Draft 2nd Edition of the
Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans

Submitted by the

Interagency Advisory Panel on Research Ethics

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Comments on this document can be sent to:

Interagency Secretariat on Research Ethics
350 Albert Street
Ottawa, ON Canada
K1A 1H5
Tel: 613-996-0072
Fax: 613-996-7117
draft2e@pre.ethics.gc.ca
www.pre.ethics.gc.ca
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Chapter 1

ETHICS FRAMEWORK

A. The Importance of Research and Research Ethics

Research is a distinctly human enterprise, a natural extension of our desire to understand and to improve the world in which we live. The search for knowledge about ourselves and the world around us has been an aspect of human endeavour throughout recorded history. We observe, we question, and then we test our observations and theories. Over time, these instinctive activities have developed into disciplined inquiry to extend knowledge.

The scope of research is vast. On the purely physical side it ranges from seeking to understand the origins of the universe, down through the fundamental nature of matter. At the analytic level it covers mathematics, logic and metaphysics. Research involving humans ranges widely, including attempts to understand the broad sweep of history, the workings of the human body and the body politic, the nature of human interactions and the impact of nature on humans – the list is as boundless as the human imagination.

There can be no doubt that research has greatly enriched and improved our lives. A fundamental premise of this Policy is that research can benefit society. But research is, by any definition, a step into the unknown: it seeks to understand something not yet revealed. Because we do not know where it will lead us, research may entail risks. These risks can be trivial or profound, physical or emotional – but they do exist.

History offers unfortunate examples where participants in research have been needlessly and at times profoundly harmed by research. It offers many more examples where people have been gratified and their lives enriched by their participation in research and the sense that they have contributed to the expansion of knowledge. Given the fundamental importance of research and of human participation in research, we must do all we can as a society to ensure that research proceeds in an atmosphere of public confidence and trust. By promoting and guiding the ethical conduct of research involving humans, this Policy seeks to contribute tangibly to that essential public confidence and trust.

Respect for human dignity has been a founding value of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (“the Policy”) since its inception. The term lends itself to a wide variety of interpretations. At its most basic, it requires that research involving humans be conducted ethically – that is, in accordance with an agreed-on set of principles. This Policy takes human dignity as the foundation for three core principles that transcend disciplinary boundaries and are therefore relevant.
to the full range of research covered by this Policy. The intent is that the three core
principles will collectively constitute a functional definition of human dignity, one that
will provide clarity and guidance for the purposes of this document.

No single document can provide definitive answers to all ethical issues that may arise in
an undertaking as complex as research involving humans. This Policy sets out guiding
principles for the design, conduct and oversight of ethical research. Its aim is to assist
those who use it – researchers, sponsors, members of research ethics boards (REBs),
research participants and the public – to identify ethical issues in the design, conduct and
oversight of research and to point the way to arriving at reasoned and ethical responses
to these issues.

B. Core Principles

Article 1.1 The three core principles that are the basis for the guidelines developed
in the Policy are:

- Concern for welfare;
- Respect for autonomy; and
- Respect for the equal moral status of all humans.

These principles are not absolute. They may, at times, conflict. They do not apply in all
circumstances, to all types of research, as is set out in the following chapters. How they
apply and the weight to be accorded to each one will depend on the nature and context of
the research being undertaken.

Welfare

Welfare is a broad concept that encompasses the full range of concerns that form the
basis of an individual’s decisions. It includes the individual’s own well-being, such as
his or her physical and mental health, but it is broader. It also involves all concerns
regarding the individual’s physical, social, economic and cultural environments,
including the welfare of those who are important to the participant. One key aim of this
Policy is not only to safeguard the well-being of the individual research participant, but
to do so in a way that preserves and respects the broader values with which that
individual identifies.

The researcher is responsible for considering welfare when designing and conducting a
research project. However, concern for a participant’s welfare does not imply that
research must present no risk. Welfare must be assessed in light of the aims and the
methodology of the research. Some risks are legitimate and necessary if the researcher is
to gain the desired knowledge.

Researchers must be conscious of the impact their research can have, not only on those
who participate in it, but also on others not directly involved. Just as the benefits of
research can be enjoyed by larger groups, it is also possible that the knowledge gained
from research can have negative effects, such as the stigmatization of groups. Consultation during the design of the research with groups who may be affected can help clarify the potential impact of the research and may provide the best assurance that any negative impact of the research is minimized.

Prior to the research’s being presented to prospective participants, the REB is responsible for ensuring that the risks of research are reasonable. It is the assessment of whether the relative risks and potential benefits (the “risk-benefit ratio”) that should determine to the advancement of knowledge. Researchers should then explain to prospective participants the known or expected risks their research presents. In the end, since they bear the risks, it is the research participants themselves who must judge whether the risks and benefits of participating are acceptable. This imperative follows from the next core principle, autonomy.

**Autonomy and the Decision to Participate in Research**

Respect for autonomy implies that participation in research should usually be voluntary – a matter of choice. To be meaningful, that choice should be informed. This means it should be based on as complete an understanding as reasonably possible of the purpose of the research, what it entails, and its foreseeable risks and benefits, both to the participant and to others.

How researchers obtain and maintain consent for participation in their projects will differ according to the nature of the research and the circumstances and capacity of the potential participants. While research ethics policies traditionally refer to autonomy as a condition for participation in research, we must consider the reality that:

- Not all research participants are capable of exercising their autonomy;
- Even those with the capacity to express their autonomy may experience constraints on how they do so; and
- In certain research contexts, incomplete disclosure of relevant information or deception is necessary for the successful conduct of the research.

Autonomy is not always the paramount consideration. Indeed, for some types of research, free and informed consent is not even required. The real inquiry, therefore, is the extent to which the exercise of autonomy is possible, and whether it can be validly exercised: either directly, by the prospective participant, or by an authorized third-party decision maker. Beyond the decision of an individual participant or an individual’s authorized third-party decision-maker, the exercise of autonomy is influenced by an individual’s various connections: to family; to community; and to cultural, social, linguistic, religious and other groups. The individual’s decision can have an impact on and be constrained by any of these. Under some conditions, the views of the groups affected may have to be considered by the researcher and the REB in approving the research. The weight given to it will depend on the nature of the research being undertaken and the individuals or groups in question. This does not, however, imply that group consent is a condition of ethics approval.
The ethical recruitment of participants in human research goes beyond an evaluation of autonomy, which often seems to focus primarily on whether an adult person has signed a consent form. It is a more complex consideration of whether the recruitment of participants has been carried out on a basis that is ethically legitimate and methodologically justified. It should be a process that respects and reflects, wherever possible, the values and preferences of the individual participants and, where necessary, engages the groups that may be affected by the research.

**Equal Moral Status of All Humans**

Equal moral status means that all human beings should be accorded the same level of respect and concern in the conduct of research. This means that, for example, researchers may not be arbitrarily discriminatory in the recruitment of participants and that participants should share the burdens and the benefits of research equitably. Researchers may choose particular groups as the focus of their research, so long as the selection criteria for those to be included in the research are germane to answering the research question.

Respect for the equal moral status of all individuals is also important because the relationship between researcher and participant is often marked by an imbalance of power. The participant will generally not understand the research in the same way and in the same depth as does the researcher. In some cases, historically, this power imbalance has been a source of harm or abuse. Participants must have the assurance that they will be treated fairly and not be exploited. Researchers should conduct themselves in a way that earns the trust of participants. Respect for the equal moral status of all individuals is an important element in establishing that trust.

A special problem of according equal treatment to all emerges with regard to research populations that may be particularly vulnerable. In light of a few notorious cases of abuse, there has been a tendency to try to afford extra protection to certain categories of participants. While some such measures may be warranted, equal moral regard for all requires that the protection not be so comprehensive as to deny the groups access to participation in ethical research.

In designing and conducting research, researchers should consider their relationship to participants as a form of collaboration, even in fields where participants do not (indeed cannot) contribute to the design of the research. The touchstone for the researcher should be to respect the welfare, autonomy and equal moral status of all participants. That will engender trust, and the trust of individual participants, as well as public trust, is necessary for the research process. Researchers should also consider the implications of the core principles for sharing the benefits of the research.

In summary, the importance of research and the need to ensure the ethical conduct of research forces both researchers and REB members to navigate a sometimes difficult course between insufficient protection and overprotection of research participants. The three core principles, which characterize respect for human dignity, provide the compass for that journey.
To be effective, a research ethics policy should provide guidance for the interpretation of the principles of research ethics. This Policy aims to strike an appropriate balance between recognizing the potential benefits of research and the need to protect participants from research-related risks. Given that research involving humans covers the full spectrum from minimal to high risk, the first element of the approach laid out in this Policy is to ensure that the degree of scrutiny applied to ethics review is proportionate to the level of risk that the research presents.

Proportionality is the key to ensuring that those who volunteer to participate in research are not exposed to unnecessary risks, while at the same time avoiding the creation of unnecessary barriers or delays to research. Those involved in the design and the review of research should keep ethical considerations in mind. For any given research question, the design should be structured so that research risks are minimized. Equally, those involved in reviewing research (both initial and continuing review) should do so with an appreciation of the level of review that is appropriate to the risks of the project. The scope and intensity of ethics review should be proportionate to the level of risk involved. When those involved in the review of research tailor their level of scrutiny to the level of risk, they reduce unnecessary impediments and facilitate the progress of worthwhile and ethical research. This is the crux of proportionality, and it is a message that recurs throughout this Policy.

It is equally important that ethics review be appropriate to the disciplines, fields of research and methodologies of the research being reviewed. This means that REBs must understand the discipline and methodology under review and be able to assess the research on its own terms.

Finally, it is not enough to say that ethics review must be approached from the perspective of the participant. It is necessary to consider the context – social, economic, cultural or other – that shapes the participant’s life.

Together, the core principles and proportionality form the basis of a sound approach to research ethics – one that recognizes the value of research, while respecting, valuing and protecting research participants.

Members of REBs should view the Policy’s guidelines, not as rules to be applied, but as principles to be interpreted. This requires a thorough understanding of the principles in this Policy. It also requires the exercise of sound judgment in deciding how to apply those principles. Because the principles are intended to cover a wide variety of approaches to research and types of research, they may and should be interpreted differently in different circumstances. The use of discretion in the exercise of interpretation will be necessary. A certain variability of decisions among REBs may therefore be inevitable. These should not be so great, however, as to result in fundamental conflicts among the decisions of REBs.
This Policy is designed to provide general guidance with respect to the ethical conduct of research involving humans. It is divided into chapters, each of which focuses on a different aspect of the ethics of research and research ethics review. The chapters are divided into articles that provide targeted guidance on specific issues. Each article is followed by an explanatory section – “Application” – that describes in more detail considerations relevant to interpreting the article. In some cases, illustrative examples are provided, and in some sections other sources – “References” – are provided for more detailed guidance on particular topics.

Where the articles and their applications do not address an ethical issue in question, the researcher or REB should return to the core principles in order to resolve their dilemma.

This Policy, which provides a distinctive, comprehensive approach to considering research ethics, will continue to evolve as new issues emerge.
Chapter 2

SCOPE AND APPROACH

The purpose of this Policy, as set out in Chapter 1 ("Ethics Framework"), is to establish principles to guide the design, conduct and review of research involving human participants. This chapter outlines the scope of application of the Policy and the approach to ethics review that flows from the core principles: welfare, autonomy and equal moral status of all humans. It sets out the preferred approach to ethics review by a research ethics board (REB) – a proportionate approach, which tailors the level of scrutiny by an REB to the level of risk presented by the research, both at the stage of the initial review and throughout the period the research is active, to ensure the continued ethical acceptability of research. The establishment, governance, jurisdiction, composition and operational issues related to the functioning of REBs are addressed in Chapter 6 ("Governance of Research Ethics Review").

A. Scope of 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 chapter.

Article 2.1 (a) All research that involves human participants requires review and approval by a research ethics board (REB) in accordance with this Policy before the research commences, except as stipulated below.

(b) Research involving human remains, cadavers, tissues, biological fluids, embryos or fetuses shall also be reviewed by an REB.

(c) Researchers who intend to secure identifiable personal information about participants shall secure REB approval.

Application REB review is limited to those activities defined as “research” in this Policy, and involving “human participants” as defined in this Policy. There are many activities outside the scope of these definitions that may raise ethical issues requiring some form of review or guidance. REBs are not the sole forum for ethics guidance, however. Their role should be restricted to the scope of research involving human participants as set out below.

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

A determination of the intended purpose of the undertaking, as distinct from the use of potentially similar methods, is key for differentiating activities that require review by an REB and those that do not.

For the purpose of this Policy, “research participants” (or simply, “participants”) are those living individuals whose data or responses to questions, stimuli or interventions by the researcher are material to the research question. They are unique among the many parties involved in research, because they bear the primary risks of the research. The focus of this Policy is to ensure respect for their welfare, autonomy and equal moral status. 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. In particular, it reflects the range of research covered by this Policy, as well as the varied degree of involvement by participants that different types of research offer.

Article 2.1(b) describes the scope of REB review beyond living individuals. This includes research involving human materials such as biological fluids, tissues and gametes, and human remains. Note that this covers only research involving the physical remains of a deceased person, and not deceased persons themselves. For further information regarding what type of research is exempt from REB review, see Article 2.2.

The use of human tissues for the purpose of research is further elaborated on in Chapters 12 and 13 (“Human Tissue” and “Human Genetic Research”).

For the purposes of this Policy, “identifiable personal information” means information relating to an individual that could be used to identify or re-identify that individual through a combination of indirect identifiers (such as date of birth, place of residence, or a unique personal characteristic). It includes information about personal characteristics such as age, culture, educational background, employment history, health care, life experiences, religion, social status and other matters where an individual has a reasonable expectation of privacy. (See Chapter 5 [“Privacy and Confidentiality”] regarding types of information and Chapter 3 [“Free and Informed Consent”] regarding consent procedures specific to securing identifiable personal information.)

Subject to the exceptions in this chapter, research based exclusively on publicly available information requires REB review only if the participant is approached directly for interviews or for access to private papers, and then only to ensure that such approaches are conducted according to professional protocols and to Articles 3.1 and 3.2 (free and informed consent). Where the research involves interaction with an individual in public life or an artist as a
research participant by way of a request for an interview or for access to private papers, the REB review should focus only on whether these requests will be made in accordance with appropriate ethical and professional standards. Similarly, REBs should ensure that interviews with third parties are conducted according to a professional interview protocol and to Articles 3.1 and 3.2 (free and informed consent), and that the potential interviewees be fully informed about publication of the interview and their identity. REBs should not require such third-party interviews to be controlled in any way by the person who is the primary focus of the research.

Research based on critical inquiry – focusing, for example, on public policy issues, modern history, or literary or artistic criticism – may involve interaction with living individuals, notably through interviews. Where the aim of the researchers is to engage in a critical examination of a body of artistic work, a public policy, other comparable types of work, the role of the REB should be limited to ensuring that researchers conduct their work respecting the professional standards of their discipline(s) or field(s) of research. The need to ensure freedom of inquiry and to protect the ability of researchers to criticize the work (or organization, political party, corporate enterprise, etc.) they are examining takes precedence over the need to protect individual parties from harm.

**Research Not Requiring REB Review**

The requirement for REB review is not absolute. This Policy allows some exemptions and exceptions, as outlined below and complemented in the Appendix by examples of activities that do not require ethics review by an REB.

Beyond the exceptions listed below, others may arise. Because principles are designed to guide ethical reflection and conduct, they require flexibility and admit exceptions. To preserve the values, purpose and protection that they attempt to advance, the onus for demonstrating a reasonable exception to a principle should fall on those claiming the exception. The opinion of the REB should be sought whenever there is any doubt about the applicability of this Policy to a particular research project.

Community processes may apply to research beyond the scope of REB responsibilities. For example, research on the interface between environmental and human systems that does not involve individual participants does not require REB review. In these cases, the guidelines of this Policy can be used as a model to help fill gaps, accommodate overlap and resolve other types of ethical conflicts between community and institutions.

**Article 2.2** Research that relies exclusively on publicly available information does not require research ethics board review. This includes research on living
individuals and research on organizations such as governments or corporations, so long as the research is based entirely on material to which the public has access.

**Application** Archival materials and records conserved by libraries, documentation centres and archival services (public and private) that are open to the general public on the basis of transparent procedures, including consultation policies, are considered to be publicly available for the purposes of this Policy. An archival document or a database that is subject to restrictions under access to information and privacy legislation may nevertheless be considered publicly available for the purposes of this Policy, insofar as it meets the criteria set out in this definition.

Research about a living individual involved in the public arena (politicians, artists, public figures, business or labour leaders, etc.) or about organizations and institutions (governments, corporations, criminal organizations, political parties, etc.) based exclusively on publicly available information such as documents, records, material from public archives, performances, archival materials, third-party interviews, public policy documents, published works and the like, available in print, electronic or other media, to which the public is granted access, is not required to undergo REB review, because such research involves no interaction with the person or organization who is the subject of the public records. In these cases, there is no presumption of privacy. The safeguard for those in the public arena is through public debate and discourse or, in extreme cases, through action in the courts for libel.

**Article 2.3** Research ethics board review is usually not required for research involving public policy issues, the writing of modern history, or literary or artistic criticism.

**Application** While all the areas of research noted in Article 2.3 may involve interaction with living individuals, this exception is based on the fact that the research relies either on published or publicly available information, including performances, archival materials, or on information derived from publicly available third-party interviews. This exception could, for example, cover research about a living individual with a public profile, or criticism of a living artist, so long as the research involves no interaction with the person who is the subject of the publicly available information.

**Article 2.4** Quality assurance and quality improvement studies, program evaluation, and performance reviews or testing within normal educational requirements are not subject to research ethics board review.

**Application** Studies related directly to assessing 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, do not
require REB review.

Activities other than research as defined in this Policy may still raise ethical issues that would benefit from careful consideration by a body capable of providing some independent guidance, other than an REB. Such issues may include, for example, the potential for real or perceived coercion in certain quality assurance or evaluation studies. Bodies capable of providing such guidance may be based in professional or disciplinary associations, particularly where those associations have established best-practices guidelines for research in their discipline.

**Article 2.5**  
Research involving observation of people in public places that does not allow for the identification of the individuals in research material and that is not staged by the researchers does not require research ethics board review.

**Application**  
Observational research is a form of qualitative research. The exemption of observational research that meets the specific criteria set out in this article is addressed more fully in Article 10.2 of Chapter 10 (“Qualitative Research”).

**Article 2.6**  
Creative practice activities in and of themselves do not require research ethics board 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 review by an REB, but they may be appropriately governed by ethical practices established within the cultural sector. As a form of artistic expression, creative practice does not fall within the definition of research in this Policy. It is therefore not subject to REB review.

Research that employs creative practice to obtain responses from human participants that will be analyzed to generate or to address a research question is, however, subject to REB review.

### B. Approach to Research Ethics Board Review

**REB Review Shall be Proportionate**

**Article 2.7**  
The research ethics board should adopt a proportionate approach to ethics review, based on the principle that as the risk to participants increases, so should the level of scrutiny in assessing the research and the level of expertise involved in the review process.

**Application**  
The concept of proportionate review gives practical expression to the core principle of concern for the welfare of participants in research, such that the
more potentially invasive or harmful is the proposed and ongoing research, the higher the level of scrutiny and expertise that should be applied to the ethics review process. While all research must be reviewed adequately, proportionate review is intended to direct the most intensive scrutiny, time and resources, and correspondingly the most protection, to the most ethically challenging or high-risk research.

A proportionate approach to ethics review starts with an assessment of the character, magnitude and probability of potential harms and benefits inherent in the research. 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.

The concept of minimal risk (described below) provides a foundation for proportionate review. The various applications of the proportionate approach to REB review are addressed in Chapter 6 (“Governance of Research Ethics Review”).

Concept of Potential Risks and Benefits

Applying the principles of concern for welfare and respect for autonomy of research participants requires an assessment of foreseeable risks and benefits to research participants and to others. The ethical acceptability of research is dependent on a judgment as to whether the potential benefits justify the risks, thus ensuring that research involving humans is designed and conducted in such a way as to answer as well as possible the question posed by the research, while ensuring that the participant is not unduly or unnecessarily exposed to risk. It is the responsibility of the REB in reviewing a research proposal to decide whether the research presents an ethically acceptable balance of risks and potential benefits. The subsequent decision to participate in approved research is one that potential participants make based on their own appreciation of whether it serves their welfare to do so. Participants should share both the burdens and the benefits of research.

Potential Risks

Three considerations (informed by the principle of concern for welfare) are relevant to the assessment and categorization of risks to research participants and of the possible risks to third parties:

- The nature of the harm;
- The magnitude or seriousness of the harm; and
- The probability of occurrence of the harm.
Potential harms are usually understood in relation to risks, which are defined in terms of the magnitude of harm and the probability of its occurrence. Both potential harms and potential benefits may span the spectrum from minimal through substantial. An explanation of “risk” should clarify risk as the combination of the probability of harm and the magnitude of harm. For example, the various kinds of harms that a participant might incur, the likelihood of participants’ actually incurring harms, and the available methods of ameliorating the harms all need to be considered. 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.

For the purpose of this Policy, a “minimal risk” situation is defined as one in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by the participant in those aspects of his or her everyday life that relate to the research.

Above the threshold of minimal risk, research warrants a higher degree of scrutiny and greater provision for the protection of the interests of prospective participants.

Because research involves advancing the frontiers of knowledge, its undertaking often involves uncertainty about the precise magnitude and kind of harms that attend proposed research. 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 study will proceed and any associated risks will be known only as the study unfolds. (See Chapter 3 [“Free and Informed Consent”] and Chapter 10 [“Qualitative Research”].) In cases in which patients participate in research on interventions undertaken for purposes of therapy for that individual, the concept of minimal risk raises special issues in clinical research, especially clinical trials. (See Chapter 11 [“Clinical Trials”].)

Risk may be perceived differently by different groups in society. Researchers and REBs should take this into account in designing and reviewing research. In assessing risks for specific populations, researchers and REBs should understand the role of the culture, values and beliefs of the populations to be studied, as well as any guidelines that exist for conducting research with these populations. (See Chapter 8 [“Multi-jurisdictional Research”], Chapter 9 [“Research Involving Aboriginal Peoples’] and Chapter 10 [“Qualitative Research”].)
Research involving humans is intended to produce benefits for participants themselves, for other individuals, or for society as a whole through the advancement of knowledge. Just as there are uncertainties concerning the risks of research, so there is uncertainty about its expected benefits. In most research, the primary benefits produced are for society and for the advancement of knowledge.

**Balancing Risks and Benefits**

Risks and benefits must be evaluated in the context of research and, to the extent possible, from the perspective of participants, because both risks and benefits may be perceived differently by different individuals.

The analysis, balance and distribution of risks and benefits are critical to the ethics of human research. Modern research ethics, for instance, requires a favourable risk–benefit balance – that is, the anticipated benefits should outweigh the foreseeable harms.

The uncertainty of research outcomes often makes it difficult to reliably predict the precise nature and magnitude of the resulting benefits and harms. This reality, coupled with the principle of concern for welfare, imposes an ethical obligation to design, assess and conduct research in a way that protects research participants from any unnecessary or avoidable harm. This is particularly true in the areas of biomedical research, where the physical well-being of participants may be at stake.

These considerations do not apply in the same way in certain areas of research in the social sciences and humanities, such as political science, economics or modern history (including biographies), where the purpose of the research may be to cast a critical eye on organizations, political institutions, or systems or individuals in public life. The outcome of these types of research may harm the reputation of public figures or institutions in politics, business, labour, the arts, or other walks of life. Such harm may, however, be an unavoidable outcome of research that seeks to shed light on or to critically assess the work of a public figure or institution. Where the purpose of the research is to advance knowledge about the workings, for example, of a public office or a public figure, the risk–benefit analysis by the REB should focus on whether the approach they have adopted respects the professional standards of the researcher’s discipline or fields of research. Just as a bruise is an unavoidable risk of research that requires a needle-stick, so harm to reputation is an unavoidable risk of certain types of social science inquiry, and it must be treated as such.
**Requirement of Continuing REB Review**

**Article 2.8** Further to the initial review of research that falls within the scope of this Policy, research ethics boards shall review ongoing research throughout the life of the project. This includes review of departures from approved research that result in a change in the level of risk of research, or other ethical implications that have an impact on the welfare, autonomy and equal moral status of all humans. As with initial review, continuing ethics review should be based on a proportionate approach.

**Application** The primary goal of continuing ethics review is to ensure that all stages of a research project are conducted in accordance with the guiding principles outlined in this Policy, thus ensuring the continued ethical acceptability of research. At the time of initial review of the research, the REB has the authority to determine the level at which continuing ethics review occurs (for example, the frequency of reports and the type of information to be provided in reports). The level of review and reporting schedule may be adjusted throughout the life of the project if the need arises in situations where the risk level increases because of the discovery of new information or changes in procedures.

Continuing ethics review by an REB provides those involved in the research process (in particular, researchers, REBs, participants or participant groups) 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 or participant groups. This reflective practice enables both researchers and REBs to be more effective in protecting research 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 is characterized as a continuing dialogue between the participants or participant groups, REBs and researchers to enable the principles and practices surrounding research ethics to evolve.

In the conduct of their approved research, researchers should be cognizant of the requirement to report to their REB, in a timely manner, events or issues that have ethical implications or that change the risk to participants. The level of REB review required to assess these changes shall follow a proportionate approach to ethics assessment.

Further details related to the application of continuing ethics review and the REB review of departures to approved research are outlined in Chapter 6 of this Policy.
Scholarly Review as Part of REB Review

Article 2.9 The research ethics board should satisfy itself that research posing more than minimal risk has undergone scholarly review.

Application Scholarly review (referred to as peer review or scientific review in clinical research) is generally understood as a review of the importance of the research question and the validity of the methodology. When research poses more than minimal risk, exposing participants to research that has not been subject to scholarly review may be considered unethical.

Scholarly review is assessed by those familiar with the disciplines or methods of the proposed research. REBs may themselves assume the responsibility for scholarly review in the rare circumstances where there is no other more appropriate body to do so. In these cases, the REB will review research approaches and methodologies to the extent necessary to determine that the approach or methodology adopted is capable of answering the research question in a manner appropriate to the discipline or disciplines in question.

Traditions for scholarly and ethical review undertaken vary between disciplines or fields of research. The tradition for biomedical research is that it undergoes peer review prior to or as part of the REB review process. The extent of peer review required for minimal-risk biomedical research will vary according to the research being carried out. The tradition in the humanities and the social sciences for researchers is to undergo peer review at the grant application or publication stage. REBs therefore shall not require peer review for research in the humanities and the social sciences that poses, at most, minimal risk.

The possible mechanisms for REBs to seek evidence of scholarly review of more-than-minimal-risk research are detailed in Article 6.14 of Chapter 6 (“Governance of Research Ethics Review”).

