research site; (b) a written decision or documentation of an oral decision taken in a group setting to approve the proposed research or to decline further participation; and (c) a written summary of advice received from a culturally informed advisory group or ad hoc committee (e.g., an urban community of interest). Where community engagement is not being proposed, perhaps due to the nature of the research and the community context (see Articles 9.1 and 9.2), researchers shall provide a rationale acceptable to the REB.

Provision of a research agreement is particularly emphasized in health research funded by CIHR (see CIHR Guidelines for Health Research Involving Aboriginal People in References at end of this chapter).

Where a researcher has an ongoing relationship with a community, a letter from formal or customary leaders in the relevant community may signal approval, and suffice to proceed with the research.

Where, under the provisions of Articles 6.11 and 10.1, a community signals during preliminary discussions with researchers, prior to REB review, that the research may proceed but that it does not want further community engagement, researchers shall document and present to the REB the steps they took to invite and facilitate engagement by the community. See Article 9.14 on how researchers may assist in capacity building.

Although researchers shall offer the option of engagement, a community may choose to engage nominally or not at all, despite being willing to allow the research to proceed. A community may, for example, support a research project carried out
independent of community influence, or without any further collaboration of the community in the actual implementation of the research in order to use scientifically defensible results to validate a negotiating position.

Research Agreements

**Article 9.11** Where a community has formally engaged with a researcher or research team through a designated representative, the terms and undertakings of both the researcher and the community should be set out in a research agreement before participants are recruited.

**Application** Research agreements serve as a primary means of clarifying and confirming mutual expectations and, where appropriate, commitments between researchers and communities. Research agreements, where applicable, shall precede recruitment of individual participants and collection of, or access to, research data. The scope of the agreement will depend on the level of engagement which the community desires, and the availability of resources to support community participation.

At a minimum, the agreement should address the ethical protections that would apply to securing individual consent for a comparable project, and should specify any commitments regarding collective community participation and decision making, sharing of benefits and review, and updating of the agreement. Expanding on information normally provided to an individual participant (see Article 3.2), agreements typically set out the purpose of the research and detail mutual responsibilities in project design, data collection and management (see Article 5.3); analysis and interpretation; credit due to knowledge holders; protection (and non-disclosure) of restricted knowledge; sharing of benefits or royalties flowing from intellectual property where applicable; production of reports; co-authorship; dissemination of results; and a conflict resolution process. Provisions for any anticipated secondary use of the information or human biological material, and associated data collected, should also be addressed at that time, and documented in the research agreement (see Article 9.20).

Where a community has adopted or adheres to a code of research practice, the agreement may set out responsibilities in accordance with that code and the specific requirements of the research project. In less formal circumstances, the agreement may be relatively brief, and subject to clarification as the project unfolds. The CIHR *Guidelines for Health Research Involving Aboriginal People* (2007) provide examples of elements that may be included in research agreements (see References at the end of this chapter).

Research agreements are increasingly being recognized by academic institutions (and the researchers associated with them) as providing reference points for research ethics review process and approval on such elements as consent, confidentiality, and access to and use of information. Agreements that specify procedures for community research ethics review, included as part of the institutional ethics