Nothing in this section, however, shall be interpreted to mean that other relevant parts of this Policy – such as the need for REB review, interview protocols, free and informed consent and privacy – are not applicable to their research.

Balance of Ethics and Law

Article 2.10 In ethics review and the conduct of research, research ethics boards and researchers have an obligation to be aware of applicable laws.

Application The law establishes principles and rules that affect and regulate the conduct of research involving humans. These include legal rules about privacy,
confidentiality, competence of research subjects, intellectual property, and many other topics. Researchers should be aware of applicable laws. For research conducted in multiple jurisdictions or research outside Canada (addressed in Chapter 8 [“Multi-jurisdictional Research”]), this may require knowledge of laws in multiple jurisdictions. REBs may satisfy this obligation through expertise among their memberships or through wider consultation.

Legal rules and ethical principles are not always consistent. Researchers may face situations where they experience a tension between the requirements of law and the guidance of ethical principles. In such situations, researchers should do their best to uphold ethical principles while complying with the law. Consultation with colleagues, the REB or any relevant professional body will help resolve any conflicts between law and ethics and guide an appropriate course of action. This may include providing the researcher with access to legal advice, if needed.
Examples of Research that does not Require Research Ethics Board Review

The following are examples of activities that do not require review by a research ethics board (REB). These may, nevertheless, raise ethical issues that would benefit from careful consideration outside of the REB.

- Scholarship based on personal reflections and self-study where no one other than the researcher is involved in the research (e.g., autoethnography).

- Occasions when individuals other than the researcher provide information, but are not themselves the focus of the research; for example:
  - data collection about organizations, policies, procedures, professional practices or statistical reports (e.g., information provided by authorized personnel in the ordinary course of their employment); or
  - consultation to frame or develop the research (e.g., a graduate student interviews an agency manager to determine if the data he or she is interested in can be accessed, and how the information from the interview will inform planning decisions about the research).

- Program evaluation, quality assurance, quality improvement, or the review and assessment of the program or service; for example:
  - student course evaluations;
  - staff performance reviews;
  - website usability testing;
  - discussion with stakeholders and consultants; or
  - data collection for internal or external organizational reports.

- Public health surveillance that is legally mandated.

- Secondary use of information in research that does not involve identifying or identifiable information (see Chapter 5 [“Privacy and Confidentiality”] for a definition of identifying or identifiable information).

- Analysis or scrutiny of material in the public domain:
  - studies of people's writings that appear in the public domain (e.g., letters to the editors of newspapers; postings to public websites); or
– studies of public figures (e.g., politicians or celebrities) based on material such as interviews with a journalist or broadcast on television; biographical profiles based on materials in a public archive.

– research for a critical biography not involving living participants (i.e., based exclusively on published or publicly available material) (see Article 2.2).

Student assignments that pose minimal risk; teach about the design, conduct and process of research; and might involve “practice” data collection.
Chapter 3

FREE AND INFORMED CONSENT

Respect for human dignity implies that individuals who participate in research should do so voluntarily, understanding the purpose of the research and its risks and potential benefits as fully as reasonably possible. The decision to participate is therefore generally seen as an expression of autonomy – the result of an individual’s weighing the risks and potential benefits of a research study prior to agreeing to participate.

These are not, however, the only circumstances under which research takes place. Some potential participants, such as young children, lack the capacity to decide for themselves whether to participate. Consent in these cases requires the intervention of third parties to decide whether participation would be appropriate, based on considerations of well-being and welfare. These circumstances also involve considerations of equal moral status: it is important that those who lack capacity have the opportunity to participate in research that may benefit themselves or others.

The circumstances of the research itself may not allow for full disclosure of all relevant information prior to its commencement. This is the case, for example, with research in individual medical emergencies. It is also the case with certain research methodologies, where partial disclosure or an element of deception may be necessary in order for the research to be valid. In these cases, consent is still important, but it may have to be addressed, at least in part, following the research rather than preceding it.

These variations in the approach to consent raise a number of ethical issues. For example, what constitutes coercion or undue influence? When is partial or late disclosure ethically acceptable? What are the appropriate limits on the types of research in which individuals who lack the capacity to decide for themselves may participate?

In assessing consent, much emphasis has been placed on the signing of a consent form. Consent, however, may be evidenced in many equally legitimate ways. The primary focus of ethical concern should be on the quality of the consent, and not on how it is documented.

A. General Principles

Consent Must Be Voluntary

Article 3.1 Consent must be given voluntarily and, where feasible, may be withdrawn at any time.
Application

The element of voluntariness is important, because it means that an individual has chosen to participate in research according to his or her own values, preferences and wishes. To maintain the element of voluntariness, the participant should be free to withdraw from the research at any time.

Researchers and research ethics boards (REBs) must be aware of the approach to recruitment as an important element in assuring voluntariness. In particular, who recruits participants, and how and when they are approached, are important elements in assuring (or undermining) voluntariness.

Undue influence and manipulation may arise when potential participants are approached by individuals in a position of authority over them. The influence of power relationships on voluntary choice should be judged according to the particular context of prospective participants. For example, the voluntariness of prisoners, members of organizations with authoritarian structures (such as the military, police, some religious groups, or street gangs), or of employees or students, may be restricted because their institutional context implies that the individuals being recruited may feel constrained to follow the wishes of those who have some form of control over them. This control may be physical, financial, or professional, for example. It may involve offering some form of inducement or threatening some form of deprivation. In such situations, the control may place undue pressure on the prospective participants. There can be no voluntariness if consent is secured by the order of authorities – the most explicit exercise of undue influence.

REBs should also pay particular attention to the elements of trust and dependency – for example, within doctor–patient or professor–student relationships – because these can impose undue influence on the individual in the position of dependence to participate in research projects. Undue influence is particularly likely in situations of ongoing or significant dependency.

Voluntariness is especially relevant in research involving restricted or dependent participants. Any relationship of dependency, even a nurturing one – as, for example, between an individual with a debilitating chronic condition and his or her caregiver – may give rise to undue influence, even if it is not applied overtly.

Beyond undue influence, potential participants may be subjected to coercion, which involves a threat of harm or punishment for failure to participate. This more extreme form of influence would, of course, negate the voluntariness of a decision to participate or to remain in a research study.

The offer of benefits in some contexts may amount to undue inducement and thus negate the voluntary aspect of the consent of participants, who may perceive such offers as a way to gain favour or improve their situation. The issue of reasonable versus excessive compensation for participation in
research is an important consideration in assessing voluntariness. Compensation for participation is intended to ensure that participants are not put at a financial disadvantage for the time and inconvenience of participation in research. In some cultures, the giving and receiving of gifts symbolizes the establishment of a relationship comparable to consent. Compensation or gifts should not be so attractive as to constitute an inducement to take risks that one would otherwise not take. This is a particular consideration in the case of healthy volunteers for the early phases of clinical trials, as discussed in Article 11.1 of Chapter 11 (“Clinical Trials”).

In considering the possibility of undue inducement in research projects where participants will be compensated, REBs should be sensitive to issues such as the economic circumstances of those in the pool of prospective participants, and to the magnitude and probability of harms.

Participants should be able to change their mind, for any reason or even for no reason, and decide to withdraw from a research study. In some cases, however, the physical practicalities of the study may prevent withdrawal partway through – for example, if the study involves only a single intervention or personal information is de-identified and added to a data pool.

Consent Must Be Informed

Article 3.2 Subject to the exceptions in Articles 3.8 and 3.9, researchers shall provide, to prospective participants or authorized third parties, full and frank disclosure of all information relevant to free and informed consent.

Application Researchers should ensure that prospective participants are given adequate opportunities to pose any questions they may have, and to discuss and consider whether they will participate. For the purposes of this Policy, “authorized third party” refers to an individual with the necessary legal authority to make decisions on behalf of an individual who lacks the capacity to decide whether to participate in a particular research project.

At the commencement of the process of free and informed consent, researchers or their qualified designated representatives should provide prospective participants with the following, as appropriate to the particular research:

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

(b) A comprehensible statement of the research purpose, the identity of the researcher, the identity of the funder or sponsor, the expected duration and nature of participation, a description of research procedures, and an explanation of the responsibilities of the participant;
(c) A comprehensible description of reasonably foreseeable harms and benefits, both to the participants and in general, that may arise from research participation, as well as the likely consequences of non-action, particularly in research related to treatment, or where invasive methodologies are involved, or where there is a potential for physical or psychological harm;

(d) An assurance that prospective participants are under no obligation to participate; have the right to withdraw at any time without prejudice to pre-existing entitlements; and throughout the course of the research will be given, in a timely manner, information that is relevant to their decision to continue or withdraw from participation;

(e) Information concerning the possibility of commercialization of research findings, and the presence of any apparent or actual or potential conflict of interest on the part of researchers, their institutions or sponsors;

(f) The measures to be undertaken for dissemination of research results, and whether participants will be identified directly or indirectly;

(g) The identity of the qualified designated representative who can explain scientific or scholarly aspects of the research;

(h) Information on the appropriate resources outside the research team to contact regarding possible ethical issues in the research;

(i) An indication of who will have access to information collected on the identity of participants, descriptions of how confidentiality will be protected, and anticipated uses of data;

(j) Information on the circumstances under which the researcher may terminate the participant’s participation in the research;

(k) Information on any costs, payments, reimbursement for expenses or compensation for injury; and

(l) A statement to the effect that, by consenting, participants have not waived any legal rights.

Once research results have been compiled, researchers should make them readily available to participants, to the extent that it is feasible and in a manner that is appropriate.

Where there is a research team, the principal researcher is ultimately responsible for the actions of those acting with delegated authority. This includes responsibility for ensuring that the consent process has been respected.
Article 3.2 states the requirement to provide prospective participants with the information they need to give free and informed consent to their involvement in the research project. While the list of required information in Article 3.2 is extensive, additional information may be required in particular types of research or under particular circumstances.

Rushing the process of free and informed consent, or treating it as a perfunctory routine, violates the principles of autonomy and welfare, inasmuch as it may not allow for the assimilation of information for the participant, nor allow adequate time for the participant to make a considered judgment. The time required for providing an initial free and informed consent will depend on such factors as the magnitude and probability of harms, the complexity of the information conveyed, the setting where the information is given, and the participant’s situation (for example, his or her level of apprehension or curiosity about the research, or the importance to the participant of the potential benefit).

Paragraphs (a) to (c) require researchers to clearly explain the nature and goals of the research and other essential information, in a manner that best promotes understanding on the part of potential participants.

Paragraph (b) requires disclosure of those who support a particular research project, through funding or sponsorship. It is unethical for researchers to engage in covert activities for intelligence, police or military purposes under the guise of research. REBs must disallow any such research.

Article 3.1 and paragraph (d) in the Application of Article 3.2 help to ensure that a prospective participant’s choice to participate is voluntary. Pre-existing entitlements to care, education and other services should not be prejudiced by the decision of whether to participate. Accordingly, for example, a physician should ensure that continued clinical care is not linked to research participation, and teachers should not recruit prospective participants from their classes, or students under their supervision, without REB approval. Nothing in this section should be interpreted as meaning that normal classroom assessments of course work or other comparable performance evaluation undertakings require REB approval.

Paragraph (d) also requires that researchers provide all the new information pertaining to the risks of the research and any new ethical implications as that information becomes available, in order to ensure that, throughout the research, participants have all the information that could affect their consent. It is equally important that prospective participants be made aware of their right to withdraw from a research study at any time.

Paragraph (e) aims at managing potential or actual conflicts of interest. Researchers should separate, to the extent possible, their role as researcher from their roles as therapists, caregivers, teachers, advisors, consultants,
supervisors, employers or the like. If a researcher is acting in dual roles, this fact must always be disclosed to the participant. Conflict of interest matters are further elaborated in Chapter 7 (“Conflict of Interest”).

Paragraph (f) requires that researchers provide a reasonable explanation of the measures to be undertaken to publish and otherwise disseminate the results of the research. Beyond the ethical obligation to do so in such areas as clinical trials (see Articles 11.11 and 11.12 in Chapter 11 (“Clinical Trials”)), this requirement is grounded on the reasonable expectation of participants in research that the results will be published or otherwise disseminated in the public domain to advance societal knowledge.

Paragraph (h) acknowledges that some institutions may decide either to name an ombudsman for research participants, or designate a resource person to handle queries, receive complaints, and transmit those complaints to the REB. This is a matter for institutions to determine.

Paragraph (j) is intended to inform the prospective participant of circumstances under which the researcher may end the participant’s involvement in a research project. While participants need no reason to justify withdrawing from a research project, researchers must establish the basis on which they terminate the research or end the participation of a particular individual. For example, clinical trials have stopping rules – statistical points determined in advance, which, once reached, dictate that the trial must be terminated. These are discussed further in Chapter 11 (“Clinical Trials”).

Paragraph (k) is intended to prevent the development of a payment structure for research participation that might place undue pressure on research participants, either to join or remain within a research project. It also ensures that participants receive information regarding inducements for those who recruit participants. It should not be taken to mean that participants should be paid for their participation in research.

The list of information to be disclosed to potential participants is extensive. Not all of it may be applicable to all forms of research. It is up to the researcher to explain to the REB why, in a particular project, some of the listed disclosure requirements do not apply. It is also up to the REB to consider whether all elements are necessary in a given research project.

The Duty To Inform Is Ongoing

Article 3.3 Free and informed consent must be maintained throughout participation in the research.

Application Consent encompasses a process that begins with the initial contact and carries through to the end of – and sometimes beyond – the involvement of research.
participants in the project. Throughout the process, researchers have a continuing duty to provide participants and REBs information relevant to the participant’s free and informed consent to participate in the research. The researcher has the obligation to bring to the participant’s attention changes in circumstances germane to the research or to the particular circumstances of the participant. The participant is, of course, free to withdraw consent at any time for any reason. The ongoing obligation to provide new information that may be relevant to the participant’s consent, however, provides the participant with the opportunity to reconsider the basis for his or her consent in light of the new information. As used in this Policy, the process of free and informed consent refers to the dialogue, information sharing, and general process through which prospective participants choose to participate in research.

Incidental Findings

Incidental findings is a term that describes unanticipated discoveries made in the course of research (or care). This policy is concerned only with incidental findings in the context of research. They are findings that may have important psychological, social, health-related or other implications for the participant, but they are not the focus of the research itself. For example, a sociologist doing research on early childhood education may receive information that a child is suffering abuse, or a health-care worker doing research on one disease may discover evidence that a participant suffers from an entirely different and perhaps more serious disease. In a research setting, this raises particular ethical issues, because the consent process did not anticipate (and perhaps could not have anticipated) that such information would surface. Incidental findings frequently arise in the course of genetic research. This is addressed more specifically in Chapter 13 (“Human Genetic Research”).

Article 3.4 In their research proposal, researchers must:

(a) Develop a plan for handling incidental findings that their research may reveal and submit their plan to the research ethics board; and
(b) Advise potential participants of the plan for handling incidental findings in order to obtain free and informed consent.

Application It is not always possible to anticipate with any specificity the nature of the incidental findings that may surface in the course of research. It is therefore not possible to inform prospective participants in anything but the most general terms of what the research may reveal, beyond the realm of the research question itself.

So, for example, social science researchers embarking on questions of a personal nature should inform prospective participants of the legal obligations they are under to reveal information concerning certain types of abuse. Clinical researchers should disclose the possibility that they may come across evidence of other diagnoses beyond the particular condition they are studying.
To the extent that certain types of incidental findings are foreseeable, however, researchers should consider these possibilities when engaging in the consent process. The complexity of disclosing serious incidental findings may be mitigated to some extent by how well researchers have prepared participants for at least the possibility of discovering such information.

Incidental findings should be considered part of the obligation of ongoing disclosure to participants of information that may be germane to their continued participation in the research. The withholding or transmission of such information, particularly when it may have implications for the health or safety of the participant, may have legal consequences for the researcher. These are outside the scope of this Policy.

**Consent Should Precede Research**

**Article 3.5**  
In general, research with human participants should begin only after the participants or their authorized third-party decision-makers have provided their free and informed consent.

**Application**  
In keeping with the principle of autonomy, participants should provide their free and informed consent prior to engaging in research. This is the clearest demonstration that their participation is based on consideration of the risks and benefits of the research and other principles in this Policy.

This article does not apply to conversations that researchers, particularly those in the social sciences and humanities, may have with potential participants as part of the development of the design of their research. These preliminary conversations – including, for example, negotiations concerning the terms on which a researcher may engage with a particular community or group – do not in themselves constitute research and therefore do not require consent. (See Chapter 2 [“Scope and Approach”], Articles 9.3 to 9.6 in Chapter 9 [“Research Involving Aboriginal Peoples”] and Article 10.6 in Chapter 10 [“Qualitative Research”]).

There are exceptions to this general ethical requirement, however, set out below in Articles 3.8 and 3.9.

**Article 3.6**  
Consent is not required from an organization in order to conduct research on that organization.

**Application**  
Much, but not all, of the research undertaken concerning organizations such as corporations and governments across Canada is likely conducted with the explicit or implicit authorization, acquiescence or cooperation of the organization. Collaboration is often essential to the effective conduct of research – for example, to facilitate recruitment of participants, to enable organizations to fulfil their ethical duties, to coordinate logistical and operational aspects of research, and to respect applicable laws. When
individual participants are involved, the ethical principle of respect for
autonomy generally requires their voluntary and informed consent.

In other instances, when the goals of the research are to undertake the
form of research known as critical inquiry (which analyzes social
structures or activities, public policies or other social phenomena),
community or organizational authorization may be overridden by the
potential benefits for society to conduct research on organizations such as
corporations or governments. The exception is tailored to the needs of
different kinds of research undertaken by social science or humanities
researchers whose methods may include seeking knowledge that critiques
or challenges the policies and practices of institutions, governments,
interest groups or corporations. If institutional approval were required, it
is unlikely that research could be conducted effectively on such matters
as institutional sexual abuse or a government’s silencing of dissident
scientists. Important knowledge and insights from research would be
forgone.

Such an exception and its application requires due consideration to context,
as outlined in Chapter 1 (“Ethics Framework”). Since this Policy does not
define “organization,” REBs and researchers need to evaluate the goal, kind
and methodology of any research involving particular organizations, groups
or settings. Different considerations may apply to, for example, corporations
or governments, in contrast to community centres, schools, hospitals,
churches or Aboriginal organizations.

**Article 3.7** When conducting research on an organization, researchers should inform
potential participants who work within that organization of the extent to
which the organization is or is not collaborating with the research. Risk to
participants from the organization should be evaluated in relation to the
participants’ position of power within the organization.

**Application** Individuals who are approached to participate in a research project about
their organization must have the opportunity to give free and informed
consent. In particular, they should be fully informed about the views of the
organization’s authorities regarding the research, if these are known, and of
the possible consequences of participation. In this context, researchers
should pay special attention to confidentiality, to ensure that they do not
jeopardize the participant’s employment or status in the organization.

Situations may arise in which an organization, such as a corporation,
government, political party or criminal organization, that has been approached
about a research project, wishes to prevent that research. Researchers engaging
in critical inquiry need to be attentive to risks, both of stigmatization or breach
of privacy, to those who participate in research about their organization. In
particular, potential participants should be fully informed of the possible
consequences of participation.
B. Departures from General Principles of Consent

Article 3.8 The research ethics board (REB) may approve a research proposal and may waive the requirement to obtain informed consent, provided that the REB finds and documents that:

(a) The research involves no more than minimal risk to the participants;
(b) The waiver is unlikely to adversely affect the well-being and welfare of the participants;
(c) The research could not practicably be carried out without the waiver;
(d) Whenever possible and appropriate, the participants will be provided with additional pertinent information after participation; and
(e) The waived consent does not involve a therapeutic intervention.

Application In some circumstances, the nature of the research may justify a limited or temporary departure from the general requirement for free and fully informed consent prior to participation in research. It is the responsibility of researchers to justify the need for such a departure. It is the responsibility of REBs, however, to understand that certain research methodologies necessitate a different approach to consent and to exercise judgment on whether the need for the research justifies a limited or temporary exception to the general requirements in a particular case. (See discussion of different approaches to consent in Article 10.1 in Chapter 10 [“Qualitative Research”]).

It should be noted that in cases of randomization and blinding in clinical trials, neither the research participants nor the researchers know which treatment arm the participant will be receiving before the research commences. This is not regarded as a waiver or alteration of the requirements for consent, however, so long as the research participants or their authorized representatives are informed of the probability of being randomly assigned to one arm of the study or another.

Research Involving Partial Disclosure or Deception

Some social science research, particularly in psychology, seeks to learn about human responses to situations that have been created experimentally. Such research can be carried out only if the participants do not know in advance the true purpose of the research. In some research, therefore, participants may not know that they are part of a research project until it is over, or they may be told in advance about the task that they will be asked to perform, yet given additional information that provides them with a different perspective on some aspect of the task or experiment and/or its purpose. For example, in questionnaire research, questions that are central to the researcher’s hypothesis may be embedded within distracter questions, decreasing the likelihood that participants will adapt their responses to their perceptions of the true objective of the research. Similarly, social science research that critically probes the inner workings of publicly accountable institutions might require...
limited recourse to partial disclosure or deception in order to be effective. For such
techniques to fall within the exception to the general requirement of full disclosure for free
and informed consent, the research must meet the requirements of Article 3.8.

Where partial disclosure or deception has been used, debriefing is an important mechanism
in maintaining the participant’s trust in the research community. The debriefing referred to
in Article 3.8(d) should be proportionate to the sensitivity of the issue. Often, debriefing can
be quite simple and straightforward. In sensitive cases, researchers should provide, in
addition to candid disclosure, a full explanation of why participants were temporarily led to
believe that the research, or some aspect of it, had a different purpose, or why participants
received less than full disclosure. The researchers should give details about the importance
of the research, the necessity of having to resort to partial disclosure or deception, and their
concern about the welfare of the participants. They should seek to remove any
misconceptions that may have arisen and to re-establish any trust that might have been lost,
by explaining why these research procedures were necessary to obtain scientifically valid
findings.

Immediate, full debriefing of all individuals who have contributed data may not be feasible
in all cases. In studies with data collection over a longer term, debriefing may have to be
deferred until the end of the project. In some cases – for example, in research involving
children – it may be more appropriate to debrief the parents, guardians or authorized third
parties rather than the participants themselves. In other cases, it may be more appropriate to
debrief the entire family or community. It may sometimes be appropriate to modify the
debriefing to be sensitive to the participant’s needs and feelings.

In studies in which a waiver of prior informed consent has been allowed, it may still be
practicable for participants to exercise their consent at the conclusion of the study, following
debriefing. In cases where a participant expresses concerns about a study, the researcher may
give the participant the option of removing his or her data from the project. This approach
should be used only when the elimination of the participant’s data will not compromise the
validity of the research design.

Researchers should be required, as part of their research proposal, to set out the conditions
under which they would not be able to remove a participant’s data from the study even if
the participant requested such a withdrawal. Once the deception is revealed, participants
should be given a contact on the REB if they have any concerns about the conduct of the
research.

**Consent in Individual Medical Emergencies**

This section addresses the exception to free and informed consent in situations where an
individual who requires urgent medical care is unable to provide consent, and the delay
to obtain authorized third-party consent could seriously compromise that individual’s
health. Certain types of medical emergency practices can be evaluated only when they
occur, hence the need for this exception.

This section is to be distinguished, however, from situations where there is a publicly
declared emergency (such as the SARS crisis or a major flood) that disrupts the ordinary
system for obtaining REB approval for research. The process for research ethics review during a publicly declared emergency is addressed in Articles 6.21 – 6.23 in Chapter 6 (“Governance of Research Ethics Review”).

**Article 3.9** Subject to all applicable legislative and regulatory requirements, research involving medical emergencies shall be conducted only if it addresses the emergency needs of individuals involved, and then only in accordance with criteria established in advance of such research by the research ethics board (REB). The REB may allow research that involves medical emergencies to be carried out without the free and informed consent of the participant or of his or her authorized third party if all of the following apply:

(a) A serious threat to the prospective participant requires immediate intervention;

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

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

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

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

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

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

**Application** For purposes of studying potential improvement in the treatment of life-threatening conditions, Article 3.9 outlines an exception, in addition to that in Article 3.8, to the general obligation of obtaining free and informed consent from those participating in research.

The exception is intended for a limited class of health research: that which takes place in emergency situations where obtaining free and informed consent from the participants is not possible due to loss of consciousness or capacity, and where free and informed consent from an authorized third party is not possible due to the urgent time constraints for effective intervention. Seeking consent in advance is often impossible due to the unforeseeable nature of the causes of the medical emergency. However,
individuals and those in comparable future situations should not be denied potential benefits of research because of the inability to consent.

It is the responsibility of researchers to justify to the REB the need for recourse to this exception. The underlying assumption of Article 3.9 is that direct research benefits to the participant could not be secured without forgoing the free and informed consent of the participant or of his or her authorized third party. Article 3.9 indicates that research in emergency medicine must be reviewed by the REB, be restricted to the emergency needs of the participants, and be conducted under criteria designated by the REB. Article 3.9 outlines the minimal conditions necessary for the REB to authorize research without free and informed consent in individual medical emergencies.

It is unethical to expose participants to any additional risk of harm without their free and informed consent if standard efficacious care exists, unless it can clearly be shown that there is a realistic possibility of significantly improving the participant’s condition. Accordingly, paragraphs (b) and (c) of Article 3.9 indicate that researchers and REBs must assess the potential risk of harms and benefits of proposed research against existing standard efficacious care.

To respect the autonomy of the research participant, Article 3.9(e) requires researchers to undertake diligent efforts to contact family members or authorized third parties, if reasonably feasible, and to document such efforts for the benefit of both the participant and for the monitoring or continuing review functions of the REB. The article also requires that research participants who regain capacity be promptly afforded the opportunity to give free and informed consent concerning continued participation. Concern for the patient’s well-being is paramount and should be informed by ethical and professional judgment.

Because their incapacity to exercise free and informed consent makes them vulnerable, prospective participants for emergency research are owed special ethical obligations and protection commensurate with the harms involved. Their interests, rights and welfare should be protected by additional safeguards, where feasible and appropriate. These might include additional scientific, medical or REB consultation; procedures to identify potential participants in advance to obtain free and informed consent prior to the occurrence of the emergency situation; consultation with former and potential participants; and special monitoring procedures to be followed by data safety and monitoring boards.

C. Capacity

Capacity refers to the ability of prospective participants to understand relevant information presented and to appreciate the potential consequences of any given decision. This ability
may vary according to the complexity of the choice being made, the circumstances surrounding the decision, or the time in question. The capacity to participate in research, then, may change over time, and depending on the nature of the decision the potential participant needs to make. Assessing capacity is a question of determining, at a particular point in time, whether a potential research participant meets the bar for understanding the nature and consequences, risks and potential benefits, of a particular research project.

One may therefore have diminished capacity and still be able to decide whether to participate in certain types of research.

Legislation with respect to capacity varies between jurisdictions. Researchers should be aware of all applicable legislative requirements.

In keeping with the principle of equal moral status, ethical considerations around research involving those who lack the capacity to give free and informed consent on their own behalf must seek to balance the vulnerability that arises from their lack of capacity with the injustice that would arise from their exclusion from the benefits of research. (See Chapter 4 [“Inclusion in Research”], which addresses these issues in more detail.)

As indicated in Chapter 1 (“Ethics Framework”), respect for human dignity entails high ethical obligations to vulnerable individuals. Such obligations often translate into special procedures to promote and protect their interests. The articles that follow detail the special procedures for research involving individuals who lack the capacity to participate in particular research projects.

**Article 3.10** For research involving individuals who lack the capacity, either permanently or temporarily, to decide for themselves whether to participate, the research ethics board shall ensure that, as a minimum, the following conditions are met:

(a) The researcher should seek free and informed consent from the authorized third party and shall show how that consent will be sought from the authorized third party, as well as how the participants’ well-being and welfare will be protected;

(b) The authorized third party should not be the researcher or any other member of the research team;

(c) The ongoing consent of an authorized third party will be required throughout the participation in research of an individual who lacks capacity to consent on his or her own behalf; and

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

**Application** Article 3.10 provides a means of protecting the interests and dignity of participants who lack adequate capacity, either permanently or temporarily,
by having authorized third parties make the decision about participation on
their behalf. The decision of the third parties should be based on their
knowledge of the potential participants and on a consideration of the potential
participants’ welfare. The third parties should not be in a position of conflict
of interest when making their decision.

Article 3.10 outlines other safeguards to protect the dignity, interests and
integrity of those who lack the capacity to give their free and informed
consent to participation in research. The article details various considerations
relevant to the use of third-party authorization. Beyond the legal requirements
for obtaining free and informed consent from authorized third parties, family
members and friends may provide information about the interests and
previous wishes of prospective participants.

**Article 3.11** Where free and informed consent has been obtained from an authorized
third party, and in those circumstances where a legally incompetent
individual understands the nature and consequences of the research, the
researcher shall seek to ascertain the wishes of the individual concerning
participation. The potential participant's dissent will preclude his or her
participation.

**Application** Many individuals who are legally incompetent may still be able to express
their wishes in a meaningful way, even if such expression may not fulfil the
requirements for free and informed consent. Prospective participants may thus
be capable of verbally or physically assenting to, or dissenting from,
participation in research. Those who may be capable of assent or dissent
include (a) those whose capacity is in the process of development, such as
children whose capacity for judgment and self-direction is maturing; (b) those
who once were capable of making an informed decision about informed
consent, but whose capacity is now considerably, but not completely,
diminished, such as individuals with early Alzheimer’s disease; and (c)
those whose capacity remains only partially developed, such as those
suffering from permanent cognitive impairment. While their assent would
not be sufficient to permit them to participate in the absence of consent by
an authorized third party, their expression of dissent must be respected.

**Consent should be documented**

**Article 3.12** Evidence of free and informed consent may be contained either in a signed
consent form or in documentation by the researcher of other means of
consent. Consent may also be demonstrated solely by the actions of the
participant – for example, through the return of a completed questionnaire.

**Application** While it is not necessary for consent itself to be in writing, there should be
some written evidence of the process adopted to obtain free and informed
consent and that demonstrates that consent has been obtained. Such
documentation serves a number of purposes. For the participant, it is
evidence of the fact that he or she has agreed to participate in a particular
research project. Whether or not a consent form is signed, a written
statement of the information conveyed in the consent process, signed or not, should be left with the participant. It may serve as a reminder to the participant of the terms of the research. It may also facilitate the ability of the participant to consider and re-consider his or her involvement as the research proceeds.

For the researcher, it is evidence that he or she has satisfied the ethical obligation of obtaining the free and informed consent of the participant prior to involving that individual in a given research project. In cases where the consent is inferred from the professional responsibilities of the research participant, it is not necessary to provide a written confirmation of this to the research participant. In some cases it may not be appropriate to leave a written statement, such as in cultural settings where such written documentation is contrary to prevailing norms.

For the research sponsor, for the REB and for the institution, such evidence demonstrates that the consent obligations have been fulfilled, at least at the outset.

Written consent through a signed statement from the participant is a common means of demonstrating consent. However, for some groups or individuals, a verbal agreement, perhaps with a handshake, is evidence of trust, and a request for a signature may imply distrust. In some types of research, oral consent may be preferable. In others, written consent is mandatory. Where oral consent is appropriate, the researcher may wish to make a contemporaneous journal entry of the event and circumstances. These and like elements may sometimes need to be refined in concert with the REB, which plays an essential educational and consultative role in the process of seeking free and informed consent.

The consent process must reflect trust between the research participants and the researcher. Often this is based on mutual understanding of the project’s intentions. In qualitative research, the nature of the methodology may lead the research participant to sense attempts to legalize or formalize the process as a violation of trust. Hence, written consent is not the norm in qualitative research. Rather, qualitative researchers use a range of consent procedures, including oral consent, field notes, and other strategies, for documenting the consent process. In qualitative research conducted with research participants in positions of authority, trust may be based upon that participant’s confidence in his or her ability to take care of himself or herself or to deter undesirable behaviour on the part of the researcher by denying access to social or professional networks, through the threat of litigation or by other means.

When in doubt about an issue involving free and informed consent, researchers should consult their REB.
Chapter 4

INCLUSION IN RESEARCH

A. Introduction

An important aspect of the principle of equal moral status is the fair distribution of benefits and burdens in research. Benefits of research participation may be direct, where, for example, an individual participant experiences amelioration of a health condition because of an experimental therapy or learns new information about social issues by participating in a research focus group. Benefits may be indirect, where an individual’s research participation contributes to advancement in knowledge that may lead to improved conditions for a group to which the participant belongs or to society in general.

Historically, concern for justice in research involving human participants focused on whether research participants were treated fairly: were they overburdened relative to the direct benefits they received from their participation in research? Contemporary concerns with justice in research have broadened: are the overall benefits and burdens of research distributed fairly, and have disadvantaged individuals and groups received a fair share of the benefits of research?

The above two concerns flow from the principle of equal moral status, which holds that particular individuals or groups in society should neither bear an unfair share of the direct burdens of participating in research, nor should they be unfairly excluded from the potential benefits of research participation. Inclusiveness in research and fair distribution of benefits and burdens should be of concern to researchers, research ethics boards (REBs), research institutions and sponsors.

Overprotectionist attitudes or practices of researchers or REBs that intentionally exclude some members of society from participating in research may, in fact, fail to respect the equal moral status of those individuals and deprive them of the potential benefits of research. For example, age has been used to exclude individuals from participation in research, particularly health research. The result of such exclusion is that insufficient research has been done involving the young and the elderly.

Whether intentional or inadvertent, the exclusion of some from the potential benefits of research violates the principle of equal moral status of all humans. Researchers, institutions and REBs all have important roles to play in advancing that societal commitment and ensuring a fair distribution of the benefits and burdens of research. Research should navigate somewhere between the dangers of exploitation and the dangers of overprotection of research participants.
B. General Inclusivity of Research

Article 4.1 Researchers must not exclude individuals from participation in research on the basis of attributes such as culture, religion, race, disability, sexual orientation, ethnicity, sex or age unless there is a valid reason for the exclusion.

Application Article 4.1 is based on the principles of equal moral status and just distribution of benefits of research participation across all groups in society. It imposes a duty on researchers not to discriminate against individuals or groups for reasons that are unrelated to the research inquiry. Groups have been disadvantaged in the context of research on the basis of characteristics such as sex, colour, ethnicity, age and disability. Among those who have been disadvantaged in the context of research, women warrant special consideration, as elaborated on in Article 4.3.

Article 4.1 is not intended to preclude research focused on a single living individual (such as in a biography) or on a group of individuals who share a specific characteristic (as in a study of an identifiable group of painters who happen to be all of one sex, race or religion, or of a religious order that is restricted to one sex).

Researchers who plan to actively exclude particular groups from research must explain the exclusion to the REB. The REB will assess the validity and reasonableness of the exclusion, based on the nature of the research inquiry, the context in which the research is conducted, and other objective grounds for the inclusion and exclusion criteria.

Article 4.2 Individuals who are not proficient in the language used by the researchers should not be automatically excluded from the opportunity to participate in research.

Application The exclusion of potential research participants on the basis of language proficiency may undermine the objective of Article 4.1 to avoid exclusions based on culture, race or ethnicity. With appropriate measures to ensure effective communication between potential participants and researchers, language proficiency should not bar inclusion in research. Where a language barrier exists, various measures may be used to ensure effective communication between potential participants and researchers in recruitment and informed consent discussions. For example, an intermediary who is not part of the research study or team, but who is competent in the language used by the researchers as well as that chosen by the research participant may assist with communication between potential participants and researchers. The intermediary’s activities will depend on the nature and risks of the research. For example, where risks are minimal and researchers intend to seek oral consent from participants, an intermediary may help facilitate oral communication. In other situations...
involving written consent materials, the intermediary may translate or
approve an existing translation of consent documents and any other
information relevant to participation in the study. The intermediary should
not be in a role or relationship that may influence the potential participant’s
free and informed consent.

C. Research Involving Women

Women have historically been inappropriately excluded from participating in some
research. Exclusion of women, where unwarranted, delays advancement of knowledge,
denies potential benefits to women, and may expose them to harm if research findings
from male-only studies are generalized inappropriately to women. The inclusion of
women in research advances the commitment to equal moral status, improves the
generalizability of research results where that is a goal of the research, and is essential to
ensure that women and men benefit equally from research.

Article 4.3 Women must not be automatically excluded from research solely on the
basis of sex or reproductive capacity.

Application Like Article 4.1, Article 4.3 imposes obligations on REBs and
researchers to ensure equitable treatment of potential participants. While
some research is properly focused on particular research populations that
do not include women or include very few women, women should be
represented in most studies.

Article 4.3 rejects discriminatory and unethical use of inclusion or exclusion
criteria that presumptively or automatically exclude women because of their
sex or reproductive capacity. In considering research on pregnant or
breastfeeding women, researchers and REBs must, however, take into
account potential harms and benefits for the woman and her embryo, fetus
or infant.

D. Research Involving Vulnerable Persons or Groups

Respect for equal moral status and welfare entails special ethical obligations toward
individuals or groups who may be vulnerable in the context of research, such as children
and individuals who are institutionalized, or those in dependent situations or other
situations that may compromise voluntariness of consent. Researchers and REBs should
be mindful of the fact that poverty may also impede an autonomous choice to participate
in research.

Article 4.4 Vulnerable individuals or groups must not be automatically excluded from
research that may benefit them or a group to which they belong.

Application Characteristics that may make an individual or group vulnerable in the
context of research may vary over time and with changing circumstances.
Also, individuals should not automatically be considered vulnerable
because of a group with which they may be identified. Researchers and
REBs should recognize and address changes in a participant’s
circumstances that may create, heighten or attenuate vulnerability and
provide special protections for those who are vulnerable to abuse,
exploitation or discrimination. Researchers and REBs should also be
aware of applicable laws, regulations and other requirements that
establish rules regarding participation of vulnerable individuals in
research.

Children may be particularly vulnerable as research participants because
of their developmental status. Researchers and REBs must consider a
child’s stage of physical, physiological, psychological and social
development to ensure adequate protections for a child’s welfare.
Physical or psychological harms a child experiences in a research setting
may have long-lasting effects. In addition to vulnerability that arises from
their developmental status, children may also lack capacity to give
consent to participate in research.

Similarly, adults who are institutionalized may be vulnerable because
they live under the care of others, but they may also lack capacity to
consent due to cognitive disability or other impairment. The following
section provides further guidance on the ethical conduct of research with
participants who cannot give consent for themselves.

E. Research Involving Those Who Lack Capacity to
Consent for Themselves

Respect for equal moral status and concern for welfare entails special ethical obligations
toward individuals who do not have capacity to give free and informed consent for research
participation. Individuals who do not have capacity to give consent to participate in
research should not be automatically excluded from research. Based on the core principle
of concern for welfare, however, this section sets out conditions that apply to research
involving those who cannot give consent for themselves. This section should be read in
conjunction with Section C (“Capacity”) of Chapter 3 (“Free and Informed Consent”).

Article 4.5 Where a researcher seeks to involve individuals in research who do not
have capacity to give free and informed consent, the researcher must
satisfy the research ethics board that:

(a) The research question can be addressed only with the participation of
individuals who do not have capacity to consent; and

(a) If the research involves more than minimal risk, it has the potential to
provide direct benefits for participants or a group to which they belong.

Application This Policy recognizes the need to include individuals or groups in
research who have historically been excluded, including those who lack
capacity to give consent for themselves. For example, young children and individuals with cognitive or intellectual disabilities may lack capacity to give consent to participate in particular research initiatives. Yet the advancement of knowledge about their social, psychological and health experiences and needs may depend on their participation in research.

Article 4.5 and Article 3.10 in Chapter 3 (“Free and Informed Consent”) establish conditions regarding research that involves individuals who lack capacity to give consent. Researchers and REBs must consider the degree of risk to which participants are exposed and the potential of direct benefits to the participant or a group to which they belong.

Note: The World Medical Association Declaration Of Helsinki: Ethical Principles For Medical Research Involving Human Subjects (October 2008), s. 27, states, with respect to research involving those who lack capacity, that “these individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the population represented by the potential subject, the research cannot instead be performed with competent individuals, and entails only minimal risk and minimal burden.” The Panel presents this statement here as a point of comparison in the discussion of proposed Article 4.5.
Chapter 5

PRIVACY AND CONFIDENTIALITY

There is widespread agreement about the rights of research participants to privacy and the corresponding duties of researchers to treat personal information in a confidential manner. Indeed, the respect for privacy in research is an internationally recognized norm and ethical standard. Privacy rights are protected in the Canadian Constitution, our country’s most fundamental statement of rights and freedoms, and they are also protected in federal and provincial/territorial statutes. Model voluntary codes have also been adopted to govern access to, and the protection of, personal information. Some professional organizations have also established privacy codes that establish the rights and obligations of their members regarding collection, use and disclosure of personal information.

This Policy is based on a proportionate approach to ethical assessment of research, where more stringent review and protections are applied to research that poses greater risks to participants. Privacy risks in research relate to the identifiability of participants and the potential harms they may experience from collection, use and disclosure of personal information. Privacy risks arise at all stages of the research life cycle, including initial collection of information, use and analysis to address research questions, dissemination of research results, retention of information, and disposal of research records or devices on which information is stored. Researchers and research ethics boards (REBs) should identify and mitigate privacy risks, keeping in mind that a matter that is not considered sensitive or embarrassing in the researcher’s culture may be so in a prospective participant’s culture.

A. Key Definitions and Principles

Privacy

Privacy refers to an individual’s right to be free from intrusion or interference by others. It is a fundamental right in a free and democratic society. Individuals have privacy interests in relation to their bodies, personal information, thoughts and opinions, personal communications with others, and spaces they occupy. Research affects these various domains of privacy in different ways, depending on its objectives and methods. An important aspect of privacy is the right to control information about oneself. The concept of consent is related to the right to privacy. Privacy is respected if an individual has an opportunity to exercise control over personal information by consenting to, or withholding consent for, collection, use and/or disclosure of information. (For further discussion of consent, see Chapter 3 [“Free and Informed Consent”].)
The duty of confidentiality refers to the obligation of an individual or organization to safeguard information entrusted to it by another. The duty of confidentiality includes obligations to protect information from unauthorized access, use, disclosure, modification, loss or theft. Fulfilling the duty of confidentiality is essential to the trust relationship between researcher and research participant, and to the integrity of the research enterprise.

Security refers to measures used to protect information. It includes physical, administrative and technical safeguards. An individual or organization fulfils its confidentiality duties, in part, by adopting and enforcing appropriate security measures. Physical safeguards include use of locked filing cabinets and location of computers containing research data away from public areas. Administrative safeguards include development and enforcement of organizational rules about who has access to personal information about research participants. Technical safeguards include use of computer password, firewall, anti-virus, encryption and other measures that protect data from unauthorized access, loss or modification.

Types of Information

Researchers collect, use, share and seek access to different types of information about research participants. Privacy concerns are strongest in regard to information that identifies a specific research participant, and they attenuate as it becomes more difficult or impossible to associate information with a particular participant. Privacy concerns also vary with the sensitivity of the information and the extent to which access, use or disclosure may harm an individual by exposing them to embarrassment, stigma, discrimination or other detriments.

Information may be categorized as follows:

- Identifying information: The information identifies a specific research participant through direct identifiers (e.g., name, address, social insurance number or personal health number).

- Identifiable information: The information could be used to re-identify a participant through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic) using reasonably foreseeable means.

- De-identified/coded information: Identifiers are removed and replaced with a code. Depending on access to the code, it may be possible to re-identify specific research participants (e.g., participants are assigned a code name and the principal investigator retains a list that links the code name with the participant’s
actual name so data can be re-linked if necessary.) Researchers who have access to the code and the data have identifiable information.

- Anonymized information: Information is irrevocably stripped of identifiers, and a code is not kept to allow future re-linkage.
- Anonymous information: Information never had identifiers associated with it (e.g., anonymous surveys).

In this Policy, the term “personal information” refers to identifying and identifiable information about an individual. This includes identifiable information about personal characteristics such as age, culture, educational background, employment history, health care, life experiences, religion, social status and other matters where an individual has a reasonable expectation of privacy. In assessing privacy risks, researchers and REBs should also consider the possibility that, despite the removal of personal identifiers, a small or unique group (such as a group with a rare condition or an Aboriginal community) may be identified. Individuals within that group may experience stigma, embarrassment or other harm resulting from being identified individually or being associated with the group. If researchers are uncertain if the information to which they seek access constitutes personal information under this Policy, they should consult their REB.

Collection and use of anonymous data in research is the easiest way to protect participants, although this is not always possible or desirable. A “next-best” alternative is to anonymize the data at the earliest opportunity. While anonymization often protects participants from identification, the ability to link anonymized datasets with other information sources may lead to re-identification of individuals. Growing technological capacities facilitate re-identification, as is discussed in Section E (“Data Linkage”). Failing the feasibility of using anonymous or anonymized data for research – and there are many reasons why data may need to be gathered and retained in an identifiable form – the duty of confidentiality becomes paramount.

B. The Duty of Confidentiality

Article 5.1 Researchers must maintain confidentiality of personal information about research participants, subject to any legal and ethical duties to disclose confidential information.

Application When researchers obtain personal information with a promise of confidentiality, following through with that promise is integral to respect for research participants and the integrity of the research enterprise. Breaches of confidentiality may cause harm to the trust relationship between the researcher and the research participant, to other individuals or groups, and/or to the reputation of the research community.

The duty of confidentiality applies to information obtained directly from participants or from other researchers or organizations that have legal, professional or other obligations to maintain the confidentiality of personal
A researcher’s duty of confidentiality is not absolute. In certain exceptional and compelling circumstances, researchers may have legal and ethical obligations to disclose information revealed to them in confidence, such as reporting information to authorities to protect the health, life or safety of a research participant or third party. Researchers should be aware of laws (such as laws that require reporting of children in need of protection) or ethical codes (such as professional codes of conduct) that may require disclosure of information they obtain in a research context.

Researchers who believe they may have a legal or ethical duty to disclose information obtained in a research context should consult with colleagues, any relevant professional body, the REB and/or legal counsel regarding an appropriate course of action.

**Article 5.2**

Researchers must describe measures for meeting confidentiality obligations and explain any limits on confidentiality:

(a) In application materials they submit to the research ethics board; and

(b) During informed consent discussions with potential research participants.

**Application**

Researchers should inform potential research participants of these legal and/or ethical disclosure duties at the time of obtaining consent so the participants understand the limits of the confidentiality promise.

Researchers should also inform participants if personal information may be provided to government departments or agencies, personnel from an agency that monitors the research, a research sponsor (such as a pharmaceutical company), the REB or a regulatory agency.

In rare cases, a third party may seek access to information obtained and/or created in a research context. An access request may seek voluntary disclosure of information or may seek to compel disclosure through force of law (such as seeking a subpoena). Researchers must make reasonable efforts to maintain their promise of confidentiality to research participants within the extent permitted by law and ethical principles. This may involve resisting requests for access, such as opposing court applications seeking disclosure.

When designing their research, researchers should incorporate any applicable statute-based or other legal principles that may afford protection for the privacy of participants and confidentiality of research information.
C. Safeguarding Information

Article 5.3 Researchers should assess privacy risks and threats to the security of information for all stages of the research life cycle and implement appropriate measures to protect information. Researchers must provide details to the research ethics board regarding their proposed measures for safeguarding information, for the full life cycle of information – that is, its collection, use, dissemination, retention and disposal.

Application Safeguarding information helps respect the privacy of research participants and helps researchers fulfil their confidentiality obligations. In adopting measures to safeguard information, researchers should follow disciplinary standards and practices for the collection and protection of information for research purposes. Formal privacy impact assessments are required in some institutions and under legislation or policy in some jurisdictions. Security measures should take into account the nature and type of data (e.g., paper records or electronic data stored on a mobile device; whether information contains direct or indirect identifiers).

Principles for safeguarding information apply both to original documents and copies of information.

Factors relevant to the REB’s assessment of the adequacy of the researchers’ proposed measures for safeguarding information include:

(a) The type of information to be collected;
(b) The purpose for which the information will be used;
(c) Limits on the use, disclosure and retention of the information;
(d) Appropriate security safeguards for the full life cycle of information;
(e) Any modes of observation (e.g., photographs or videos) or access to information (e.g., sound recordings) in the research that may allow identification of particular participants;
(f) Any intended uses of personal information from the research; and
(g) Any anticipated linkage of data gathered in the research with other data about participants, whether those data are contained in public or personal records. (See also Section E [“Data Linkage”].)

In considering the adequacy of proposed data protection measures for the full life cycle of information, REBs should not automatically impose a requirement that researchers destroy the research data. Data retention periods vary depending on the research discipline, research purpose and kind of data involved. Data destruction is not a typical part of the qualitative research process; in some situations formal data sharing with participants may occur – for example, by giving individual participants copies of a recording or transcript as a gift for personal, family or other
archival use. Similarly, some funding bodies, such as the Social Sciences
and Humanities Research Council and the Canadian Institutes of Health
Research, have specific policies on data archiving and sharing. ¹

In disseminating research results, researchers should not disclose direct
identifiers without the consent of research participants. Researchers
should take reasonable measures to ensure against inadvertent
identification of individuals or groups in publications or other means of
dissemination, and they must address this issue to the satisfaction of the
REB.

In some instances, participants may wish to be identified for their
contributions to the research. Where possible, researchers should
negotiate agreement with participants about if and how participants may
be identified to recognize their contribution. Negotiation may help resolve
any disagreement on this issue between individual participants and groups
of which they are a member (where, for example, an individual wants to
be recognized, but the broader group or community expresses objection).
Researchers and REBs should also pay heed to disciplinary standards
regarding identification and acknowledgment of research participants.

In disseminating results, researchers should avoid being put in a position of
becoming informants for authorities or leaders of organizations. For
example, when records of prisoners, employees, students or others are used
for research purposes, the researcher should not provide authorities with
results that could identify individuals, unless the prior written consent of the
participants is obtained. Researchers may, however, provide administrative
bodies with aggregated data that cannot be linked to individuals, for
purposes such as policy-making or program evaluation. To obtain informed
consent, researchers should advise potential participants if aggregated data
from a study may be disclosed, particularly where such disclosure may pose
risk of harm to the participants. For example, aggregate data provided to
authorities about illicit drug use in a penitentiary may pose harms to the
prisoners, even though they are not identified individually.

Consideration of future uses of personal information refers not just to
research, but also to other purposes, such as the future use of research videos
for educational purposes. It is essential that proposed future uses of
information be specified in sufficient detail that prospective participants
may give free and informed consent. In most cases, it is inappropriate to
seek prospective permission for unspecified future uses of personal
information at the same time consent is being sought for participation in a
specific study. (Refer to Chapter 12 [“Human Tissue”] for guidance on
establishment of large-scale biobanking projects where participants may
have an option of agreeing to broader categories of future uses.) Secondary
use of personal information is discussed further in the next section of this
chapter, and Chapter 3 (“Free and Informed Consent”) addresses free and
informed consent in detail.

Internet research may raise special privacy, confidentiality and security issues that researchers and REBs need to take into account. Research data sent over the Internet may require encryption or use of special denomalization software to prevent interception by unauthorized persons or other risks to data security. In general, identifying data obtained through research that is kept on a computer and connected to the Internet should be encrypted.

**Article 5.4** Institutions or organizations where research data are held have a responsibility to establish appropriate institutional security safeguards.

**Application** In addition to the security measures researchers implement to protect data, safeguards put in place at the institutional or organizational level also provide important protection. Such data security safeguards should include physical, administrative and technical measures.

### D. Secondary Use of Personal Information for Research Purposes

Secondary use refers to the use in research of personal information originally collected for a purpose other than the current research purpose. Common examples are social science or public health survey datasets that are collected for specific research or statistical purposes, but then re-used to answer other research questions. Other examples are health-care or school records or biological specimens, originally created or collected for therapeutic or educational purposes, but later sought for use in research. Chapter 12 (“Human Tissue”) provides further guidance on research involving secondary use of previously collected human tissue.

Secondary use avoids duplication in primary collection and therefore reduces burdens and costs for participants and researchers. Privacy concerns arise, however, when information can be linked to individuals and when the possibility exists that individuals can be identified in published reports.

Personal information refers to identifying and identifiable information, as described in Section A of this chapter (“Key Definitions and Principles”). Articles 5.5 and 5.6 do not apply to secondary use of information that is anonymous, anonymized or de-identified/coded and where the research team has no access to the code. For example, this article does not apply to a researcher who receives a de-identified dataset from an organization, but who does not have access to a code that permits re-identification of individuals. Research use of personal information that relies exclusively on publicly available sources such as public archives and published works does not require REB review, as discussed in Chapter 2 (“Scope and Approach”).

**Article 5.5** Researchers must seek research ethics board (REB) approval for secondary research use of personal information. Researchers must satisfy the REB...
that:

(a) Identifying or identifiable information is essential to the research;

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

(c) Individuals to whom the data refer did not object in principle to secondary use at the initial stage of collection or otherwise make known their objection; and

(d) They have obtained any other necessary (e.g., legal) permission to access personal information for secondary research purposes.

**Application**  
If a researcher satisfies the conditions in Article 5.5(a) to (d), the REB may approve the research without requiring consent from individuals to whom the information relates.

Databases vary greatly in the degree to which information identifies or could be used to identify individuals. The REB must carefully appraise the possibility of identification and the harm or stigma that might result from identification. A proportionate approach should be applied by the REB to evaluate the identifiability of the information in the database and to modulate its own requirements accordingly.

REBs and researchers should be sensitive to the context in which information was initially obtained, such as in a relationship of trust and confidence, as well as to the understanding and/or expectations of the individual about use, retention and disclosure of the information. Known objections to secondary use should be respected. An individual may express objection to future uses at the time of initial data collection or may, at some later point, contact the organization or individual who holds the data to request that it not be used for secondary research. For example, a former patient may hear in the media about research being conducted at a local hospital and contact the facility administrators to request that her or his medical records (in their identifying or identifiable form) not be used for research.

Legislation governing protection of personal information may impose specific rules regarding disclosure of personal information for secondary research purposes. These laws may require the individual or organization that has custody or control of requested personal information to obtain approval from a privacy commissioner or other body before disclosing information to researchers, and may impose additional requirements such as information sharing agreements that describe conditions for disclosure of personal information. Researchers should be aware of relevant laws that regulate disclosure of personal information for research purposes.
Article 5.6

In highly sensitive situations, such as when personal information will be published or other instances where there is a substantial privacy risk, the research ethics board (REB) may require that a researcher’s access to personal information for secondary use be dependent on the informed consent of individuals about whom the information relates or the informed consent of authorized third parties, unless it is impossible or impracticable to obtain consent.

If the REB is satisfied that it is impossible or impracticable to obtain consent, it may require that access to personal information be dependent on:

(a) An appropriate strategy for communicating to relevant groups that personal information is intended to be used for a specified research purpose; or

(b) Consultation with representatives of individuals or groups about whom the information relates.

Researchers must report outcomes of communication or consultation under (a) or (b) to the REB.

Application

In considering the applicability of this article, REBs should apply a proportionate approach to ethical assessment of research. This involves considering the likelihood and magnitude of privacy risks for individuals about whom the information relates, as well as the potential benefits of the research.

Where use of identifying or identifiable information for secondary research raises a substantial privacy risk, Article 5.6 states that the REB may require researchers to seek consent from individuals or authorized third parties. It may, however, be impossible or impracticable to contact all individuals or authorized third parties to obtain informed consent for secondary research use of information. In some jurisdictions, privacy laws may preclude researchers from using personal information to contact individuals to seek their consent for secondary use of information. Consent may also be impossible or impracticable when the group is large or its members are likely to be deceased, geographically dispersed or difficult to track. Attempting to track and contact members of the group may raise additional privacy concerns. Seeking consent from only a partial set of group members may introduce undesirable bias into the research. Financial, human and other resources required to contact individuals and obtain consent may impose undue hardship that jeopardizes the research.

Where an REB is satisfied that consent is impossible or impracticable, Article 5.6(a) states that the REB may require an appropriate strategy for distributing information to relevant groups about the proposed research. For
example, researchers who propose to access identifiable patient records may
post notices or distribute pamphlets at a health-care centre, because former
patients may still have contact with the centre. Alternatively, under Article
5.6(b), the REB may require that there be consultation with representatives
of the individuals or group. For example, researchers may develop a way to
sample the opinions of a subset of individuals in the group or contact one or
more organizations that are likely to represent the views and interests of the
individuals. The goal of such communication or consultation is to provide an
opportunity for input regarding the proposed research. In some situations, the
consultation under Article 5.6(b) may take place with an organization that
provides access to personal information. For example, researchers who
obtain a dataset of personal information from a government agency may
consult with that agency about the proposed research.

In their application materials, researchers must explain to the REB why it is
impossible or impracticable to obtain informed consent from individuals.
Their application should also propose a communication or consultation
strategy for the REB’s consideration. Where the REB is satisfied that
consent is impossible or impracticable, and that the sensitivity of the
situation warrants communication or consultation under Article 5.6(a) or (b),
the researchers must report the outcomes of those activities to the REB. For
example, if consultation with a representative group reveals concern with an
aspect of the proposed research, researchers must report this feedback to the
REB. Any changes to the research must comply with guidelines regarding
departures from approved research, as set out in Article 6.16 of Chapter 6
(“Governance of Research Ethics Review”).

Article 5.7 Researchers who wish to contact individuals about whom personal
information relates must obtain research ethics board approval prior to
contact.

Application In certain cases, a research goal may be achieved only through follow-up
contact with individuals to collect additional information. However, contact
with individuals whose previously collected information is used for
secondary research purposes raises privacy concerns, especially where a
relationship with individuals has not been maintained. Individuals might not
want to be contacted by researchers or might be upset that their information
was disclosed to researchers. The research benefits of follow-up contact
must clearly outweigh the potential harms to individuals of follow-
up contact, and the REB must be satisfied that the proposed manner of follow-
up contact minimizes potential harms for individuals.

E. Data Linkage

Article 5.8 Researchers who wish to engage in data linkage that may lead to
identification of individuals must obtain research ethics board approval prior
to carrying out the data linkage.
Advances in our abilities to link databases create both new research opportunities and new threats to privacy. These techniques may provide avenues for addressing previously unanswerable questions and for generating better social and health-related information. The values underlying the ethical obligation to respect privacy oblige researchers and REBs to exercise caution in the creation and use of data of this kind. REBs should also be aware of relevant legislation and any criteria required by governments for authorization of use of data in governmental databanks.  

Only a restricted number of individuals should perform the function of merging databases. Researchers should either destroy the merged file immediately after use, or use enhanced security measures to store it. Whether the data are to be used statistically or otherwise, all members of the research team must maintain security of the information. When a merged database identifies a person or a group who might be at risk of substantial harm, it may be appropriate to contact those at risk or the appropriate authorities. The REB and the record holder should also be notified.

Endnotes

2 See, for example, the Canadian Standards Association’s Model Code for the Protection of Personal Information.
3 See the SSHRC Research Data Archiving Policy and the CIHR Policy on Access to Research Outputs.
4 See, for example, Statistics Act, Revised Statutes of Canada, 1985, Chapter S-19 as amended.
Chapter 6

Governing Research Ethics Review

This chapter sets out the process of research ethics review: the elements necessary to establish a research ethics board (REB) and operational guidelines for the REBs and the review process, 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 and authority and that roles and responsibilities are clearly defined. REBs need operational independence to carry out their role effectively and to properly apply the core principles of welfare, autonomy and equal moral status to their review of research projects. These operational guidelines are meant to ensure that independence, yet 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 and Powers

Article 6.1 Institutions shall establish independent research ethics boards to review the ethical acceptability of 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 In fulfilling this responsibility, institutions are required to develop the necessary structure of independent REBs for the ethics review of research involving humans.

Where research with human participants takes place within the jurisdiction or under the auspices of an institution, that institution must establish an REB (or REBs) capable of reviewing the ethical acceptability of that research. To ensure integrity and safeguard public trust in the research process, the REB must maintain an arm’s-length relationship with, and act independently from, the parent organization.

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 the articles below relating to composition and membership.
Article 6.2  The highest appropriate body within an institution shall establish the research ethics board (REB) or REBs and provide them with sufficient and appropriate financial and administrative independence to fulfil their duties. REBs shall report directly to the highest level of the institution that has the overall responsibility for research involving humans conducted under its auspices or within its jurisdiction.

Application  REBs should be established by and report to the highest appropriate body of the institution. This could be an individual such as the president, rector, or chief executive officer, or an equivalent body such as a governing council or board of directors. The highest body may delegate the reporting function as it deems appropriate.

In order to ensure that REBs are able to operate effectively and independently, institutions should dedicate the appropriate financial and human resources to their support. Institutional policies and procedures should also support and promote the effective and independent operation of REBs. Similarly, institutions should avoid situations that may undermine the independence of REBs. For example, REBs should not report (other than for purely administrative purposes) to institutional officers who are directly responsible for promoting research, as this may result in situations of real or apparent conflict of interest. (See Chapter 7 [“Conflict of Interest”].)

While the REB should have the independence to conduct ethics review free of inappropriate influence, it remains accountable to the institution for the integrity of its processes, including its decision-making processes. REB independence, therefore, does not mean that the REB is immune from scrutiny.

Article 6.3  The institution grants the research ethics board 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 human participants that is conducted under its auspices or within the jurisdiction of the institution, using the considerations set forth in this Policy.

Application  The institution shall delegate the authority of the REB through its normal process of governance. In defining the scope of the REB’s mandate, the institution must clearly define the types of research that the REB may review. 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. An institution may wish to use different models for the ethics review of research conducted under its auspices. Institutions must have clear written policies describing the mandate of each REB.

Institutions must respect the authority delegated to the REB. While an
individual researcher may appeal a decision of an REB, an institution may not override REB decisions simply to promote or prevent a particular research project. Institutions may, however, as a matter of policy, refuse to allow certain types of research to be conducted under its auspices regardless of the ethical acceptability of that research.

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 research ethics board (REB) shall consist of at least five members, of whom:

(a) At least two members have expertise in relevant research disciplines and methodologies covered by the REB;
(b) At least one member is knowledgeable in ethics;
(c) At least one member is knowledgeable in the law (but that member should not be the institution’s legal counsel or risk manager); and
(d) At least one member has no affiliation with the institution, but is recruited from the community served by the institution and has relevant experience or training.

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. Senior administrators should not serve on the REB (see Article 7.3 in Chapter 7 [“Conflict of Interest”]), in order to avoid the perception of perceived, potential or real conflict of interest.

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 based on the needs of the institution. Institutions should ensure proper gender representation on REBs where possible. Institutions may therefore need to exceed these minimum requirements in order to ensure an adequate and thorough review, or to respond to other local, provincial/territorial or federal requirements or legislation. For example, for 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. Community representation should be proportionate to the size of 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 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, and proportionate to, 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 have different contextual and disciplinary knowledge in ethics than has a member of 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, 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 institutions’ 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 sit as a member of that institution’s REBs while working for the institution.

In some instances, the legal issues 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 with no affiliation 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, local communities. The role of community members on REBs during the research ethics process is both unique and at arm’s length from the institution. Their primary role is to reflect the perspective of the research participant. This is particularly important when research participants are vulnerable and/or risks to research participants are high. Institutions should seek to appoint former
research participants as community members. Their experience as research participants provides the REB with a vital perspective and important contributions to the ethics review process. Institutions should provide training opportunities to community members.

To maintain effective community representation, the number of community representatives should be commensurate with the size of an REB and should increase as the size of an REB increases.

**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 use of substitute members should not, however, alter the REB membership structure as set out in this article. Substitute members should have the appropriate knowledge, expertise and training to contribute to the ethics review process.

### Ad hoc Advisors

**Article 6.5** The research ethics board should have provisions for appointing ad hoc advisors in the event that it lacks the specific expertise or knowledge to review a research proposal competently.

**Application** In the event that the REB is reviewing a project that requires particular community or research participant representation, or a project that requires specific expertise not available from its members, it should have provisions for appointing ad hoc advisors. The REB maintains its composition and representation as outlined in Article 6.4.

Ad hoc advisors are appointed for a specific task and for the duration of the 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 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 complement.

While an ad hoc advisor may complement the REB through his or her experience or expertise, his or her input is a form of consultation that may or may not be considered in the final decision of an REB. He or she is not an REB member and, as such, does not necessarily have the knowledge and experience gained from reviewing applications as a member. 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** Research ethics board members shall be appointed by the appropriate body at the
highest level of the institution such that their terms allow for continuity of the 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.

**Article 6.7** Research ethics board (REB) members should have the qualifications, expertise and training necessary to review the ethical issues raised by research proposals that fall within the mandate of their REB.

**Application** In selecting new members for appointment, the REB should consider the qualifications it needs in order to fulfil the requirements of Article 6.4.

REBs should have adequate expertise, experience and training to understand the research disciplines, methodologies and approaches of the research that it considers for ethics review. Each REB member brings complementary expertise and knowledge. It is not sufficient for an REB to possess the necessary expertise globally, however. It must ensure that the members in attendance at any given meeting have the specific expertise necessary to review the proposals under consideration at that meeting.

All members of the REB should understand core ethics principles and concepts as set forth in this Policy to contribute to the review process. Institutions should ensure that all REB members receive appropriate education and training in the ethics review of research involving humans, to enable them to fulfil their duties. This training should be offered both on the appointment of new members and periodically throughout a member’s tenure. Institutions should promote and recognize the contribution of REB members to the ethics review process, as a valued and essential component of the research enterprise.

**Article 6.8** The research ethics board (REB) Chair is responsible for ensuring that the operations of the REB comply with institutional policies and procedures concerning the ethics review process.

**Application** The role of the REB Chair is to facilitate the REB review process, operations and procedures, 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 properly and that they are communicated to researchers in writing as soon as possible. The institution should provide the Chair with administrative support in fulfilling his or her role.
Institutions shall establish quorum rules for research ethics boards subject to the range of competence and knowledge required by this Policy to ensure the soundness and integrity of the ethics review process.

Quorum rules should be established by institutions such that REB decisions requiring full review should be adopted only if the members attending the meeting possess relevant competence and knowledge and meet the minimum requirement of membership as outlined in Article 6.4. Among the REB members there should be at least two members who have relevant expertise in the methods or areas of research that are covered by the REB, one member who is knowledgeable in ethics, one member who has no affiliation with the institution but is recruited from the community served by the institution, and one member who is knowledgeable in the law. Quorum should be proportionate to the increases of the REB membership necessary to ensure adequate ethics review.

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

Research ethics boards shall have regular face-to-face meetings to discharge their responsibilities.

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. REBs shall meet face-to-face to review proposed research that is not assigned to delegated review.

Planning regular meetings is essential to fulfilling REB responsibilities. Regular attendance by REB members at meetings is important, and frequent absences should be construed as a notice of resignation. Unexpected circumstances such as emergencies may prevent individual member(s) from attending the REB meeting. In these exceptional cases, input from member(s) by other means (e.g., use of technology) would be acceptable.

Videoconferencing and use of other technologies may occasionally 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, such as during a public emergency. All efforts should be
made to ensure that technical difficulties do not prevent the maintenance of quorum throughout the meeting. Respecting the principles of this policy, institutions should develop written procedures for the occasional use of videoconferences or other technologies by an REB.

REBs and researchers may request informal meetings with each other prior to the formal review process to 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 or observers 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 could affect REB members in a way that would affect REB research ethics review deliberations and decisions. Individuals who are not REB members should be aware of how their institutional functions, how their roles may be perceived at REB meetings, and how they have the potential to unduly influence REB members in their decision-making procedures (see Chapter 7 [“Conflict of Interest”]).

REBs should also hold general meetings, retreats and educational 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 should submit their research project for research ethics board review and approval prior to the start of the formal data collection.

Application For some types of methodologies, such as in qualitative research or fields of research such as those involving Aboriginal peoples, the design of the study may not be known at the onset, but only after the researcher has engaged with prospective participants.

Prior dialogue with individuals or communities of interest is a normal component in community-based research or in some types of fields or disciplines of research. This may precede REB review.

Article 6.12 Research ethics boards shall follow a research ethics review process proportionate to the level of risk in research under review.
REBs must assess the level of risk that the research under review poses to participants to determine the appropriate proportionate approach to use in the ethics review. At the time of initial review of the research, the REB has the authority to determine the level at which continuing ethics review occurs (e.g., frequency of reports, required details in reports). The level of review and reporting schedule may be adjusted throughout the life of the project if the need arises in situations where the risk level of the research increases because of the discovery of new information or changes in procedures.

Two levels of ethics review may apply:

1. Full REB review
   Ethics review by the full REB should be the default requirement for research involving human participants.

2. Delegated REB review of minimal-risk research
   The REB delegates ethics review to an individual or individuals. Delegates may be selected from among the REB membership or at the faculty or department level.

Where it is determined that the research is of minimal risk, an REB generally may authorize a delegated ethics review, in accordance with its institutional policies. The REB may decide that its Chair or another individual(s) (e.g., delegated reviewer[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 revert back to the full REB.

In delegating the conduct of review, the REB should carefully select delegated reviewer(s) and should ensure that all delegated reviewers who are not members of the REB have the appropriate expertise and training to review all aspects of the proposal consistent with this Policy.

Examples of categories delegated for ethics review include:

- categories of research that are confidently expected to involve minimal risk;
- minimal-risk changes to approved research;
- annual renewals of approved research; or
- situations in which there is evidence that requirements laid down by the REB have been met.

An REB that decides to authorize a delegated review process must 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, thus permitting the REB to maintain surveillance over the decisions made on its
behalf so as to protect the interests of participants.

REBs retain the authority to accept the report as presented or to request a more rigorous review process. It is imperative that delegated reviewer(s) be accountable to the full REB. With the support of their institutions, REBs may develop their own mechanisms under which delegation of the conduct of review and the associated reporting process will occur. Those mechanisms and procedures should be made public.

REB Decision-Making

Article 6.13 The research ethics board shall function impartially, provide a fair hearing to those involved and provide reasoned and appropriately documented opinions and decisions. Approvals and refusals need to be communicated in writing to researchers in print or by electronic means.

Application The REB shall accommodate reasonable requests from researchers to participate in discussions about their proposals, but those researchers must 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.

The formal REB decision on whether to approve the research will often be preceded by extensive discussion of ethical concerns and of possible means of improving certain aspects of the research. These may include the research design or the information to be provided in the process of free and informed consent that affect the welfare or autonomy of participants or others affected by the research. 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 mandated by the institution. In such instances, the position of those disagreeing may be communicated to the researcher.

Participation by the researcher in such discussions is often very helpful to both REBs and researchers. Such discussions 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.

Scholarly Review

Article 6.14 As part of ethics review, research ethics boards should consider the appropriate mechanism for scholarly review of more-than-minimal-risk research, informed by
the traditions for scholarly review in various disciplines.

**Application** Where it is determined that the research presents more than minimal risk to participants, the full REB should consider some of the following mechanisms in their review:

- Conclude that the proposed research has already passed appropriate peer review – for example, by a funding sponsor;
- Establish a permanent peer review committee reporting directly to the REB; and/or
- Where no other venue for scholarly review is available, and if the REB has the necessary scholarly expertise, assume complete responsibility for the scholarly review, or if the REB does not have the necessary scholarly expertise, establish an ad hoc independent peer review committee.

REBs should normally avoid duplicating previous professional peer-review assessments unless there is a good and defined reason to do so. However, they may request that the researcher provide them with the full documentation of those reviews.

When evaluating the merit and the scholarly standards of a research proposal, the REB should be concerned with a global assessment of the degree to which the research might further the understanding of a phenomenon, and not be driven by factors such as personal biases or preferences. REBs should not reject research proposals because they are controversial, challenge mainstream thought, or offend powerful or vocal interest groups. The primary tests to be used by REBs should be ethical probity and high scientific and scholarly standards.

**Continuing Ethics Review**

**Article 6.15** The research ethics board shall make the final determination as to the nature and frequency of the continuing ethics review in accordance with a proportionate approach to ethics review.

**Application** Research is subject to continuing ethics review from the date of initial REB approval until completion of the study. At the time of first review, the REB should determine the term of approval. For some types of research (e.g., qualitative research or longitudinal research), there may be some difficulty in establishing start or end dates. For these cases, the REB should work with researchers to determine a reasonable timeline for continuing ethics review. The reporting schedule for continuing ethics review may be adjusted throughout the life of the project if the need arises in situations where the risk level of the research increases because of the discovery of new knowledge or addition of new procedures.
Research that involves minimal or no risk to the research participant should be held to the minimum standard of continuing ethics review – for example, a short annual report. Research that poses greater-than-minimal risk may require a more extensive continuing ethics review. This could include more frequent reporting to the REB, review of the consent process, and review of participant records, etc. Other reporting mechanisms for continuing ethics review may be required by funding sponsors.

While REBs make the final decision about the nature and frequency of continuing ethics review, continuing ethics review should be understood as a collective responsibility, to be carried out with a common interest in maintaining the highest ethical and scientific standards. For example, researchers must monitor their research to ensure that the research is conducted in an ethical manner. Researchers are responsible for supervising all team members in the application of the research procedures, and for ensuring that they are versed in the conduct of ethical research.

Departures From Approved Research

Article 6.16 Research ethics boards shall make decisions on the ethical acceptability of researchers’ departures from the originally approved research, in accordance with a proportionate approach to research ethics review.

Application Three categories of departures from approved research may occur during the conduct of research. These include (1) unanticipated or unexpected events or issues that the researcher did not anticipate or expect when originally submitting the research for ethics review, (2) changes that the researcher makes to the approved research, and (3) deviations from approved research when unavoidable single-incident departures from the originally planned research procedure occur.

In the conduct of their approved research, researchers should be cognizant of the requirement to report to their REB, in a timely manner, departures from approved research that have ethical implications and/or change the level of risk to participants, which could adversely affect their well-being or welfare. Any non-trivial or substantive changes to the research should not be implemented without documented approval or acceptance by the REB, except when necessary to eliminate an immediate hazard(s) to the research participants.

Institutions must have an established process for the REB to review and take appropriate action regarding departures from approved research, including reporting to senior administration and other administrative units where necessary and appropriate.
The level of REB review required to assess the changes or deviations from approved research that have ethical implications and/or change the level of risk to participants shall follow a proportionate approach to ethics assessment, including changes to the continuing ethics review process. It is not the size of the change that dictates the review process, but rather the ethical implications and risk associated with the proposed change. In general, regardless of the term of approval, projects will need to be re-reviewed or amended if the context surrounding the research project changes. Although the REB holds responsibility for reviewing the ethics of research in light of changes in context, the researcher has a responsibility to be familiar with the environment in which the research is being conducted and to notify the REB about changes that may affect the ethics of the research.

The final decision as to which type of deviations to report to the REB is up to the REB. The report to the REB should include a description of the incident, including details of how the researcher(s) dealt with the situation. The point in reporting is informational and educational: it is to enable the REB to better protect research participants in future research projects. Depending on the nature of the event or issue, REBs may require that researchers adjust their procedures to prevent such events from re-occurring during the research project.

In the case of clinical trials, unexpected or unanticipated events and reporting requirements are defined in *International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use Guidance E6: Good Clinical Practice: Consolidated Guideline (ICH-GCP)*. An REB may stipulate a timeframe for the reporting of such events. In some cases, such events may be identified by Data and Safety Monitoring Boards or study sponsors. If the event has immediate implications for the safety and protection of research participants, the REB may require that the research be halted until the matter can be addressed. (See Articles 11.3 and 11.4 in Chapter 11 [“Clinical Trials”].)

In still other kinds of research (especially in the social sciences and humanities), it is not always clear before the research is undertaken what events may occur during the course of the research project. Here, researchers should report any event that occurred as a result of the research and that may affect the safety and well-being of the research participants. In many cases, researchers will simply need to use their best judgment as to what should be reported to the REB. In other cases, the researchers and REBs may work together to develop a list of types of reportable events.

**Record Keeping of REB Documents**

**Article 6.17** Research ethics boards (REBs) shall prepare and maintain comprehensive files, including accurate minutes reflecting research ethics review decisions.
and attendance of all REB meetings, as well as all documentation related to
the studies submitted to the REB for review.

**Application** REBs need to act, and to be seen to be acting, fairly and reasonably. REBs
should maintain complete study files, including the original application, as
well as annual and end-of-study reports. REBs should be guided by their
institutional record-keeping policies and other relevant legislation or
requirements when deciding the retention period of their files. Minutes and
other relevant documentation must be accessible to authorized representatives
of the institution, researchers, sponsors and research agencies when
applicable 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
and 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 is mandatory when a proposal is refused; it is optional
when it is approved.

REBs should maintain reports and decisions on departures from approved
research, including a description of the unexpected or unanticipated event,
change or deviation; details of how the researcher dealt with the situation;
and the REB’s approval or acceptance of such changes.

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

### C. Reconsideration and Appeals

Appeals of REB decisions follow a two-tiered approach. The first step – reconsideration –
must be exhausted before a researcher may proceed to the second step – the appeal process.

**Reconsideration of REB Decisions**

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

**Application** REBs are to follow principles of natural and procedural justice in their decision-
making. Such principles include providing a reasonable opportunity to be heard;
an explanation of the reasons for opinions or decisions; and the opportunity for
rebuttal, fair and impartial judgment, and reasoned grounds for the decisions.
Researchers and REBs should make every effort to resolve their disagreement.
through deliberation, consultation or advice. If a disagreement cannot be resolved by the researcher and REB, recourse to the appeals process may be considered.

In the case of protocols reviewed by delegated review, requests by the researcher for reconsideration of a delegated review decision should be forwarded by the researcher for review by the full REB. Researchers must justify on what grounds they request a reconsideration and indicate the breaches to the research ethics process or the elements of the delegated REB decision that are not supported by this Policy.

### Appeal of REB Decisions

**Article 6.19**

(a) In cases when researchers and research ethics boards (REBs) cannot reach agreement through discussion and reconsideration, an institution should permit review of an REB decision by an established appeal process.

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

**Application**

Institutions must have an established mechanism and procedure in place for entertaining appeals.

By nature of their role and lack of frequency of meeting, appeal committees are typically, de facto, ad hoc. Therefore, the appeal mechanism may be an ad hoc committee or a permanent committee, as long as individuals involved in the appeal process have the relevant knowledge and competence to review REB decisions and procedures based on this Policy (see Article 6.4).

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

**Article 6.20**

The scope of any appeal will be limited to assessment of the consistency of the research ethics board’s decision with this Policy.

**Application**

Researchers have the right to request an appeal of an REB decision once the period of reconsideration has expired or the reconsideration process has been exhausted and the REB has issued a final decision. Researchers must justify on what grounds they request an appeal and indicate the breaches to the research ethics process or the elements of the REB decision that are not supported by this Policy.

The Appeal Committee will determine whether the REB acted outside its mandate and/or committed a breach of the process for ethics review as set out in the most recent version of the institution’s guidelines or policies and this Policy.
The Appeal Committee has no jurisdiction to make a decision regarding the ethical acceptability of the research study involved in the process under appeal. It should be stressed that the appeals process is not a substitute for the REB’s and the researcher’s working closely together to ensure high-quality research, nor is it a forum to merely seek a second opinion. It is expected that an appeal will be an exceptionally rare occurrence.

The Appeal Committee shall do one of the following:

1. Dismiss the appeal; or
2. Declare the original REB decision void and direct the responsible REB to reconsider the application while ensuring that the REB is compliant with all procedural and jurisdictional requirements.

The Appeal Committee shall function impartially, provide a fair hearing to those involved, and provide reasoned and appropriately documented opinions and decisions. Approvals and refusals should be communicated in writing to researchers in print or by electronic means.

D. Research Ethics Review During Publicly Declared Emergencies

There is a growing awareness of the need for institutional planning to respond to public emergencies and the associated potential challenges for research ethics review. Public 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 institutional, community and individual life.

This section addresses research ethics review within the context of the official declaration of public emergencies, which initiates emergency procedures and provides special responsibilities and powers to authorized officials in accordance with provisions of the law. Given the extraordinary circumstances that research participants are potentially subjected to in public emergencies, special attention and effort should be given to upholding the core principles of welfare, autonomy in the decision-making process, and the equal moral status of all humans in such emergencies.

Institutional Emergency Research Ethics Preparedness Plans

In concert with their researchers, institutions and their research ethics boards should develop emergency research ethics preparedness plans. Research ethics review during emergencies may follow modified procedures and practices.
Application

Preparedness plans should outline policies and procedures for addressing research ethics review during and concerning public health outbreaks, natural disasters and other public emergencies. Research ethics policies and procedures and their implementation should adhere rigorously to a rule of reasonable, fair and principled design and use for emergency purposes.

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 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 ethics review in institutions/REBs; how REBs conduct business or meet; what research needs should be planned in advance of, or done 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 ethics review; and what evaluation methods need to be developed. 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, 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 consider the following:

1. What constitutes “essential” research during the emergency;
2. The initial 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);
3. Continuing ethics review of research undertaken prior to the occurrence of the emergency; and
4. The review process for departures from approved research, because new information may become available very rapidly during emergencies (see Article 6.16).

REB procedures may warrant reasonable adjustments to address the timing, locale, expertise, form and scope of 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 ethics reviews, quorum rules, or special agreements with other institutions), while considering the impact of the emergency on research participants, researchers, REB members, institutional staff and others. 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 ad hoc advisors with relevant expertise, negotiate reciprocity agreements with other institutions for REB reviews, and revisit how scholarly review would be applied in such instances.

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

**Application of Research Ethics Review Policy and Procedures in Publicly Declared Emergencies**

**Article 6.22** The application of research ethics policy and procedures for emergencies is limited to officially declared public emergencies. It should cease immediately after such declaration is withdrawn.

**Application** Public emergencies for the purposes of this Policy are limited to those that are declared by an authorized public official. This section therefore applies to narrow, limited and exceptional circumstances. Because emergencies present extraordinary public risks that warrant special responses, legislation or public policies usually require that they be officially proclaimed or declared. The exercise of those responsibilities may temporarily modify normal procedures or practices. In extreme instances, public emergencies might warrant the suspension of some civil liberties. The ethical rationale behind such powers and duties is beneficence-based public necessity: that the exceptions to, and infringements of, principles such as autonomy may prove necessary to preserve or protect human life or public health, safety, order and welfare. An important concern regarding such powers is that they not be used beyond the scope of the emergency, nor used arbitrarily or unreasonably or otherwise abused. For such reasons, they are circumscribed. Research ethics review policies and procedures for declared emergencies should, accordingly, be applied only to compelling public necessities occasioned by a public emergency.

**Respecting Core Principles: Limiting Derogations**

**Article 6.23** Research ethics boards should give special care to requests for derogations from the principles outlined in this Policy involving or during publicly declared emergencies.
Especially during times of emergency, researchers, REBs and institutions need to be vigilant and exercise due diligence in respecting ethical principles and procedural standards. To preserve the values, purpose and protection that the principles of this Policy advance, the onus for demonstrating a reasonable public-emergency exception to an ethical principle or procedural standard should fall on those claiming the exception.

To guide fair and reasonable implementation for emergency circumstances, any derogations from or infringement of ethics principles and standards need to be demonstrably justified by those urging the infringement. Sometimes a proposed infringement or derogation will not be justified for research purposes. Justified derogations from or infringement of ethics principles and standards should correspond directly, and be calibrated, to the benefit targeted by the goal of the policy. Derogations should be narrowly tailored to address the necessities occasioned by the public emergency, such that the least restrictive or least intrusive means necessary to achieve the policy goal are relied on. This approach – consistent with international bioethics and human rights norms – maximizes respect of ethical principles and helps to ensure that exceptions or infringements and the means to implement them are not unduly broad, overreaching or unjustifiably invasive.

Recognizing and respecting the principle of equal moral status 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 equal moral status advances a fair and balanced distribution of burdens and benefits even in the face of public emergencies.

REBs and researchers should be aware that individuals, potential participants, researchers, and institutions that may not normally be considered vulnerable may become so by the very nature of public emergencies. Those already vulnerable may become acutely so. REBs and researchers should ensure appropriate evaluation of the risks and potential benefits posed by any proposed research, including provisions for greater-than-normal attention to risk, where applicable. The increased public risks and devastation on which public emergencies are declared threaten autonomy and physical, emotional, institutional and social well-being or safety. They also bring inherent tensions and pressures that may impact deliberative decision-making. Research ethics policy and review for public emergencies should recognize that in such situations the affected population, as individuals or as a body, may become more vulnerable. Therefore, the need to promote, protect and respect the welfare and autonomy of participants must be accordingly addressed (see Article 4.4 in Chapter 4 [“Research Involving Vulnerable Persons or Groups”]).
Chapter 7

CONFLICT OF INTEREST

Researchers and research ethics boards (REBs) hold trust relationships with research participants, research sponsors, institutions, their professional bodies and society. These trust relationships can be put at risk by conflicts of interest that may compromise independence, objectivity or ethical duties of loyalty. Although the potential for such conflicts has always existed, pressures to commercialize research or suspend dissemination of research outcomes heighten concerns.

Research institutions, too, hold trust relationships with research participants, research sponsors, researchers and society. Research institutions may have financial or reputational interests that conflict with the institution’s obligations to protect and respect human dignity as characterized by the core principles of this Policy. Institutions have an interest in ensuring that the conduct of research is not compromised by real, potential or perceived conflicts of interest.

Conflicts of interest that jeopardize the integrity of research and the protection of potential research participants are contrary to the core principles on which this Policy is based. Conflicts that create divided loyalties may distract researchers, REBs and institutions from the welfare and well-being of participants. Failures to disclose and manage conflicts may impede the informed and autonomous choices of individuals to participate in research. Conflicts of interest may also undermine the respect for participants that is fundamental to the principle of equal moral status. Researchers, their institutions and REBs should identify and address conflicts of interest – real, potential or perceived – to maintain public confidence and trust, discharge professional and institutional obligations, and ensure accountability.

A. Institutions and Conflicts of Interest

Article 7.1 Institutions should develop conflict of interest policies and procedures to identify, prevent, disclose and manage conflicts of interest that may affect research involving humans. Institutions should act in a transparent manner in addressing conflicts of interest and should make their written conflict of interest policies and procedures publicly available.

Application When developing institutional policies and procedures on conflicts of interest, institutions should clarify the roles and the distribution of responsibilities, and clarify associated potential for conflicts. This clarity should reduce or eliminate
the possibility for confusion of roles that may ultimately lead to conflicting obligations. Ideally, institutional policies will organize roles, responsibilities, reporting lines and accountabilities to minimize, manage or avoid conflicts of interest. (See Articles 6.1 and 6.2 in Chapter 6 [“Governance of Research Ethics Review”] and Article 7.2.) Institutions must respect the autonomy of the REB and ensure the REB has the appropriate financial and administrative independence to fulfil its duties. (See Articles 6.1 and 6.2 in Chapter 6 [“Governance of Research Ethics Review”].)

Measures to manage conflicts of interest should be proportionate to potential harms and should be founded on an assessment of relevant institutional operations. Institutions should consider the following measures to address conflict of interest at the institutional level:

- Apply firewalls to insulate potentially conflicting roles and duties;
- Refine or redesign roles and responsibilities to minimize or avoid the potential for conflicts;
- Prevent or minimize conflict of interest in institutional design and structuring when creating new roles, responsibilities or relationships;
- Withdraw from, or not participate in, roles or functions unduly compromised or disabled by perceived or real conflict; and
- Create central institutional mechanisms such as a conflict of interest committee or other delegated body within the institution to help identify and manage conflicts of interest.

Conflict of interest policies and procedures should be developed in a transparent manner and should be publicly available to all members of the research enterprise, including research participants, REBs, researchers, administrators, research sponsors and others.

The goal of such policies is to identify and disclose potential, perceived or real institutional conflicts of interest to make them transparent and open to scrutiny.

**Article 7.2** Institutions should ensure that the research ethics board is informed of real, potential or perceived institutional conflicts of interest that may affect research involving humans.

**Application** An institutional conflict of interest involves a conflict between at least two substantial institutional obligations that cannot be adequately fulfilled without compromising one or both obligations. Conflicts may be real, potential or perceived. Institutional conflicts of interest may compromise duties of loyalty and lead to biased judgments. Conflicts may also undermine public trust in the ability of the institution to carry out its missions, operations and ethical responsibilities in research involving humans.
An individual acting in a professional role with the institution is in a conflict of interest when he or she is subject to competing incentives or functions that significantly interfere with the impartial exercise of duties, including legal and ethical obligations within the institutional structure. An institutional conflict of interest may thus directly divide one’s professional duties and loyalties when the incentive structure of the institution places individuals acting in institutional roles in conflicts of loyalty and function. The conflict may be chronic, relating to recurring situations occasioned by the institutional structure, or it may be triggered by a unique situation that is not likely to recur.

To meet obligations to protect research participants, institutional policies should address the roles, responsibilities and process for disclosing and managing institutional conflicts of interests relevant to research involving humans, including disclosure to REBs. Institutions may consider establishing relevant structures such as a competent institutional authority, a delegated body, or conflict of interest committee within the institution (see Article 7.1).

A senior administrator, researcher, REB member or other individual who is aware of potential sources of institutional conflicts of interest that may affect research involving humans should refer to the institutional policy to inform the REB of such conflicts. Likewise, when a significant real, potential or perceived institutional conflict of interest is disclosed and brought to its attention, the REB should be guided by the central institutional mechanisms for consulting with the relevant body to manage the conflict.

### B. REB Members and Conflicts of Interest

**Article 7.3** Research ethics board (REB) members must disclose real, potential or perceived conflicts of interest to the REB, and, where necessary, members must withdraw from REB deliberations and decisions.

**Application** To maintain the independence and integrity of ethics review, members of the REB must avoid and disclose real, potential or perceived conflicts of interest. For example, REB members are in a conflict of interest when their own research projects are under review by their REB.

When REB members are or have been in direct conflict with researchers on academic or scientific issues, or when they have collaborated with the researcher whose proposal is under review, REB members should disclose and fully explain to the REB the conflict of interest to prevent bias or undue influence in the outcome of the review process. In such cases, the researcher should be able to raise with the REB any concerns with respect to conflict of interest. To manage such conflicts, REB members should withdraw from the committee when such projects are under consideration.

While the presence of administrative staff may be relevant and appropriate to
support REB procedures, an institutional senior administrator should not serve on an REB, attend meetings, or influence the REB decision-making process. (See Articles 6.2, 6.4 and 6.10 in Chapter 6 [“Governance of Research Ethics Review”].) The presence of a non-voting institutional senior administrator at REB meetings may undermine the independence of the REB by unduly influencing REB deliberations and decisions.

Research involving small communities or community-based organizations with scarce human resources may present particular issues related to multiple roles of some individuals. In some cases, securing informed advice on cultural or other aspects of research rests with the researcher or the sponsoring institution and requires engagement with a community advisor, who may assume various roles in the research process. The same individual may be involved in providing preliminary information as well as reviewing the ethics of a research proposal at the community level and even co-managing the approved research. As outlined in Article 7.1, an approach proportionate to the level of harms, such as disclosure of the possible conflicts between multiple roles, may be sufficient to manage the conflict.

Institutional conflicts of interest may give rise to professional conflicts or divided loyalties for individuals working in affected institutions. Reasonable compensation by institutions for REB members is appropriate. However, in some instances, individual members of the REB may have a conflict of interest in accepting undue or inappropriate honoraria for their participation in the REB. The REB must avoid or manage such conflicts of interest.

C. Researchers and Conflicts of Interest

Article 7.4 Researchers should disclose to the research ethics board real, perceived or potential individual conflicts of interest, as well as any institutional conflicts of interest of which they are aware that may have an impact on their research.

Application Individual conflicts of interest may arise from interpersonal relationships (for example, family or community relationships), financial partnerships, other economic interests or any other incentives that may compromise integrity, confidence of the research participant, or respect for the core principles of this Policy. Conflicts may arise from an individual’s involvement in dual and multiple roles within or outside an institution. While generally it is impossible to eliminate all conflicts of interest, researchers are expected to recognize, disclose, limit and manage their individual conflicts in a manner that is satisfactory to the REB.

Managing conflict of interest is a process, of which the first step is disclosure. Upon disclosure to the REB, the steps taken by the REB to manage the conflict should be context-based and proportionate to potential harms. For example, in some cases, the REB might conclude that the identified conflict of interest
does not warrant specific actions. In other cases, when disclosure to the REB is not enough to manage the conflict of interest, the REB, guided by established institutional policies, may require that the researcher abandon one of the interests in conflict by withdrawing from the research or allowing others to make research-related decisions.

Dual roles of researchers (for example, acting as both a researcher and a therapist, caregiver, teacher, advisor, consultant, supervisor, student or employer) may create conflicts, undue influences, power imbalances or coercion that could affect relationships with others and affect decision-making procedures (for example, free and informed consent of participants). Article 3.2(e) reminds researchers of relevant ethical duties that govern potential, perceived or real conflicts of interest as they relate to the free and informed consent of participants. To preserve and not abuse the trust on which many professional relationships rest, researchers should be fully cognizant of conflicts of interest that may arise from their dual or multiple roles, and they should attempt to manage the conflict.

Care should also be exercised in developing relationships between researchers and authorities, so as not to compromise the free and informed consent and privacy of participants and the confidentiality obligations of researchers, and to maintain public confidence and trust.

As part of the research plan for REB review, researchers should provide details on the research project, budgets, commercial interests, consultative relationships and other relevant information and documentation, and identify strategies to prevent, disclose and manage conflicts properly. Disclosure of the kinds and amounts of payments, and other budgetary details, especially if the researcher also holds a therapeutic, clinical or other fiduciary relationship with research participants, will assist the REB, or other delegated body within the institution, to assess potential conflicts of interest and will help the researcher in resolving them. (See Articles 11.8 and 11.9 in Chapter 11 [“Clinical Trials”].)

The appearance of a conflict may in many cases be as damaging as a real conflict. The REB should assess the likelihood that the researcher’s judgment may be influenced or appear to be influenced by private or personal interests, and it should assess the level of harm that is likely to result from such influence or from the perception of undue influence.

In addressing conflicts of interest, disagreements may arise about the scope and reach of disclosure, including disclosure of new information to participants, or other aspects of managing the conflict. Resolution of disagreements should be guided by a paramount principle of respecting the autonomy and welfare of participants and by relevant institutional policies. If disagreement cannot be resolved by the researcher and REB, recourse to the appeals process should be considered. (See Articles 6.19 and 6.20 in Chapter 11.)
6 [“Governance of Research Ethics Review”].)
Chapter 8

MULTI-JURISDICTIONAL RESEARCH

Modern research often involves collaborative partnerships among researchers from multiple institutions or countries. It may call upon the participation of a number of local populations and involve multiple research ethics boards (REBs).

Collaborative research may require institutions to adopt policies and procedures that permit arrangements for REB review off-site at other institutions. To be effective, these review arrangements should ensure that research involving humans is designed, reviewed and conducted in a way that is informed by the core principles of welfare, respect for autonomy and equal moral status for all humans. These core principles should be balanced with a proportionate approach to the research ethics review process for research being undertaken in Canada or abroad.

G. Review Mechanisms for Research Involving Multiple Institutions and Research Ethics Boards

This section primarily addresses research involving multiple sites and at least one institution that adheres to this Policy.

Institutions are accountable for research conducted under their auspices, irrespective of the location where it takes place. Prior ethics review of the proposed research at each collaborating institution affords the opportunity for local issues and values to be considered. However, multiple, independent reviews may lead to different decisions, which may delay or jeopardize the implementation of the research.

Research involving humans that may require the involvement of multiple REBs includes, but is not limited to, the following situations:

(a) A research project conducted by a team of researchers affiliated with different institutions;
(b) Several research projects independently conducted by researchers affiliated with different institutions, with data combined at some point to form one overall research project;
(c) A research project conducted by a researcher affiliated with one institution, but that involves collecting data or recruiting research participants at different institutions;
(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);
(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) Researcher(s) working under the auspices of a Canadian research institution but conducting research in another province, territory or country.

Adoption of Alternative Review Models is an Institutional Responsibility

Article 8.1 An institution that has established a research ethics board (REB) may define specific review models for research involving multiple REBs or institutions, in accordance with this Policy.

Application In addition to the traditional review processes (see Point 1, below), the following models for multiple REBs or multi-institutional review are intended to provide flexibility and efficiency and avoid unnecessary duplication of review without compromising the protection of research participants. All other provisions of this Policy remain applicable.

1. Independent Review by Several Single REBs

The REBs involved at each participating institution conduct their independent research ethics review and provide their separate decisions, either concurrently or sequentially.

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. REBs may therefore wish to coordinate their review of projects requiring multiple REB involvement, and to communicate any concerns that they may have with other REBs reviewing the same project. When multiple REBs are involved, the REB of the principal investigator should define mechanisms to address inconsistencies or disagreements, defining criteria, roles and responsibilities.

Researchers should provide their REB with the name and contact information of the other REBs that will also review the project.

2. Research Ethics Review Delegated to a Specialized or Multi-institutional REB

Institutions allow research on specific content areas (e.g., clinical oncology research, research involving Aboriginal peoples) or research methods (e.g., qualitative research) to be reviewed by an external, specialized or multi-institutional REB, where such a body exists. In the agreements between the selected REB and the institutions submitting research for review, the specialized or multi-institutional REB must agree to adhere to this Policy.
Specialized or multi-institutional REBs may be established regionally, provincially/territorially, or nationally, as necessary.

Another situation would include two or more institutions pooling their resources to create a single joint REB to whom the research ethics review is delegated. Such a delegation may be based on geographical proximity or other considerations such as capacity, volume of reviews, or shared expertise.

Some provinces have introduced legislation that designates one or more REBs for the review of certain types of research within the province. In addition to other provisions, provincial legislation may require adherence to this Policy.

Roles and responsibilities should be clearly defined in the agreement between institutions or in the legislation. The 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 specialized or multi-institutional REB will assure familiarity with particular populations that may be involved in the research. Central review by a specialized or multi-institutional REB need not be preceded or followed by local REB review.

3. Reciprocal REB Review

Multiple institutions may enter into agreements under which they will accept, with an agreed level of oversight, the ethics reviews of each other’s REBs. This might involve specific agreements between institutions for sharing the workload of reviewing collaborative research.

Institutions may also decide that reciprocity agreements between institutions involved in such research are to be established for each research proposal on a case-by-case basis.

Whether the review is done by a single REB or reciprocal REB, researchers should 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. Otherwise, local REBs might be called upon to provide such information, in addition to the information provided by the researchers.

Every institution remains responsible for the ethical acceptability of research undertaken within its jurisdiction or under its auspices, regardless of the model adopted for multi-jurisdictional review of any given research project.

The selection, establishment and implementation of alternative models for REB review is a collective/collaborative responsibility within and between
the participating institutions, their REBs, and the investigators whose research is reviewed. Regardless of the review model adopted for any given research purpose, the institution remains responsible for the ethics review and for decisions regarding research involving human participants that is carried out under its auspices or within its jurisdiction, irrespective of the location where the research is conducted. The ultimate responsibility for the REB reviews and decisions remains with the individual institutions.

Alternative procedures can range from multiple reviews of the same project to accepting the review of other REBs constituted in accordance with this Policy. An institution may authorize its REB to accept reviews of another institution’s REB if both institutions have an official agreement that includes at least the following components:

- All institutions involved must agree to adhere to the requirements of this Policy, and the cross-institutional agreement must be formalized and documented;

- The decision to allow an REB to recognize decisions made by another institution’s REB must be made at the highest institutional level, by the body that originally defined the jurisdiction of the REB and its relationship to other relevant bodies or authorities (in accordance with Article 6.2 in Chapter 6 [“Governance of Research Ethics Review”]); and

- Approvals based on cross-institutional agreements should be brought to the attention of the full REB in each institution, in the same way as decisions made by delegated review.

Researchers should use the review models defined by their institution and facilitate coordination of ethics review when submitting their proposal to the REB. Whatever model is chosen, roles and responsibilities of all involved in the process should be defined and agreed to at the outset. Institutions might decide to adopt different models for the review of different research projects.

**Adoption of a Review Model Relevant to the Research Project is a Shared Responsibility Between Researchers and REBs**

**Article 8.3** Researchers and research ethics boards (REBs) should, together, determine which review model is the most appropriate for proposed research involving multiple institutions and REBs.

**Application** When planning for research involving multiple institutions and REBs, researchers and REBs should identify which review models have been approved by their institution and determine which one would be most relevant for the proposed research. Researchers should consider alternative review models at the planning and design stage of their research, and they
should consult with their REB to facilitate the selection and coordination of the appropriate review model.

Sensitivity to context is a key issue in the application of the core principles of this policy in ethics review of research involving multiple institutions and REBs. In choosing the appropriate review model, the researcher and the REB should pay attention to characteristics of the populations targeted by the research and the research context. When choosing alternative REB review models, 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 potential for conflict of interest and undue influence, including from funding sources;
- The scope of the project to be reviewed and appropriateness of the proposed review mechanism;
- The vulnerability of the study population overall and the local population at individual sites, 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/countries;
- Relationships between institutions and REBs, and conflict resolution mechanisms;
- Any differences in the standard of care or access to services that might be relevant to the conduct of the research, normally followed at the participating institutions; and
- Any operational issues that need addressing.

B. Review of Research Conducted Outside a REB’s Jurisdiction

Researchers affiliated with Canadian institutions are undertaking research in numerous countries around the world or sites within Canada. Such research may be carried out with or without any collaboration with host institutions and local researchers. Researchers should familiarize themselves with the rules applicable in the host institution and conduct their research in conformity with them. Most developed countries, and many developing countries, have laws, policies or guidelines governing the conduct of research involving humans. However, for some types of research, such formal frameworks or requirements for review do not exist.
National and international standards for research involving human participants are evolving continually, but methods for comparing the precise levels of protection afforded participants in different countries or jurisdictions, and 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 outside its jurisdiction, the Canadian REB must satisfy itself that the requirements of this Policy are met, both within the Canadian institution and within the host country or site, taking appropriate steps to ensure they are responsive to ethically relevant aspects of the research context.

Article 8.4 (a) Subject to Article 8.4(b), research conducted under the auspices of a Canadian research institution and conducted outside its jurisdiction, whether elsewhere in Canada or outside Canada, shall undergo prospective ethics review both by the research ethics board (REB) at the Canadian institution under whose auspices the research is being conducted and by the REB or similar body, where such exists, at the collaborating institution(s) in the host research site.

(b) Where research conducted under the auspices of a Canadian research institution and performed in whole or in part outside Canada is covered by an ethics review model involving multiple institutions or REBs consistent with this Policy, the terms of that model apply.

Application An institution is responsible for the ethical conduct 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 research by the institution’s REB is required in addition to review by an REB having jurisdiction at the research site in the host country or elsewhere in Canada, where such exists. Approval of a research proposal by an REB at the host 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 warrant to begin the research without the approval of the REB or other appropriately constituted review body at the host site.

In some cases, researchers undertake research in Canada or abroad without seeking formal collaboration with other academic institutions. In such 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 such exists. They should inform the REB whether or how they will seek permission to proceed with the research at that site and with the target research participants. Some organizations or groups have established mechanisms or guidelines (e.g., school boards, Aboriginal communities, correctional services, service agencies and community groups) to review requests for research prior to allowing access to their members or individuals, or access to data about them, under their authority. When designing their research, researchers should consider such provisions. This article does not apply to research using critical
inquiry about organizations or institutions. (See Article 3.6 in Chapter 3 [“Free and Informed Consent”].)

In other cases, no such provisions or requirements exist. Researchers should inform the REB about the absence of any other review mechanisms available at the research site. In such cases, researchers and REBs should apply the core principles outlined in this Policy.

Some countries have not established formal ethics review mechanisms for some types of research. REBs should not prevent such research from proceeding solely because the research cannot be reviewed and approved through a formal REB review process in the foreign country. 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 and REBs should afford the prospective participants no less protection and respect than what this Policy requires. Respect for the welfare, autonomy and equal moral status of all humans considered in the context of the particular research project and setting should guide researchers in the design of their research and REBs in their review.

**Article 8.5**

(a) Subject to Article 8.5(b), when conducting research outside the jurisdiction of their home institution, whether at a site abroad or in Canada, researchers should provide their home research ethics board(s) (REBs) with:

- the relevant information on the rules governing human research and the ethics review requirements at the host site;
- the names and contact information for the relevant REBs or comparable ethics bodies, if known, that will review the proposal at the host site; and
- relevant information about the target populations and circumstances that might have a bearing on the ethical review by the researcher’s home REB.

(b) Where a review model involving multiple institutions and REBs is in place, the information to be provided to the home REB will be determined by the provisions of that model.

**Application**

As Canada’s role in national and international research and research funding continues to grow, researchers and REBs should be aware of the research ethics requirements and the types of protection afforded to human research participants in proposed research locations. Researchers and REBs should consult relevant resources for details of policies and for appropriate REBs in the host country or...
research site in Canada (see References, below). 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 the provisions of this
Policy for the particular research project are followed at such sites, within the
host country or in Canada, at a minimum.

Subject to Article 8.5 (b), disagreements may arise when one of the REBs or
equivalent review body (Canadian or foreign) grants approval while the other
does not. Such disagreements require open communication among the
investigator(s) and the REBs or equivalent review body involved. (See also
Section A [“Review Mechanisms for Research Involving Multiple Institutions
and Research Ethics Boards”], above.) 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 rationales 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 host country.
The REBs should engage in dialogue and may even 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 a given research
proposal (see also Article 8.2).

C. Other Ethics Considerations When Reviewing Research
Conducted Outside the Jurisdiction of the REB

Benefit Sharing and Obligations of Care for Research Participants and Communities

Researchers should consider the implications of the core principles for sharing the benefits of
the research. (See Chapter 1 [“Ethics Framework”] and Chapter 9 [“Research Involving
Aboriginal Peoples”].) They should be familiar with the social and economic circumstances in
the host site or country. As well, they should anticipate, to the best of their ability, obligations
of care that might arise in any given research proposal. In general, researchers should ensure
that any services or care necessary to complete a given study, or to respond effectively to any
foreseeable harms that may be experienced by research participants, are provided at the site of
the research. But researchers should also anticipate, and prepare to the best of their ability and
based on available resources, for demand for ancillary care that might arise in the course of the
research. Joint planning with local collaborators and/or advisors can help to clarify the most
likely nature of the ancillary care demand, as well as the most appropriate division of
responsibility for meeting it, where appropriate.

Researchers should also be sensitive to the expectations and opinions of participants regarding
potential benefits of the research, and they should arrive at agreements with the community
about the scope and nature of the benefits that will be provided to participants and/or their
communities during and after the research. The agreements should, to the extent possible, be
explicit about the planned division of responsibilities for realizing these benefits. In many
cases, benefits may be delivered most effectively in partnership with local organizations. Benefit sharing may, for example, take the form of information sharing, training for local personnel both in the host country and in Canada, or health care or similar services. Where applicable, these benefit-sharing agreements, whether formal or informal, should be submitted to the Canadian REB and the REB of the host site or country for review. Since researchers are not aid agencies, REBs should be vigilant to ensure that the proposed distribution of benefits is fair, without imposing undue burdens on the researcher that would make it too difficult or costly to complete the research reliably.

Researchers should pay special attention to cultural or other values that differ from their own. They should also take care not to create unrealistic expectations among participants with respect to the potential benefits of the research.

Researchers should normally provide copies of publications or other research reports arising from the research to the institution or organization – normally the host institution – that is best suited to act as a repository and disseminator of the results within the participating communities. This may not be necessary in countries when the results are readily available in print or electronically.

**Protection of Research Participants in Authoritarian Countries**

Various international conventions and treaties have espoused the position that researchers should be permitted free movement across national boundaries to conduct their research. REBs should, therefore, not veto research about authoritarian countries on the grounds that the regime or its agents have not given approval for the research project or have expressed a dislike of the researchers. REBs should, however, legitimately concern themselves with the safety of research participants and the security of research materials. (See Article 3.12 in Chapter 3 [“Free and Informed Consent”]. When copies of field material are provided to participants in countries with authoritarian regimes, researchers should concern themselves with commitments concerning anonymity and confidentiality of participants to ensure that human rights of the participants and the ethical principles set out in this Policy are not compromised. (See Articles 5.1 - 5.4 in Chapter 5 [“Privacy and Confidentiality”].)

**Risks to Researchers**

Researchers undertaking research in other countries may be exposed to risks of harm. They should consult the appropriate bodies within their institutions and abroad who may provide advice on conditions in other countries prior to starting the research.

In fulfilling their review role, REBs have access to details of the context within which the research takes place in other jurisdictions and countries, and which may raise safety concerns for the researcher. In those cases, and while it is not a formal part of their responsibilities, REBs may raise such concerns as part of their communication to the researchers of the results of the ethics review, and the REB should flag such concerns with the institution.
References

- Office for Human Research Protections (OHRP), International Compilation of Human Subject Research Protections.
Chapter 9

RESEARCH INVOLVING ABORIGINAL PEOPLES

A. Interpreting the Ethics Framework in Aboriginal Contexts

This chapter interprets how the value of respect for human dignity and the core principles of concern for welfare, respect for autonomy and equal moral status of all humans, as articulated in Chapter 1 (“Ethics Framework”), apply in varied contexts of research involving Aboriginal peoples, including First Nations, Inuit and Métis.

Ethical codes to protect human dignity have historically been concerned with the well-being of individual participants, interpreted in this Policy as concern for participants’ physical and mental health. Concern for welfare includes individual well-being, but broadens the focus of ethics to consider individuals imbedded in relationships in their physical, social, economic and cultural environments. This Policy acknowledges the important role of Aboriginal communities, particularly those that exercise local or regional governing authority, in promoting collective interests that also serve individual well-being. The Policy also directs attention to ethical protections for the autonomy of individual members within communities and to the interests of urban and other Aboriginal populations who may not have formal representation in an Aboriginal governance structure.

Communities are particularly concerned that research should enhance their capacity to maintain their cultures, languages and identities as distinct peoples and to facilitate their full participation in Canadian society. The interpretation of welfare and the balance between concern for individual well-being and broader concerns for collective welfare may therefore differ significantly in an Aboriginal context, as compared with more individualistic social situations.

Where the social, cultural or linguistic distance between the community and researchers from outside the community is significant, the potential for misunderstanding is likewise significant. Engagement between the community involved and researchers, initiated prior to the actual research activities and maintained over the course of the research, can enhance ethical practice and the quality of research by promoting mutual trust and communication, establishing mutually beneficial research goals, and ensuring that the conduct of research is respectful of the well-being of individuals and the welfare of the collective, as understood by all parties involved.

Respect for autonomy is expressed principally through securing the voluntary, informed consent of research participants. First Nations, Inuit and Métis concerns for their continuity as peoples with distinctive origins, identities and rights have led to the development of
ethical protocols to guide community–researcher relations. These protocols typically assign decision-making authority to a body or bodies acting for the collective. Community engagement in these situations, particularly when First Nations, Inuit or Métis communities with local governments are involved, may take the form of formal approval of a research undertaking. While such endorsement may be required to enable research, group approval is not a substitute for consent by participating individuals. A key consideration for researchers, research ethics boards (REBs) and participants is determining when voluntary, informed consent of individuals is sufficient and when the welfare of the relevant group is implicated, making community engagement a priority.

Respect for the equal moral status of all humans is easily compromised when a serious imbalance of power prevails between the researcher and participants. Resulting harms are seldom intentional. In the case of Aboriginal peoples, abuses have historically included appropriation of cultural property such as songs, stories and artifacts, devaluing of Indigenous knowledge as primitive or superstitious, violation of community norms regarding the use of human tissue and remains, and dissemination of information that stigmatized whole communities. Affirmation of Aboriginal rights and respect for community ethics codes and protocols are means to better ensure balance in the relationship between researchers and participants and mutual benefit in researcher–community relations.

B. Ethical Concerns in Research Involving Aboriginal Peoples

Aboriginal peoples have rights and interests that deserve recognition and respect by the research community. The articulation of ethics guidelines for research involving Aboriginal peoples is situated in a broader movement transforming the relationship between Aboriginal peoples and Canadian society. Research has a critical role to play in creating the knowledge base for mutually respectful relationships and full participation in Canadian life, with all its responsibilities and benefits.

The Aboriginal and treaty rights of Aboriginal peoples, including First Nations, Inuit and Métis peoples, were recognized and affirmed in the Constitution Act, 1982, creating an obligation on public institutions to acknowledge and support the desire of Aboriginal peoples to maintain their collective identity and the continuity of their cultures. This affirmation marks a break with Canada’s colonial past, in which the goal of public policy was to absorb Aboriginal peoples into Euro-Canadian society and erase their distinctive identities.

Research conducted ethically can benefit Aboriginal people and communities. However, intrusive or insensitive research can contribute to negative stereotypes of Aboriginal peoples, as well as inaccurate perceptions of research and researchers in Aboriginal societies. In the past, research concerning Aboriginal peoples has usually been initiated outside the Aboriginal community and carried out by non-Aboriginal personnel. Aboriginal people have had little opportunity to correct misinformation or to challenge ethnocentric and racist interpretations. In light of such experience, many Aboriginal people feel apprehensive about the activities of researchers.
First Nations, Inuit and Métis communities and organizations are assuming an increasingly active role in defining how they will relate to external researchers and sponsoring institutions. Community initiatives are grounded in the assertion of inherent Aboriginal rights and go beyond protective measures to ensure that research does no harm. They propose participation as partners in all phases of research to protect their cultural heritage, to ensure that their knowledge systems and understandings of the world are authentically reflected in research practice, and to secure equitable distribution of benefits between researchers and participant communities.

Cultural heritage may include artifacts, cultural property, collective knowledge and skills, and other intangibles that are transmitted from one generation to the next, such as folklore, customs, representations or practices. International instruments such as the United Nations Declaration on the Rights of Indigenous Peoples have helped to raise awareness of the substance of cultural heritage, the risks of misappropriation, and ethical obligations to respect and conserve the integrity of Indigenous knowledge systems.

Aboriginal or Indigenous knowledge is usually described as holistic, involving body, mind, feelings and spirit. Knowledge is specific to place, transmitted orally and rooted in the experience of multiple generations. Indigenous knowledge is expressed in symbols, arts, ceremonial and everyday practices, narratives and, most especially, in relationships. Indigenous peoples value their relationship with the land as a living entity that reveals the way of right living. Indigenous knowledge has gained recognition as a resource of potential benefit to modern society – for example, through traditional techniques of sustaining environmental systems in balance with human usage or knowledge of plant life for agricultural, medicinal and cosmetic purposes. Commercialization of Indigenous knowledge without benefit to communities from which the knowledge originated has prompted efforts to protect the interests of holders of Indigenous knowledge.

Aboriginal peoples in Canada encompass great diversity. First Nations, Inuit and Métis representatives declare that the term “Aboriginal” glosses over the distinctions among them, as peoples with their own histories, cultures and languages. Communities may be large and urbanized or small and isolated. They may be relatively close to a traditional, land-based way of life or integrated in a market economy. Governance may be exercised by a First Nation band council, an Inuit hamlet council, a Métis settlement council or a regional authority. First Nation, Inuit and Métis people who reside off a reserve, land claim territory or settlement now make up the majority of the Aboriginal population of Canada. They do not ordinarily have a governance or administrative structure to represent their interests. Communities are also becoming more diverse internally, as a result of formal education, employment, mobility and intermarriage with non-Aboriginal persons.

In light of ethical obligations to respect the rights of Aboriginal peoples as expressed in community codes and protocols; the local variations in cultural heritage and Indigenous knowledge; and the diversity among and within First Nation, Inuit and Métis communities, researchers should seek culturally informed advice appropriate to the context when their work involves Aboriginal participants.
C. Applying Provisions of this Policy in Aboriginal Contexts

This Policy provides guidance on issues that have been raised frequently in public consultations on revision of the original version of this Policy (1998), in the CIHR Guidelines for Health Research Involving Aboriginal People (2007), and in community protocols and ethics codes. The development of policy applications has also been informed by international dialogue that increasingly acknowledges the unique interest that Aboriginal peoples have in ensuring accurate and informed research concerning their heritage, customs and communities.

Applying this Policy in a way that accommodates the diversity of Aboriginal cultures and communities is complex. The fit between community protocols and institutional policies may be unclear, requiring researchers to adapt conventional practice or broker agreements. Multiple geographic communities or an urban community of interest engaged in research may not have representative bodies to provide guidance to researchers. Researchers and REBs are reminded that ethical judgment must be attentive to the specific context of a proposed project. Researchers and REB members unfamiliar with the changing context of Aboriginal research are advised to consult reference documents that provide a fuller exploration of the concerns cited in this chapter.

D. Research Processes and Ethics Review

When Articles in this Chapter Apply

Article 9.1 Researchers and research ethics boards should consider whether application of the core principles of this Policy require interpretation or adaptation in the context of proposed research involving Aboriginal participants, to demonstrate respect for Aboriginal rights and cultural heritage, the integrity of Indigenous knowledge systems, and the diversity among and within Aboriginal communities.

Application Protections for human research participants set out in this Policy apply to research involving Aboriginal people, with the provision that application of the principles and requirements may require interpretation or adaptation, in situations such as the following:

(a) Research is conducted on a defined First Nation territory, Inuit land claims territory or Métis settlement;

(a) The analysis of the research data will use Aboriginal identity or membership in an Aboriginal community as a variable;

(a) The research involves cultural property, Indigenous knowledge, or input from an Aboriginal community;

(a) There is a reasonable expectation that the research population will include a significant number of Aboriginal individuals;
Recruitment criteria include Aboriginal identity as a factor for the entire study or for a subgroup in the study;

The research question is concerned with Aboriginality or membership in a formal or informal Aboriginal community, or with characteristics of the community; or

The interpretation of the research results will refer to Aboriginal peoples, language, history or culture.

In some primary research, Aboriginal identity of participants may become known only at the point of conducting the research. In such cases, researchers will need to consult with individuals providing data to determine whether cultural accommodations, such as access to a culturally informed advisor or linkage with a community, are appropriate.

General Requirement to Inform REBs on Community Engagement

Article 9.2

In research proposals involving one or more Aboriginal communities or a significant number of Aboriginal participants, researchers shall inform the research ethics board of how they have engaged or intend to engage the community in approving, advising on or managing the project. The nature and extent of community engagement should be appropriate to the type of community and proportionate to the level of Aboriginal involvement in the research.

Application

First Nation, Inuit, Métis, urban and rural communities differ significantly from one another, and they are characterized by increasing internal diversity. Engagement with the relevant community throughout the research process is the preferred means of ensuring that the ethical protections incorporated in a project respect the identities, interests and circumstances of participants. In the following examples, List A illustrates degrees of Aboriginal involvement in a variety of research projects and List B gives examples of community engagement proportionate to the level of Aboriginal involvement in each type of project cited.

List A: Examples of Aboriginal involvement

1. Research directly involving a defined Aboriginal community with formal leadership. Example: a project that examines the incidence of diabetes in Pond Inlet.

2. Research involving Aboriginal people who comprise a sizable proportion of the study or community and where Aboriginal-specific conclusions are intended. Example: a comparative study of access to public housing in Prince Albert, Saskatchewan.
3. Research involving Aboriginal people who are part of a larger community
(regardless of their proportion) that is the subject of research, and where
Aboriginal-specific conclusions are anticipated. Example: a study of
student retention in high schools in the Sault Ste. Marie district of
Ontario.

4. Research involving Aboriginal people who comprise a sizeable
proportion of the larger community that is the subject of research even if
no Aboriginal-specific conclusions will be made. Example: research on
employment development programs serving residents of Winnipeg’s
inner city.

5. Research that may incidentally involve a small proportion of Aboriginal
individuals but is not intended to single out or describe characteristics of
Aboriginal people in the study. Example: a study of the effectiveness of
therapies to control high blood pressure in a sample of hospital out-
patients.

6. Natural sciences research on First Nation or Inuit territories where
Aboriginal people may act as co-investigators or benefit from findings.
Example: research on contaminants in sources of country food in northern
Quebec.

List B: Examples of proportionate community engagement

1. Permission of the land claims organization that carries authority to
approve research in Nunavut is required. Agreement of the hamlet council
in Pond Inlet will normally be a condition of approval. The local health
committee may co-manage the project.

2. The tribal council representing local First Nation communities may
partner with the Prince Albert city council to sponsor, implement and use
the results of the housing study.

3. A committee to advise the District Board of Education and the
researchers conducting the retention study may be convened, representing
First Nations, Métis organizations and urban Aboriginal people whose
children are affected.

4. Aboriginal service agencies may be engaged to help recruit Aboriginal
participants and secure community representation on an oversight
committee, to ensure cultural sensitivity in collecting and interpreting
data on employment program impacts.

5. If Aboriginal individuals self-identify during the collection of primary
data in the blood pressure study, researchers should inquire whether
culturally appropriate assistance is desired to interpret or support
compliance with protocols. Since Aboriginal participation is incidental rather than scheduled, informing the REB is not required. However, it should be noted that including markers of Aboriginal identity in data may reveal anomalies that warrant further, more targeted, research.

6. Research that involves the collection and analysis of tissue samples from animals and does not involve human participants does not require REB review under provisions of this Policy. Inuit and First Nations protocols may, nevertheless, require regional and local permission and reporting of findings to communities on whose traditional territories the research takes place and who may benefit from the research.

The evidence of community engagement in a project may vary from a formal agreement setting out terms of co-management, to verbal approval of the proposed research in a group setting (which should be recorded), to informal advice from an ad hoc committee. Where a researcher has an ongoing relationship with a community, a letter or equivalent evidence of endorsement by a relevant leader or authority may signal approval to proceed with the research.

Communities vary widely in the level of human and material resources they have available to collaborate with research initiatives. First Nation communities have gone furthest in developing bodies to provide ethics oversight. Inuit land claims organizations have the authority to oversee research but have limited personnel available to fill the technical and professional roles in research implementation. Small, remote communities and urban populations have the most limited organizational resources to advise or collaborate in research. The least organizationally developed communities are the most vulnerable to exploitation and should be supported in expanding their capacity to participate rather than suffering dilution of ethical safeguards.

Where Aboriginal participants or communities do not designate an organization or individuals to represent their interests, the responsibility for securing culturally informed advice on ethical protections rests with the researcher or the sponsoring institution.

Research involving multiple Aboriginal communities may adopt varied models of community engagement. Regional bodies or national organizations such as the Mi’kmaq Ethics Watch in Nova Scotia or the Assembly of First Nations provide guidance on research and ethics for constituent communities. Review and endorsement of a research initiative by such an organization may facilitate but not substitute for local engagement.

Historical, genealogical or analytical research that does not collect data from living persons is not ordinarily subject to REB review. Findings of such research nevertheless may have an impact on the identity or heritage of
persons or communities. Seeking advice to ensure that cultural perspectives
are acknowledged would constitute good practice.

Research on First Nations, Inuit or Métis Territory Requires Consultation

Article 9.3 Where a proposed research project is to be conducted on territory where a First
Nation or Métis government has authority or on territory included in an Inuit
land claim settlement, researchers are required to consult with formal leaders of
the territory or administrators of the settlement agreement, except as provided
under Articles 9.7 and 9.8.

Application Community engagement is set out as a basic expectation in research involving
Aboriginal participants and communities (Article 9.2, above). Where Aboriginal
authorities exercise jurisdiction over designated territory provisions of Article
8.4 in Chapter 8 (“Multi-jurisdictional Research”) may also apply, requiring
ethics review of research proposals “by the REB or similar body, where such
exists, at the collaborating institution(s) in the host research site.”

Representative Inuit organizations have mandates under land claims agreements
to review, approve and monitor research conducted on their territories. Many
First Nations have adopted ethical codes and research protocols as an expression
of self-determination and an inherent right to self-government, which has been
recognized in federal government policy. National bodies such as the First
Nations Information Governance Committee of the Assembly of First Nations
and regional bodies such as the Mi’kmaq Ethics Watch provide guidance on
ethical practices but defer to local communities to make decisions on endorsing
research activities.

Mail-out, telephone and Internet surveys to poll members on First Nation or
Inuit territories are subject to the same requirements of community engagement
and ethics review as are other forms of research involving Aboriginal peoples.

While the legal basis for governance of research may vary depending on the
community, the practical requirement of engaging community leaders and the
ethical obligation to respect community views on well-being and welfare remain
consistent.

Article 9.4 Researchers are required to obtain free, and informed consent of individual
participants in research projects involving Aboriginal people, in accordance
with provisions of Chapter 3 (“Free and Informed Consent”) and in addition
to group engagement, where appropriate.

Application In no case is community or organizational agreement a substitute for
individuals’ informed consent to participate in a research project. Researchers
should be sensitive to the possibility that an individual’s decision to
participate or withhold participation in research may be constrained by group influence. While conformity to the group may be by choice, any undue influence on the exercise of autonomy should be mitigated where possible.

Respect for Community Ethics Codes and Protocols

Article 9.5 Where prospective participants signify that a community ethics code or protocol is in effect, researchers and research ethics boards shall take into consideration the code or protocol that applies in the territory or organization. The similarity, divergence or overlap of such code or protocol with this Policy, and clarification of mutual expectations, should be considered by all parties in advance of launching a particular project.

Application Where communities indicate that they endorse a particular ethics code or research protocol, or when individuals participate in research as members of a community or organization adhering to such protocols, researchers and REBs should take into consideration the code or protocol that applies in the territory or organization and seek to harmonize any differences that may arise between that code or protocol and this Policy.

Many First Nations communities across Canada have adopted an ethics code identified by the principles of ownership, control, access and possession (OCAP), which asserts ownership, control, access and possession of research processes affecting them. The principle of ownership asserts that a community or group owns information collectively in the same way that an individual owns personal information and that the community or group can therefore choose to share it (or not) under conditions that they specify. The principle of control asserts that First Nations peoples, their communities and representative bodies have a right to control all aspects of research and information management processes that affect them. Control can extend to all stages of a research project, from conception to completion. The principle of access asserts that First Nations peoples must have access to data about themselves and their communities collected in the course of research, and they have a right to make decisions regarding access by others to their collective information. Possession of data need not be exercised at the local level. In the case of the Regional Longitudinal Health Survey funded by Health Canada and administered by First Nation agencies, communities typically delegate stewardship of data to a regional organization that has adequate infrastructure to manage confidential personal data. OCAP principles together represent assertion of self-determination applied to research.

Inuit Tapiriit Kanatami, which represents four Inuit regions, has published a guide for negotiating research relationships with Inuit communities.

Métis communities, women’s groups and urban organizations aspire to assume a larger role in research affecting their members, but development of
these research protocols is at an earlier stage. Without a land base or official recognition of service entitlements, these sectors of the Aboriginal community generally are limited to project-based funding for research and similarly limited opportunities to develop policy on research.

Community review of research may have distinct purposes and procedures, and it will not replace REB review within institutions supporting particular projects. Having reference to parallel codes and protocols in institutions and communities is likely to pose questions of which code should prevail when expectations and/or requirements diverge. Maintaining respectful relationships will be dependent on all partners being prepared to reflect on what is essential to achieving common goals and on what degree of flexibility is consistent with their core values.

**Article 9.6** Researchers should consider entering into research agreements with those Aboriginal communities who have adopted ethics codes or protocols, as a means of clarifying and confirming mutual expectations and commitments between researchers and communities.

**Application** Research agreements serve as a primary means of clarifying and confirming mutual expectations and commitments between researchers and communities. 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, analysis and interpretation, production of reports and dissemination of results.

The level of community engagement desired and achieved will depend on the organizational infrastructure in place in the community or group and the willingness and capacity of all parties to develop the necessary supports for shared direction and responsibility. Particularly in First Nations and Inuit communities, collective endorsement of research initiatives has become a standard requirement. Such agreements are increasingly being recognized by academic institutions and the researchers associated with them as providing reference points for ethics review and approval on such elements as consent and confidentiality. Agreements that specify procedures for community ethics review, included as part of the institutional ethics application, can provide contextual information and guidance for REBs conducting initial review of applications and continuing ethics review throughout the project.

**Community Engagement at Variance with Operative Protocols**

**Article 9.7** Where alternatives to community, regional or organization protocols are deemed necessary to ensure the inclusion or safety of participants or the achievement of research objectives, the researcher shall describe such alternatives and provide a rationale to the research ethics board for pursuing them.
While protocols under the authority of formal leaders, such as chiefs and band councils or hamlet councils, generally serve community interests, First Nation, Inuit and Métis communities are far from homogeneous. Diverse communities of interest often co-exist within geographic communities, and formal leaders may not be the appropriate persons to act on their behalf.

In the case of traditional leadership structures or sacred societies, legitimate channels to endorse group participation exist. Examples are the Confederacy Council of the Haudenosaunee, whose authority derives from the Great Law of the Iroquois rather than the Indian Act, or sacred societies of the Blackfoot, which are recognized as the authorities with respect to their knowledge. REBs should respect such leadership structures when reviewing the consent process and procedures in research proposals.

In the case of persons or groups that may be vulnerable within communities, alternative avenues for engaging participation may be more appropriate. For example, women taking action against domestic violence have encountered opposition from some community leaders and so may not have access to formal approval of research to improve their safety, well-being or welfare. Alienated youth may not trust that their voices will be respected if official leadership is involved in approving the research.

Where divergent group interests within a community appear to be in conflict, problem-solving on site will be required to avoid deepening divisions or increasing the vulnerability of groups and individuals. The good offices of trustworthy persons who have moral authority in the community can often be enlisted to find ways to proceed with research that preserves respect for all parties. However, in some cases the risks involved simply outweigh the benefits to be derived from proceeding with the research.

Where alternatives to seeking approval of formal leaders are to be pursued, researchers should provide a rationale and document the nature of the process to be followed.

Research that critically examines the conduct of public institutions or persons in authority may do so ethically, notwithstanding the usual requirement, in research involving Aboriginal peoples, of engaging representative leaders. In such cases care should be taken to ensure sensitivity to culture and community contexts.

The general provision that guidance for ethical conduct of research should be obtained through engagement with the relevant community should not be a bar to critical inquiry in which the objective may be to uncover unjust or ill-conceived behaviour on the part of public institutions or persons in authority. Considerations in conducting critical inquiry are discussed more fully in Article 3.6 of Chapter 3 (“Free and Informed Consent”).
As in the case of research involving vulnerable subgroups within an Aboriginal community, critical inquiry will require creative approaches to ensure cultural appropriateness and integrity of the research. The Sisters in Spirit project of the Native Women’s Association of Canada (NWAC) illustrates successful mounting of research that incorporates a critical dimension and multiple ways of validating goals and methods of the research.

The Sisters in Spirit Project is national in scope, interviewing the families of missing and murdered Aboriginal women in urban and rural settings, on and off First Nations territory. The purpose is to document the experience of the disappeared women and their families to effect policy change and improve the safety and well-being of Aboriginal women in Canada. The research is funded by Status of Women Canada and has been endorsed by resolution of the Assembly of First Nations. NWAC assumes responsibility for monitoring the ethical conduct of its researchers. The project examines, among other matters, the adequacy of public institutions and services to protect the women’s well-being and support families in their efforts to deal with their losses. NWAC acts as its own ethical review body, builds on its established moral authority to investigate sensitive matters, welcomes endorsement by a national political organization, engages the cooperation of regional health directors where available, and informs local authorities of the presence of its researchers on First Nations territory.

**Privacy and Confidentiality**

**Article 9.9** In the context of community-based research collaboration, researchers, research ethics boards and community partners should consider early in the design of the research how community protocols on data custody and confidentiality fit with provisions for privacy set out in Chapter 5 (“Privacy and Confidentiality”) in order to resolve any inconsistencies.

**Application** Researchers should inform communities and individuals what arrangements are made in partnered research to respect privacy of individuals and communities.

Privacy and confidentiality of identifiable personal and community information may be affected in some First Nation communities by application of the principles of ownership, control, access and possession (OCAP) (see definition under Article 9.5). Negotiation of research agreements permits Aboriginal parties and academic researchers to explore the practical implications of the OCAP principles in First Nation communities or comparable principles operative in Inuit and Métis communities, to reach mutual accommodations. Where research agreements provide that community partners will have limited or full access to identifiable personal data, the consent of participants to such disclosure shall form part of the consent procedure.
Many Aboriginal communities are small and characterized by dense networks of relationships, with the result that anonymizing individual data is often not sufficient to mask identities. Some Aboriginal research participants are reluctant to speak to interviewers from their own community because of privacy concerns. Other participants, in qualitative studies or life histories, may wish to be acknowledged individually for their contributions. Communities themselves have distinguishing characteristics, which in some cases have compromised efforts to disguise the site of research and led to the communities’ being stigmatized.

The Regional Health Survey administered by regional First Nations organizations has addressed the problem of balancing confidentiality and access by having communities designate a regional organization to hold data while local authorities make decisions on who can access the data and under what conditions. In practice, the organization that serves as data steward evaluates requests for information, and its recommendations to community authorities have considerable influence.

Privacy protections within the research context are evolving within the federal granting Agencies, with attention to harmonization with federal, provincial and territorial legislation. The Canadian Institutes for Health Research has published *CIHR Best Practices for Protecting Privacy in Health Research*. Accommodation of Aboriginal initiatives to maintain access to data for community use, applying principles such as OCAP, will be situated within the larger framework of law and policy to protect privacy.

**Protection of Indigenous and Cultural Knowledge**

**Article 9.10** Researchers should consider, and research ethics boards should review, whether tangible or intangible cultural property of Aboriginal persons or communities is at risk of misuse or misappropriation when collected in the context of research involving Aboriginal participants or communities. Researchers should include measures to mitigate such risks of misuse or misappropriation in the research ethics review proposal.

**Application** Researchers should negotiate with communities mutual understandings of appropriate respect for cultural property including Indigenous knowledge, how to proceed with community review of findings, terms of ownership of research products, and any limits on publication of materials, including how intellectual property rights to research products will be assigned: whether to community sources, to researchers, or to both on a shared basis.

REBs should review the measures researchers put in place to recognize and protect Indigenous or local knowledge in the conduct of the project and the dissemination of findings.
Cultural property often does not fit the criteria of sole ownership, innovation and representation in a tangible work that are necessary to claim protection for intellectual property rights. National laws and international consensus on these issues are evolving. The definitions of tangible and intangible cultural property over which Indigenous peoples arguably have rights are broader than the definitions of intellectual property protected under national law and international agreements. Intangible cultural property, such as traditional knowledge of the medicinal properties of plants or traditional clothing design, that is collectively held is often regarded as “folk knowledge” that is available in the public domain and that may be adapted through commercial processes to produce marketable commodities without consent of the originators.

Researchers should afford the community an opportunity to react and respond to research findings before the completion of the final report, in the final report, or even in all relevant publications. (See Article 3.2 in Chapter 3 [“Free and Informed Consent”] on information disclosure.) Collaborative research reports are regarded as a product of both community and researcher contributions rather than the sole property of the researcher. Communities consider that their review and approval of reports and academic publications is essential to validate findings, protect against misinterpretation, and maintain respect for Indigenous knowledge, which may entail limitations on its disclosure. If disagreement arises between researchers and the community, researchers should afford the group an opportunity to make its views known, or they should accurately report any disagreement about the interpretation of the data in their reports or publications.

Secondary Use of Data

Article 9.11 Consistent with the general provisions set out in Chapter 5 (“Privacy and Confidentiality), secondary use of data collected initially for other purposes, from which personal identifiers have been removed, does not require research ethics board (REB) review. Secondary use of data that is identifiable as originating from a specific community, or a segment of the Aboriginal community at large, requires REB review and may warrant seeking culturally informed advice about protection of cultural property or representations of Indigenous knowledge or society.

Application The privacy of individual participants in research is normally protected by removing information that would identify them personally. Anonymized data are added to a data pool and are available for analysis and sometimes for secondary use.

As discussed in Chapter 5 (“Privacy and Confidentiality), access to data containing identifiable personal information may be needed for some types of research. For example, longitudinal studies require access to identifiable information contained in data banks, although consent for additional studies
was not obtained from original informants and it may be impractical to obtain it subsequently. Such secondary usage requires REB review (see Articles 5.5 to 5.7 in Chapter 5 [“Privacy and Confidentiality”]), and the REB may allow a waiver of consent under certain conditions (see Article 3.8).

Misrepresentation of Aboriginal peoples, unauthorized use of data, and lack of reporting to communities on research outcomes have created ongoing sensitivity about secondary use of data collected for approved purposes. For example, members of Nuu-chah-nulth communities in British Columbia provided blood samples for research on rheumatic disease. They vigorously protested use of the blood components for subsequent genetic research that pronounced on their ancient origins and challenged traditional knowledge about their identity. There are additional fears in First Nation communities that general consent to use health data for purposes other than treatment will facilitate unauthorized government surveillance.

In light of sensitivity about harms ensuing from identification of communities, potential misuse of cultural property or misrepresentation of Indigenous knowledge when interpretation of data is no longer guided by community representatives, secondary use of data identifiable as originating from Aboriginal participants or communities should be subject to REB review. Any constraints imposed on use of the data in the original project should be noted if such information is available. Consistent with Article 5.6, the researcher should propose to the REB an appropriate strategy for securing agreement of the relevant individuals or group, or, if this is impossible or impracticable, there should be consultation with one or more organizations that are likely to represent the views and interests of the original participants.

**Benefits of Research**

Community benefit may include relevant knowledge, evidence-based policy and social interventions, and increased capacity to conduct partnered or autonomous research. In most research relationships, a primary benefit sought by communities is increased capacity to conduct autonomous research that can more readily be conducted in Aboriginal languages and oral modes. Autonomous research would enhance the exploration, articulation and application of Indigenous knowledge in its own context, with translation to other contexts following a parallel process. Articles 9.12 and 9.13 specify benefits that may accrue in the context of partnerships between Aboriginal communities and external researchers. (See reference to benefit-sharing in Section B of Chapter 1 [“Ethics Framework”].)

**Article 9.12** Communities should have access to data important to their own planning and development processes, with protections for privacy and confidentiality of personal data as noted in this chapter.

**Application** Communities participating in research place a high priority on access to research data that will allow them to address pressing issues through community-generated policies, programs and services. Divergence between
community priorities and provisions of this policy should be the subject of
negotiation and agreement at initial stages of the research.

Article 9.13 Researchers should endeavour, where appropriate and possible, to share costs
and benefits of research equitably between researchers, institutions and
Aboriginal communities, including personnel and administrative costs of
collaborating in ethics review and project oversight.

Application Aboriginal people also seek to share in the benefits of research activities
themselves in the form of direct research grants, overhead levies on shared
projects, and commercialization of research discoveries. In recent times,
community-based projects have made provisions for sharing grant resources
with community partners. Elders are now being recognized in research
proposals and grant applications as providing access to community networks,
ethical guidance to researchers, and advice in interpreting findings in the
context of traditional knowledge. Advice from the community will be
valuable in determining appropriate compensation for the time of participants
and observance of conventions of gift-giving or feasting that are important to
successful collaboration with communities. Employing Aboriginal research
assistants and translators is already common practice in community-based
projects. Implementing a rational program of training to enhance autonomous
research initiatives is less common.

Direct and indirect costs of collaborative, community-based research are
cited by researchers and Aboriginal agencies as impediments to community
engagement as endorsed in this Policy. Such costs are sometimes offset by
securing in-kind contributions from service-oriented programs engaged with
the same population – for example, counselling and shelter programs serving
urban Aboriginal youth participating in a project. The obligation to reach
agreement on ethical safeguards for participants in such cases extends to third
parties.

Direct funding to community entities conducting research is anticipated in
some current programs, although the requirement for ethics review is still met
through researcher affiliation with institutions adhering to this Policy,
collaborating with the community organizations.

Human Genetic Research

Genetic researchers and their sponsors demonstrate a high level of interest in research
among Indigenous populations, especially those that are socially isolated and homogeneous.
Genetic research has potentially important implications for Aboriginal communities.
Particular considerations in ethics review of human genetic research are discussed in
Chapter 13 (“Human Genetic Research”). In such research involving Aboriginal peoples, the
provisions of Chapter 13 should be read in conjunction with the ethical safeguards set out in
the present chapter. Attention is directed specifically to the implications of genetic research
for communities, as specified in Article 13.7.
Although the present chapter addresses research involving Aboriginal peoples in Canada, researchers, REBs, research participants and the research community at large should consider the principles articulated here in the context of research involving Indigenous peoples in other countries or in research settings where collective decision-making is the preferred procedure supporting individual consent for research participation. For considerations that apply to research conducted in another country, see Sections B and C in Chapter 8 (“Multi-jurisdictional Research”).

REB Review

Article 9.14 Research ethics boards (REBs) reviewing research involving Aboriginal participants and communities on a recurring basis should ensure that they have access to relevant expertise within regular REB membership, through ad hoc consultation with knowledgeable academic and community advisors, or through collaboration with community ethics review bodies.

Application In accordance with Article 6.5 in Chapter 6 (“Governance of Research Ethics Review”), an REB should have provisions for membership such that when context-specific expertise is lacking for the review of particular research proposals, ad hoc advisors are appointed. In cases where review of research involving Aboriginal peoples is regularly required, the REB membership should be modified to ensure cultural expertise within its regular complement.

Article 9.15 Researchers and research ethics boards should recognize that ethics review by community bodies will often pursue purposes and apply criteria that differ from the provisions of this Policy. It is therefore inappropriate to insist on uniformity between community practices and institutional policies. The objective of engagement between researchers and community entities should be to find common ground, anticipate differences, and resolve conflicts that might interfere with ethical protection of participants and achievement of research goals.

Application The express purpose of most Aboriginal community ethics codes is to ensure relevance of research undertakings to community needs and priorities and respect for Aboriginal identities, cultures and knowledge systems. While community codes and institutional policies may share many goals, the approaches to achieving those goals may differ significantly.

The membership of community review bodies 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. An expectation that conflict of interest will be managed by separating ethics review and project management functions may impose unsupportable demands on small communities. Community processes may apply to research beyond the scope of REB
responsibilities. For example, research on the interface between environmental
and human systems that does not involve individual participants does not
require REB review.

Ethics review by community entities will not be a substitute for review by
institutional REBs except where the community is the direct recipient of funding
and has constituted a local REB recognized by the sponsor of the research
initiative. This does not exempt researchers affiliated with an institution and
collaborating with the community from seeking REB approval at their
institution.

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Chapter 10

QUALITATIVE RESEARCH

Researchers in social sciences and humanities, such as sociology, psychology, criminology, business administration, political science, communications, education and history, have a common belief in the desirability of trying to understand human action through systematic study and analysis. Some researchers use quantitative research approaches, others opt for qualitative research methods, and some use a combination of both.

Qualitative research has a long history in many well-established disciplines in the social sciences and humanities, as well as many areas in the health sciences (e.g., nursing). Research developments point to an increasing prevalence of qualitative approaches, whether in health research or in social sciences and humanities disciplines. Within specific disciplines, ethics guidelines have also been created to address the issues inherent in the use of particular methods, technologies, settings, etc. Qualitative research approaches are inherently dynamic and are grounded in different assumptions than those that shape the biomedical model of research. Many of the research practices and methodological requirements that characterize qualitative research approaches parallel those that characterize quantitative approaches – concerns regarding research quality (e.g., dependability and trustworthiness of data), for example – but, as is the case with ethics principles, the criteria are adapted to the particular subject matter, context and epistemological assumptions (i.e., related to the nature and production of knowledge in a specific area of research) of the specific project.

This chapter seeks to provide some guidance on qualitative research and its implications for the ethics review process. In particular, it addresses issues of consent, privacy and confidentiality that are particular to qualitative research. Some procedural issues related to the dynamics and characteristics of qualitative research that affect the timing and scope of the research ethics review process are detailed below. Researchers and research ethics boards (REBs) should also consult other relevant chapters of the Policy for additional details on principles, norms and practices applicable to qualitative research.

A. The Nature of Qualitative Research

Qualitative approaches reflect a human-centred approach that highlights the importance of understanding how people think about the world and how they act and behave in it. This approach requires researchers to understand how individuals interpret and ascribe meaning to what they say and do, and to other aspects of the world (including other people) they encounter.
Some qualitative studies extend beyond individuals’ personal experiences to explore interactions and processes within organizations or other environments. Knowledge at both an individual and cultural level is treated as socially constructed. This implies that all knowledge is at least to some degree interpretive and hence dependent on social context. It is also shaped by the personal standpoint (and possibly also the values) of the researcher as an observer.

The section below provides a summary of general principles and methodological requirements and practices of qualitative research.

**General Principles and Methodological Requirements and Practices**

(a) **Inductive Understanding:** Many forms of qualitative research entail gaining an inductive understanding of the world of research participants to acquire an analytical understanding of how they view their actions and the world around them. In some projects, this approach also applies to the study of particular social settings, processes and experiences.

To the extent that the methods involve direct interaction with participants, there is often an emphasis on gaining insights into participants’ perceptions of themselves and others, and of the meanings that research participants attach to their thoughts and behaviours.

(b) **Diversity of Approaches:** There is no single approach in qualitative research. Each field or discipline, and even individual scholars within a discipline, have different perspectives on and approaches to the use of qualitative methods. Qualitative research uses a variety of epistemological approaches, methodologies and techniques that allow researchers to enter the research participants’ world or to engage with particular social environments. Methodological approaches include, but are not limited to, ethnography, participatory action research, oral history, phenomenology, narrative inquiry, grounded theory and discourse analysis. The term “qualitative research” covers a wide range of overlapping paradigms or perspectives.

(c) **Dynamic, Reflective and Continuous Research Process:** The emergence in the course of the research itself of questions, concepts, strategies, theories and ways to gather and engage with the data requires a constant reflective approach and questioning from the researcher. Such flexibility, reflexivity and responsiveness contribute to the overall strength and rigour of data analysis.

(d) **Diverse, Multiple and Often Evolving Contexts:** Qualitative research takes places in a variety of contexts, each of which present unique ethical issues. As knowledge is considered to be context-contingent in qualitative research, these studies tend to focus on particular individuals, sites or concepts that are empirically derived from other social settings – and the researcher’s priority is to understand that social setting involving those people at this time.
Researchers sometimes engage in research that questions social structures and activities that create or result in inequality and injustice. They may involve research participants who are highly vulnerable because of the social and/or legal stigmatization that is associated with their activity or identity and who may have little trust in the law, social agencies, or university authorities, or they may involve research participants, such as business executives or government officials, who may be more powerful than the researchers.

(e) **Data Collection and Sample Size:** There is generally a greater emphasis placed on depth of research than on breadth. Most qualitative researchers would emphasize gathering diverse but overlapping data on a limited number of cases or situations to the point of data saturation or thematic redundancy. Samples and research sites in these studies are chosen because they are viewed as strategically useful or rich sources of information for furthering one’s understanding of phenomena of interest, not because they are necessarily statistically significant.

A researcher may rely on multiple sources of information and data-gathering strategies (e.g., triangulation) as one mechanism for enhancing data quality. Researchers use a variety of methods for data gathering, including interviews, participant observation, focus groups and other human-focused techniques. Gathering of trustworthy data comes best from closeness and extended contact with research participants. Textual qualitative studies also use a variety of content analysis techniques, whether with published books, websites, interview transcripts, images or other textual forms.

Appropriate treatments of data after they are gathered may vary greatly. For some research, protection of research participants requires confidentiality, anonymity, and the destruction of data after they are used. In other cases, the data may provide a valuable historical record that must be preserved or they may make a valuable contribution by publicly attesting to the role played by particular individuals. (See Chapter 2 [“Scope and Approach”] and Chapter 5 [“Privacy and Confidentiality”].)

(f) **Research Goals and Objectives:** The aims of qualitative research are very diverse, both within and across disciplines. The intended goals of qualitative projects may include “giving voice” to a particular population, engaging in research that is critical of settings and systems or the power of those being studied, affecting change in a particular social environment, or exploring previously understudied phenomena to develop new theoretical approaches to research.

(g) **Dynamic, Negotiated and Often Ongoing Free and Informed Consent Process:** Entry into a particular setting for research purposes sometimes requires negotiation with the population of interest; the process sometimes cannot be ascertained in advance of the research, in part because the relevant contexts within which the research occurs evolve over time.
In some cases, research participants hold equal or greater power in the researcher–participant relationship – for example, in community-based and/or organizational research when a collaborative process is used to define and design the research project and questions, or where participants are public figures or hold other positions of power (for example, research involving economic, social, political or cultural elites). In other cases, researchers themselves may hold greater power when access to prospective participant populations is gained through gatekeepers with whom the researcher has established a relationship (e.g., when a researcher engages with the police to do research in relation to a problem population, or when researchers engage with prison authorities to do research with offenders).

(h) **Research Partnerships:** Access to particular settings and populations is often developed over time, and the relationships that are formed may well exist outside the research setting per se, which sometimes makes it difficult to determine exactly where the “research” relationship begins and ends. In many cases, despite in-depth, advanced preparation, a researcher may not know until the actual data collecting starts just where the search will lead. Indeed, the emergent nature of many qualitative studies makes the achievement of rapport with participants and feelings of interpersonal trust crucial to the generation of questions considered important or interesting by both parties and of dependable data. Research often becomes a collaborative process negotiated between the research participant(s) and the researcher, requiring considerable time spent initially simply figuring out the focus of the research.

In many cases, contacts between researchers and participants can extend over a lifetime, and these individuals may engage in a variety of relationships over and above their specific “research” relationship.

(i) **Research Results:** Transferability of results from one setting to another is considered, but is often viewed as more of a theoretical issue than a procedural or sampling issue.

**B. Research Ethics Review in the Context of Issues Distinctive to Qualitative Research**

This section seeks to provide guidance on particular implications of the use of qualitative approaches for the ethics review process. This section should also be read in conjunction with other chapters of this Policy.

Qualitative research can pose unique ethical issues around gaining access, building rapport, using data and publishing results. Researchers and REBs should consider issues of consent, confidentiality and privacy, and relationships between researchers and participants in the design, review and conduct of the research. Some of these may be identified in the design phase, but others will arise during the research itself, which will require the exercise of discretion, sound judgment and flexibility in the context of a proportionate approach to the level of risk and benefit arising from the research, the well-being of the individual, and welfare.
defined in a broad sense.

**Modalities of Expression of Free and Informed Consent**

**Article 10.1** Research ethics boards should consider the range of strategies for documenting the consent process that may be used by researchers using qualitative research approaches. Researchers should explain in their research design the consent procedures and strategies they plan to use.

**Application** The consent process should usually reflect trust between the research participants and the researcher. Often this is based on mutual understanding of the project’s intentions. The research participant may sense attempts to legalize or formalize the process as a violation of that trust. Under a variety of circumstances, written consent is not required in qualitative research. Qualitative researchers use a range of consent procedures, including oral consent, field notes, and other strategies such as recording (audio or video, or other electronic means) for documenting the consent process. Evidence of consent may also be via completed survey questionnaires (in person, by mail or by email or other electronic means).

REBs may need to consider the power relationship that might exist between researchers and research participants. In cases where the research participant holds a position of power or routinely engages in communicative interactions similar to those involved in the research by virtue of his or her position or profession, informed consent can be inferred by the participant’s agreeing to interact with the researcher for the purpose of the research. No further verification of consent is needed. For example, “elite” research focuses on power structures and persons in positions of power (for example, a senior partner in a law firm, a cabinet minister, or a senior corporate officer). In this type of research, the fact that a potential participant agrees to be interviewed by a researcher may be sufficient to signify consent to participate in the research.

Researchers and REBs should consult Chapter 3 (“Free and Informed Consent”) for additional details and considerations.

**Observational Studies**

**Exemption from REB Review**

**Article 10.2** Research ethics board review is not required for observation of people in public places that does not involve collecting personal identifiable information through direct interaction with the individuals, and that does not involve any intervention staged by the researcher. Such research does not involve human participants as defined by this Policy.
Application

Research involving observation of people in public spaces where there is no presumption of privacy and where no personal identifiable information is being collected directly from the individuals – for example, political rallies, demonstrations, or other public events or settings (e.g., a free concert in a public park, a shopping mall) – does not require REB review, since it can be expected that participants are aware of the public nature of the event or gathering. Where individuals should reasonably expect that their identities will be evident – for instance, as a result of their celebrity – research that refers to their presence does not require REB review. (See also Article 2.5 in Chapter 2 [“Scope and Approach”] and Chapter 5 [“Privacy and Confidentiality”].)

Article 10.3

Web-based research that uses exclusively publicly available information for which there is no presumption of privacy does not require REB review. Such research does not involve human participants as defined by this Policy.

Application

Research that is non-intrusive, does not require direct interaction between the researcher and individuals through the Internet medium, and that draws its data primarily from postings on websites is not required to obtain REB review. Cyber-material such as documents, records, performances, on-line archival materials or published third-parties interviews to which the public is given access on the Internet or that clearly seeks public visibility might be considered as publicly available information (see Chapter 2 [“Scope and Approach”]). Researchers may need to consider other factors when using this information, such as copyright, dissemination restrictions, privacy and intellectual rights. These, however, fall outside of the scope of the REB review.

Proportionate Approach to Review of Observational Studies

Article 10.4

When considering research involving observation, including web-based research where personal identifiable information is being collected or where individuals have a presumption of privacy, research ethics boards should apply a proportionate approach to ethics review.

Application

In qualitative research, observation is used to study behaviour in a natural environment. It often takes place in living, natural and complex communities or settings; in physical environments; or in virtual settings such as the Internet. Observational studies may be undertaken in public spaces or in virtual settings where individuals might have some limited expectation of privacy or in private or controlled spaces where individuals have an expectation of privacy. The spectrum of settings where observational research typically requiring review may occur include, for example, classrooms, hospital emergency wards, private Internet chat rooms, or within members-only communities or organizations.
Observational research is of two kinds: “non-participant” (i.e., where the researcher observes, but is not a participant in, the action) and “participant” (i.e., where the researcher engages in, and observes, the action).

Participant observation often is identified with ethnographic research, in which the researcher’s role is to gain a “holistic” overview of the studied context through engagement in and observation of the setting to describe its social environments, processes and relationships. Participant observation may or may not require permission to observe and participate in activities of the setting studied. In some situations, researchers will identify themselves and seek free and informed consent from individuals in that setting; in others, researchers will engage in covert participant observation. Where specific disciplines and methodological approaches provide guidelines relating to the ethics issues involved in these types of research, researchers and REBs should consider the similarity, divergence or overlap of such codes or guidelines with this Policy and seek mutual understanding and clarification to address the ethical issues that may arise in a particular project.

Observational studies raise concerns of the privacy of those being observed. REBs and researchers need to consider the ethical implications associated with observational approaches, such as the possible infringement of free and informed consent or privacy, as well as the disciplinary and methodological norms of the proposed research project. They should pay close attention to the ethical implications of such factors as the nature of the activities to be observed, the environment in which the activities are to be observed, whether the activities are staged for the purpose of the research, the expectations of privacy that potential participants might have, the means of recording the observations, whether the research records or published reports involve identification of the participants, and any means by which those participants may give permission to be identified.

Because knowledge that one is being observed can be expected to influence behaviour, research involving non-participant or covert observation generally requires that the participants not know that they are being observed (typically there is not direct interaction with the individuals being observed), and therefore they cannot give their free and informed consent. Some forms of qualitative research seek to observe and study criminal behaviours, violent groups, or groups with restricted membership or access. For example, some social science research that critically probes the inner workings of criminal organizations might never be conducted if the participants know in advance that they are being observed. Similarly, observing queuing behaviours in shopping malls is one example of a study that may be deemed minimal risk, where the research could not be completed if shoppers knew that they were being observed. Researchers should justify whether the needs for such covert research justify an exception to the general principle of free and informed consent, and REBs should exercise their judgment in this type of situation.
Such research should also be carried out according to professional and disciplinary standards.

Researchers should demonstrate to the REB that necessary precautions and measures have been taken to address privacy and confidentiality issues in the case of observational studies, commensurate with the level of risk and the research context. Researchers and REBs should also be aware that, in some jurisdictions, publication of identifying information – for example, a photograph taken in a public place, but focused on a private individual who was not expecting this action – may be interpreted in a civil suit as an invasion of privacy.

REBs should focus on projects above the threshold of minimal risk, or they should modulate requirements and protection proportionate to the magnitude and probability of harms, including the likelihood that published reports may identify individuals or groups. Observational research that does not allow for the identification of the participants and that is not staged and is non-intrusive should normally be regarded as of minimal risk.

Researchers should be aware that web-based research may pose concerns outside the scope of the research ethics review process. Such concerns may arise, for example, when the web-based setting involves minors or other populations that may become vulnerable because of the lack of surveillance in this electronic setting. Such issues, which are not related to the ethics of the research proposal itself, are not covered by this Policy.

Researchers and REBs should consult Chapter 3 (“Free and Informed Consent”) and Chapter 5 (“Privacy and Confidentiality”) for additional details and considerations.

Privacy and Confidentiality in the Dissemination of Research Results

Article 10.5 Subject to the research context and the scholarly traditions used in the research proposal, research ethics board review should acknowledge that individuals may want to be identified for their contribution.

Application In much social science and some humanities research, the biggest possible risk for researchers and REBs to manage is the harm that can result from violations of research confidentiality. This can pose a particular challenge in qualitative research because of the depth, detail, sensitivity and uniqueness of information obtained. The default approach is to guarantee confidentiality of the research data. In some cases, anonymity of the research participant may be used in publications or dissemination of research results to ensure confidentiality of data.

In some types of qualitative research, respect for the participant’s contribution is shown by identifying the individual in research publications or
other means of dissemination of the results from the research. If failing to identify participants would be unethical because of the disrespect it would involve, or if informed participants assert their desire to be named, then researchers should do so, according to the normal principles and practices of their discipline. Where confidentiality is preferred or where there is no compelling reason to the contrary, confidentiality would be maintained in a manner commensurate with the needs of the research participants and the project.

Reviewers need to be sensitive to which principle is operative in any given research context, and which disciplinary traditions are being invoked.

Researchers and REBs should consult Chapter 5 (“Privacy and Confidentiality”) for additional details and considerations.

**Timing of the REB Review**

**Article 10.6** Research ethics board (REB) review is not required for the initial exploratory phase when the researcher is developing the research design. Research ethics review is required once the terms of the research are established. The researcher must receive REB approval prior to the start of the formal data collection in the field.

**Application** It is sometimes difficult to ascertain the beginning and end of a qualitative research project. Access to particular settings and populations often develops over time, and it is not unusual for researchers to be passive observers or simply passively interested in a setting for some time before any formal effort is made to establish a “research” relationship. Preliminary activities may include note taking, scribbling, diary writing, and observation made long before the researcher has any inkling that these would turn into formal research projects. These types of preliminary activities are not subject to REB review.

Researchers need to have the opportunity to engage in preliminary visits and dialogue to explore possible research relationships and define research collaborations with particular settings or communities, including the determination of research questions, methods, targeted sample and sample size, and inclusion of community-based concerns into the project design and data collections. REBs should be aware that dialogue between researchers and communities at the outset and prior to formal REB review is an integral component of the research design. Researchers may need to consult informally the REB when ethics issues arise prior to the data collection or inform the REB of such issues over the course of the research.

Qualitative research approaches involving a community, group or population of interest (e.g., marginalized or privileged groups) follows a process of prior dialogue, exchanges and negotiation of the research, which precedes the formal
data collection involving human participants. For instance, in research in Aboriginal communities or with Aboriginal populations (see Chapter 9 [“Research Involving Aboriginal Peoples”]) or other types of community-based collaborative research, it may be desirable to obtain permission to proceed from community leaders, elders or representatives before seeking individual consent. A researcher might use a community gathering to inform the group about the research and gain agreement from the group to proceed with the actual research before seeking to obtain individual consent as a second step of the research implementation.

Although initial research questions may be outlined in the formalized research plan, REBs should be aware that it is quite common for specific questions (as well as shifts or discovering of data sources) to emerge only during the research project. Due to the inductive nature of qualitative research and the emergent design approach of the research, some of these elements may evolve as the project progresses. Some resulting changes to the research design will not merit requiring additional REB review, as they are not necessarily significant changes to the approved research. Research ethics issues may also arise over the course of the research, and it might be sufficient for the researcher to inform the REB about such issues. (See Chapter 2 [“Scope and Approach”] and Article 6.16 in Chapter 6 [“Governance of Research Ethics Review”].)

**Article 10.7** When researchers are using emergent designs in data collection, research ethics boards should review and approve the general procedure in accordance with appropriate professional and disciplinary standards.

**Application** In qualitative research involving data collection with emergent designs (e.g., unstructured interviews or focus groups), specific questions or other elements of data collection cannot be known or articulated fully in advance of the project’s implementation. In these cases, REBs may ask to review a draft set of sample questions or other outlines of the procedures to be followed in data collection. REBs should not require researchers to provide them with a full questionnaire schedule in advance of data collection. Rather, REBs should ensure that the data collection is conducted according to disciplinary and professional standards.

**References**


• Social Sciences and Humanities Research Council of Canada. SSHRC Research Data Archiving Policy.
Chapter 11

CLINICAL TRIALS

A. Overview

A clinical trial is “an investigation in respect of a drug for use in humans that involves human subjects and that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of the drug, identify any adverse events in respect of the drug, study the absorption, distribution, metabolism and excretion of the drug, or ascertain the safety or efficacy of the drug.”

Clinical trials are most frequently undertaken in biomedical or health research, although other clinically related disciplines, such as psychology, also conduct research that evaluates interventions, usually by comparing two or more approaches.

Clinical trials may include questions that are not directly related to therapeutic goals – for example, cost effectiveness or drug metabolism – in addition to those that directly evaluate the treatment of study participants. They may take the form of “n of 1” studies or multi-centre randomized controlled trials. Although the various types and forms of clinical trials naturally have methodological differences, the ethical principles and procedures articulated in this Policy can be adapted for each of them.

Clinical trials most commonly involve testing new drugs or testing established drugs for new uses. For this reason, and for convenience, references in this chapter are made primarily to drug testing. However, clinical trials also involve medical devices, biologics, radiopharmaceuticals, genetic therapies and natural health products, as well as behavioural and psychological therapies. The guidance provided in this chapter applies also, as appropriate, to trials involving these other therapies or interventions.

Researchers undertaking clinical trials intended for use in seeking regulatory marketing approval must comply with Health Canada regulations and should also respect the ICH Good Clinical Practice Guidelines, which have been adopted by Health Canada, and other applicable policy or guidance documents.

The accelerating pace of new pharmaceutical drug and device development in Canada, as well as increasing clinical trial activity in non-traditional research venues, including physicians’ offices and contract research organizations, brings the need for heightened vigilance in the clinical trial review process. Research ethics boards (REBs) must carefully monitor all aspects of clinical trials, including free and informed consent, confidentiality, safety and recruitment.
With respect to the recruitment of participants for clinical trials, it is often not possible to recruit, within a reasonable time, sufficient numbers of eligible participants from a single clinical site. It may also be desirable to draw participants from a variety of geographically diverse places to avoid bias. So, it is common that clinical trials are carried on at a number of different sites and that data collected from all of the sites are pooled for analysis. Ethical issues relating to such multi-centre clinical trials are discussed in Chapter 8 (“Multi-jurisdictional Research”).

B. Phases of Clinical Trials

Clinical trials are commonly categorized into four phases, each of which gives rise to particular ethical issues. 4

Article 11.1 When reviewing a clinical trial protocol, the research ethics board should be aware of its phase and the special ethical issues that different phases of research may raise.

Application

Phase I

In Phase I clinical trials, researchers test a new drug or treatment in a small group of people, often for the first time, to evaluate its toxicity and other side effects, and to determine a safe dosing range.

Ethical Concerns: Safety concerns are particularly acute in Phase I research, because it may be the first time human participants are exposed to the new drug (“first-in-human” trials), and there may be little or no experience with the drug. Phase I trials often depend on healthy participants who are compensated for their participation, though this is not usually the case in, for example, cancer trials. The combination of clinical risk with uncertain or no likelihood of clinical benefit, and the often substantial compensation made to participants, raises ethical concerns about safety, the selection and recruitment of participants, and the process of free and informed consent. For safety, it is important to ensure that the drug is initially given to a small number of participants and that dosing is increased in clearly defined increments only after participants’ responses to the initial dose is known. Recruitment and consent procedures should ensure that participants are aware of the untested nature of the therapy and that participants do not accept, because of the compensation being paid, risks they would otherwise refuse.

Phase I clinical trials now increasingly include participants with specific diseases for whom conventional therapies have failed. Such studies may be designated as Phase I clinical trials, but the boundaries between trial phases are not always clear. Such studies may be designated as combined Phase I/II or pure Phase II clinical trials (see below).

Phase II

Phase II clinical trials primarily examine the efficacy of new drugs and their short-term side effects. They are conducted in populations with the disease or condition sought to be treated by the drug.
Ethical Concerns: Combined Phase I/II clinical trials raise particular ethical concerns, because they are often conducted with populations whose therapeutic options have been exhausted. Patients with cancer that is incurable by standard therapies and HIV/AIDS are examples. These circumstances may affect the perceptions of patients and their families as to the balance between the harms and benefits of the study and thus may affect their decision whether to participate. Researchers should be encouraged to consult with the REB at an early stage about any recruiting, consent or safety issues that arise.

Phase II and III clinical trials, unlike combined Phase I/II clinical trials, often include a placebo control to help detect and quantify the toxicity and efficacy of an experimental drug or device. In such studies, and in addition to the other ethical concerns raised for Phase II clinical trials, the use of placebos (discussed in Section G [“Placebo-Controlled Studies”]) makes it particularly important for researchers to assess and monitor the safety of participants and ensure that the quality of their treatment is not compromised by participation in the study.

Phase III The drug or treatment is given to a large group of patients to confirm its efficacy, monitor side effects, compare it with commonly used treatments, and collect information that will allow the drug or treatment to be used safely. These studies may lead to a new drug’s being marketed in Canada or to the use of an approved drug for a new indication.

Ethical Concerns: The REB must carefully examine Phase III clinical trials to ensure that the care of patient-participants is not compromised in the random assignment to any arm of the study (including the placebo arm), that there are no conflicts of interest in the selection and recruitment of participants (see Article 7.4 in Chapter 7 [“Conflict of Interest”], that payments by sponsors to researchers are reasonable, and that no financial incentives in the nature of finder’s fees are made or offered for the recruitment of participants. The REB should also address the issue of continuing access to the experimental therapy after the trial. If the treatment proves to be effective and reasonably safe for participants, will it continue to be provided? If not, what provision will be made to ensure that participants continue to receive adequate treatment? The REB should be aware that numerous safety standards (for example, mechanical and electrical) apply to medical devices, and the REB should be assured that these standards will be met.

Phase IV Phase IV clinical trials, also known as post-regulatory approval studies, primarily examine the long-term effectiveness and toxicity of already-marketed drugs. They may also be designed to look at the use of the treatment or intervention in different populations, or to look at quality-of-life issues.

Ethical Concerns: Phase IV studies can be extremely valuable for assessing the long-term safety and effectiveness of marketed drugs and devices.
Earlier-stage studies are of limited duration, and subsequent research can identify toxicities and drug interactions that only emerge over time. However, in some cases, Phase IV trials may be designed to serve primarily as marketing initiatives – to encourage the prescription and continued use of an approved drug. For example, a physician may be paid a per capita fee by a sponsor to collect data on the side effects and acceptance by patients of a drug being marketed by that sponsor. However, the financial terms associated with these trials may compromise physicians’ professional integrity by skewing prescription practices and encouraging finders’ fees, as well as encouraging improper billing practices, inappropriate utilization of public resources, and other problems. Researchers and REBs must examine Phase IV clinical trials in light of these potential conflicts to ensure that trials are undertaken for a bona fide scientific purpose, that free and informed consent is given, that physician-researchers have the requisite expertise or experience, and that potential conflicts of interest are adequately addressed.

C. Assessing Safety and Minimizing Risk

Participants enrolled in clinical trials are commonly exposed to experimental medications or devices, each of which carries specific risks. Indeed, the most severe research-related harms often arise in clinical trial research.

**Article 11.2** Research ethics boards should ensure that drugs and other therapies used in clinical trials do not pose undue risk to human participants.

**Application** The approach of proportionate review (Chapter 2 [“Scope and Approach”]) dictates that studies with greater risks should be subject to proportionately greater scrutiny. In all clinical trial research, the REB should carefully evaluate previous laboratory, animal and human research with the drug or other therapy, or have an expert evaluation undertaken on its behalf, to ensure that the risk of harm from its use (a) is justified by the potential benefits to be gained, and (b) is appropriately minimized.

Where appropriate, based on reports of safety issues arising in the study, an REB may discontinue the study at its institution, require the disclosure of relevant safety information to existing and future participants (see Section D [“Sharing New Information”], below), or take other steps reasonably necessary to promote the safety of participants.

**Monitoring Safety and Reporting Adverse Events**

The ICH-GCP defines an adverse event as “any unfavourable and unintended sign, symptom or disease temporally associated with the use of a medicinal product, whether or not considered related to the product.” For research carried on at a single site, the principal investigator is obliged to report any safety problems and serious adverse events to the local REB, the sponsor, and regulatory authorities. Where clinical trials are carried on at multiple sites, Health Canada and ICH-GCP require that unexpected serious adverse events suffered
by participants at any site be reported to the regulatory body, the researchers and REBs at all
institutions taking part in the research.

In practice, these reports have proved challenging for many REBs, because the reports often
lack context, informed analysis or explanation of their significance to the safety of
participants. In addition, in many clinical trials, researchers at individual sites do not have
access to detailed safety data, such as the rates of similar events at other sites or the
background epidemiology necessary to determine whether an adverse event is truly
unexpected. It is important, then, that mechanisms be put in place to ensure the safety of
trials. In some cases, a researcher’s plan for reporting safety data to the REB and acting on it
may serve this purpose. A Data and Safety Monitoring Board (DSMB) is another such
mechanism.

DSMBs are multi-disciplinary expert panels organized to monitor clinical trials, particularly
large, late-stage multi-centre trials involving randomized designs. They are composed of
scientists with expertise in the clinical area, statisticians, pharmacists and individuals with
expertise in ethics. Although the DSMB reports its findings and recommendations to the
sponsor, it should act independently of the sponsor. The DSMB has intermittent access to
the accumulated unblinded trial data, and it also audits unblinded safety reports from all sites
taking part in the trial. Based on that information, and in accordance with its trial-specific
stopping rules, the DSMB can recommend that the study be stopped early for reasons of
safety, efficacy or futility. The DSMB can also recommend that sponsors change the
procedures, methods or consent form information to ensure the safety of participants and the
validity and reliability of the data being collected.

Article 11.3 Researchers should provide the research ethics board (REB) with an
acceptable plan to monitor the safety of trial participants, including a plan for
the tabulation, analysis and reporting of safety data to the REB.3

Application REBs must ensure that every clinical trial protocol includes a plan to assess
safety concerns and protect the ongoing safety of research participants. Such
a plan should include the requirement that REBs be provided, by researchers,
sponsors and/or DSMBs, with clear and up-to-date information about the
safety of participants taking part in clinical trials. Such reports should be
provided in a timely way and include information about the context and
significance of reported data to permit a fair interpretation and meaningful
review by the REB for the protection of trial participants. Where possible,
REBs should be provided with individual adverse event reports, accompanied
by an evaluation, by the sponsor, of their relevance and significance to the
trial.

A safety monitoring plan should include a mechanism by which participants
may be withdrawn for safety reasons and by which studies may be stopped or
amended if they are found to be unsafe, or for reasons of futility or efficacy.
For some trials, the researcher may be expected to perform this monitoring
function. Depending on the circumstances of the trial, safety reports may be
submitted on an annual or semi-annual basis, supplemented by notices of
serious safety threats to participants requiring urgent consideration. All information supplied to the REB should include an analysis of its significance and sufficient context to permit meaningful determinations to be made by the REB.

Article 11.4 Research ethics boards should develop procedures to review safety reports and to take appropriate steps in response.

Application For more complex trials, an institutional or external DSMB may be appointed to provide a more comprehensive mechanism for monitoring the safety of multi-centre clinical trials. The REB should be satisfied that it will receive copies of all DSMB reports and recommendations. A DSMB must be independent of the trial and its members free of conflicts of interest with the study therapy, the trial sponsor, and the outcome of the research. Where a DSMB has been appointed to oversee a clinical trial, it will be mostly responsible for reviewing safety data and making appropriate recommendations about informing participants of safety concerns or stopping the trial for safety, futility or efficacy. Even when there is a DSMB, the researcher still has a responsibility to provide reports directly to the REB of serious adverse events at his or her site, upon which the REB may be obliged to act urgently.

Balancing Risks

As part of their ongoing medical care, patients with serious medical conditions are often treated with therapies or undergo interventions or procedures having significant risks. These patients may be invited to participate in clinical trials.

Article 11.5 In clinical trials, with appropriate scientific and clinical justification, it may be acceptable to allow research involving higher risk interventions with patient-participants in which such heightened risk is primarily attributable to the therapy and not to the research, or which is consistent with the risk normally undertaken by participants in their usual clinical care.

Application Some kinds of standard or recognized treatments (for example, surgery, chemotherapy or radiation therapy) themselves pose substantial risks. An REB may approve a study that involves such high-risk therapies if there are no other reasonable alternative therapies available to patient-participants and if the research-attributable risk is no greater, or only minimally greater, than that to which participants would routinely be exposed. Such risks may be regarded as within the range of minimal risk for these patient-participants, since they are inherent in the treatment that patients undergo as a part of their everyday life. Eligible participants for such studies are those:

- who are routinely exposed to similarly high-risk treatments in the course of their usual care and for whom there is a favourable balance of risk to potential benefits;
for whom there are no other reasonable treatment options available and for whom there is a favourable balance of risk to potential benefits; or

- for whom the incremental risk of research interventions (the research-attributable risk) is minimal.

Informed consent to such studies must include a description of the risks involved as well as a description of any available alternative treatments – including no treatment. REBs should also seek to ensure that participants are aware of the risks and benefits attributable to research, as distinct from those arising from indicated therapy. (See Article 2.7 in Chapter 2 [“Scope and Approach”], dealing with comparative risk.)

D. Sharing New Information

In the course of a clinical trial, new information may arise that is relevant to participants’ free, informed and continuing consent to participate in the research. Section C addresses the REB’s obligation to ensure that the safety of participants is monitored and protected. Section D describes the obligations of REBs to ensure that any new information, including information about newly discovered risks and toxicities, that may affect the willingness of a participant to enter or continue in the trial be promptly disclosed.

Article 11.6 Researchers should share with the research ethics board, the participants and other appropriate regulatory or advisory bodies, in a timely manner, information that may be relevant to participants’ continuing consent to participate in the research.

Researchers should also share new information with former participants in the research to the extent that it may be relevant to their welfare.

Application Researchers should share with the REB and trial participants, in a timely manner, new information relating to the safety and efficacy of the study therapy, significant changes to study procedures, and other relevant information. Article 11.6 outlines a researcher’s continuing duty to share new and relevant information from the clinical trial. The more serious and urgent the information, the more promptly it should be disclosed.

New information requires disclosure if it may affect the willingness of participants to continue in the trial, or is otherwise relevant to participants’ welfare or free, informed and continuing consent (see Articles 2.8, 3.3, 3.4). To understand its particular relevance, the information should be considered from a participant-centred perspective. New information that arises outside the trial (for example, new findings in other related research), when that information is relevant to the participant’s informed and continuing participation, should also be disclosed. New information thus covers a range of matters that includes, but is not limited to, the following:
changes to the research protocol;

- evidence of new risks, determined to be serious enough to warrant disclosure;

- new information that decisively shows that the benefits of one intervention exceed those of another;

- new research findings, including relevant non-trial findings; or

- unanticipated problems involving lack of efficacy, recruitment issues, or other matters determined to be serious enough to warrant disclosure.

The duty to report such new information to the REB, along with the necessary analysis and evaluation to make the new information interpretable, lies with the researcher and the sponsor. The REB should encourage researchers to raise potentially relevant developments with the REB at an early stage to better determine the appropriate scope and timing of information-sharing with participants and regulatory authorities.

Significant information affecting the welfare of former participants may arise after the completion of the trial or after the participants’ involvement is finished. If so, the researcher should share the information with the REB and other appropriate regulatory or advisory bodies. The REB and researcher should consider whether, given its nature and urgency, the information would be relevant to any former participants’ welfare and informed choices. If so, reasonable steps should be taken to inform such participants in a meaningful and timely manner.

When sponsors refuse to report new and significant information that is relevant to the welfare of participants, then researchers and/or REBs have a duty to do so. The more relevant, serious and urgent the information, the stronger is the duty to report. Before REBs or researchers act on such duties, they should afford sponsors a reasonable opportunity to report the information to the appropriate regulatory authorities.

**E. Therapeutic Misconception**

With the exception of some Phase I studies, clinical trials usually involve individuals in need of treatment, for whom the experimental therapy is hoped to be effective. In addition, often the patient’s physician, or someone associated with the patient’s physician, makes the initial approach or provides preliminary information about trial participation. Research has shown that participants may confuse the purposes of research and therapy.

As a result, some patient-participants may assume that there must be therapeutic value in the research procedures they are undergoing, or that they have been invited to participate because their physician believes it would contribute to their welfare. Therapeutic
misconception refers to the tendency of trial participants to believe that the primary intention of research tests and interventions is to provide a therapeutic benefit to the patient-participant. Even when research risks, benefits and alternatives are explained to them, it is common that trial participants do not fully appreciate the differences between clinical care and research participation. This may be particularly true when the researcher is the participant’s own physician.

**Article 11.7** Research ethics boards and clinical trial researchers should be conscious of the phenomenon of therapeutic misconception and ensure that procedures for recruitment and informed consent emphasize which specific elements of a clinical study are required for research purposes, as well as the differences between research and the standard clinical care they might otherwise receive.

**Application** Chapter 3 (“Free and Informed Consent”) describes the requirements for informed consent to research participation. In particular, Article 3.2 provides that participants must be provided with relevant information, including a clear description of those elements of participation that are experimental in nature and those not primarily intended to benefit the participant directly. One way to help avoid therapeutic misconception is to ensure that the healthcare professionals involved in the patient’s care are involved as little as possible in recruitment, to ensure that clearly different people perform treatment and research functions.

When a treating clinician conducts research on his or her patients, special efforts may be required, as part of the consent process, to distinguish between these two roles and to ensure that patient-participants understand the research elements of the study. While the physician is ultimately responsible for patient care, participants should understand that a physician who conducts research is acting in a capacity that is outside the traditional physician-patient relationship.

**F. Financial Conflicts of Interest**

**Industry-Sponsored Research**

Clinical trials are commonly undertaken under contract with pharmaceutical or biotechnology companies in order to secure marketing approval for the drug being tested. These companies make drugs and devices in order to generate profits. This may be a source of conflict with researchers’ obligations of scientific integrity and participant welfare.

**Article 11.8** Research ethics boards should ensure that clinical trial research is designed to meet appropriate standards of participant safety and respectful treatment, and that financial considerations do not affect these standards or the scientific validity and transparency of study procedures.

**Application** Clinical trial research raises special challenges for the protection of human participants and the validity of research results because of the financial considerations associated with clinical trials. The profit motive of
commercial research can conflict with participant protection and the scientific
validity of clinical trials. The financial benefits of demonstrating efficacy and
safety in a novel therapy may have the effect of compromising standards of
human protection and scientific validity (see Chapter 7 [“Conflict of
Interest”]).

**Clinical Trial Budgets**

Budgets for clinical trials are usually calculated based on per capita costs – that is, the
sponsor pays the researcher a fixed sum for each research participant, based on the duration
and complexity of the study and the tests and procedures it requires.

**Article 11.9** Research ethics boards should ensure that clinical trial budgets are reviewed to
ensure that conflicts of interest are identified and appropriately managed.

**Application** As a general guide, payments for clinical trial procedures should be no greater
than the usual amounts charged by health-care providers for the provision of
comparable services. Budgets should also be examined to ensure that no
inappropriate payments are to be made, such as finder’s fees or other
unexplained expenses that may raise questions about conflict of interest.
Further, payment provisions should be scrutinized to ensure they do not create
ethically inappropriate incentives to recruit quickly, at the expense of a careful
review of the suitability of potential participants. Differential compensation paid
for different levels of recruitment, such as higher per-participant payments for
those recruited above a set target, may also encourage inappropriate recruitment
practices. Unreasonable payments or undue inducements may place the
researcher, and sometimes the institution, in a conflict between maximizing
financial remuneration on the one hand and protecting participants and meeting
the scientific requirements of the study on the other. Disclosure of the kinds and
amounts of payments and other budgetary details assists the REB to assess
potential conflicts of interest and encourages the researcher to manage them
appropriately.

**G. Placebo-Controlled Studies**

In studies of new drugs or other therapies, a placebo study arm allows the researcher to control
for factors that may confound a valid assessment of the value of an experimental therapy, and it
also has other methodological advantages over non-placebo designs. Placebo-controlled studies
have long been the gold-standard design for testing the efficacy and safety of new drugs and
other clinical interventions. However, the primacy of the placebo-controlled study has been
challenged, and opinions differ as to its methodological superiority for all types of clinical
trials. In addition, where there is an established effective treatment, use of a placebo may
deprive participants of needed therapy. The following article is designed to ensure that placebo
controls are used only in situations that do not compromise the safety of participants.

**Article 11.10** (a) A new therapy or intervention should generally be tested against an
established effective therapy.
(b) As with all alternative choices of a control, a placebo control is ethically acceptable in a randomized controlled clinical trial if:

- its use is scientifically and methodologically sound to establish the efficacy or safety of the test therapy or intervention;
- it does not compromise the safety or well-being of participants; and
- the researcher articulates to the research ethics board (REB) a valid scientific justification for the use of the placebo control.

(c) For clinical trials involving a placebo control, the researcher and the REB must ensure that participants or their surrogate decision-makers are well informed:

- about any therapy that will be withdrawn or withheld for purposes of the research; and
- of the anticipated consequences of withdrawing or withholding the therapy.

**Application**

The use of an active treatment comparator in a clinical trial of a new therapy is generally the appropriate study design when an established effective therapy exists for the population and clinical indication under study.

However, a placebo comparator is acceptable in any of the following situations:

1. There are no established effective therapies for the population or for the indication under study, and existing evidence raises substantial doubt within the community of treating physicians regarding the net therapeutic benefit of available therapies.

2. Patients are refractory to the available therapies by virtue of their past treatment history or known medical history.

3. The study involves adding a new investigational therapy to established effective therapies – established effective therapy + new therapy vs. established effective therapy + placebo.

4. Patients have determined that the response to the established effective therapies for their condition is unsatisfactory to them.*

5. Patients have previously refused established effective therapies for their condition.*

* For (4) and (5), the determination of response satisfaction and refusal of treatment must take place outside the context of recruitment for the clinical
trial and prior to offering trial participation to the potential participant, and they must be documented in a standardized manner.6

H. Analysis and Dissemination of the Data and Results of Clinical Trials

The rights of sponsors with respect to the ownership, analysis, interpretation and publication of study data are typically described in industry-researcher contracts (often referred to as Clinical Trial Agreements or Clinical Study Agreements), which may not always be available for REB review. These contracts may also place restrictions on the publication of findings, either directly or through provisions that seek to protect, in favour of the sponsor, the intellectual property of study procedures, data or other information.

Article 11.11 With respect to research findings:

(a) Institutions and research ethics boards should take necessary measures to ensure that researchers and institutions share research results and publish or otherwise disseminate the analysis and interpretation of research findings in a timely manner without undue restriction.

(b) Any prohibition or undue limitation on the publication or dissemination of scientific findings from clinical trials is ethically unacceptable.

(c) Institutions should develop reasonable written policies regarding acceptable and unacceptable clauses in research contracts relating to confidentiality, publication and access to data.

Application To justify the use of human participants, and the risks and other burdens they are asked to bear, research must be valuable. That is, it must have a reasonable likelihood of promoting social good. If research findings are not disseminated within a reasonable time, their value may be diminished or lost, betraying the contributions and sacrifices of participants. For this reason, and based on respect for participant expectations and protection of the public good, researchers and institutions have an ethical responsibility to make reasonable efforts to publicly disseminate the results of clinical research in a timely manner.

However, negative results of research are not always published or otherwise disseminated. Failing to publish such results may lead to publication bias and thus contribute to a series of harms, including misinformed clinical decision-making based on incomplete or skewed data, inappropriate and potentially harmful clinical practices and injury to health, needless and wasteful duplication of research with associated risks to participants, and fraud or deception in the clinical trials process and erosion of public trust and accountability in research.

REBs should require the satisfactory amendment or removal of any confidentiality clauses or publication restrictions that unduly limit either the
content of the scientific information that may be disseminated, or the timing
of dissemination. Contracts should also ensure that researchers have the
necessary access to trial data, and the opportunity to analyze them, to ensure
that they can report study findings fairly and accurately, particularly with
respect to both efficacy and safety.

Article 11.11 requires (a) that REBs and institutions take reasonable steps to
ensure that research findings are published in a timely way, (b) that such
publication may be done without undue limitation, and that (c) institutions
and REBs adopt reasonable written, publicly available policies with respect
to the publication and dissemination of results. Contracts and relevant
documents for proposed research should be reviewed for consistency with
these policies and principles. Such policies should ensure that sponsors’
legitimate interests are reasonably balanced against the researcher’s ethical
and legal obligations to participants, and to the scientific and public good to
disseminate data and research findings.

Such policies should require that clinical trial research contracts be examined
to ensure that contractual provisions comply with institutional policy
standards. They should do all of the following:

1. Require that confidentiality and publication clauses be submitted to a
   responsible authority (for example, the REB or research administration)
   for a determination of their consistency with the policy.

2. Require that any ethical concerns arising in the review be referred to the
   REB as an integral part of the ethics review process.

3. Provide that any proposed restrictions on publication should include an
   ethically acceptable justification.

4. Provide that all confidentiality and publication clauses:

   (a) Are consistent with the researcher’s duty to share new information
       from clinical trials with REBs and trial participants in a timely
       manner (Section D [“Sharing New Information”]);

   (b) Are reasonable in terms of any limitations or restrictions on the
       publication or other dissemination or communication of
       information; and

   (c) Permit researchers to access study data.

Review of ethical aspects of researcher–industry contracts should be
undertaken by a duly composed REB, or by or under the auspices of another
competent institutional authority as an integral part of the ethics review
process. If done under the latter process, the review of contracts should be
conducted in a manner that (1) conforms to the special ethical duties,
mandate and purposes of REB review, and (2) consults with the REB when necessary.

In the review process, the onus to justify restrictions on dissemination or access to data should lie with the one seeking such restriction, usually the researcher or sponsor. The reasonableness of restrictions on either the content or timing of dissemination should be measured against the written institutional policies. For example, some existing institutional policies deem unacceptable any publication restrictions that exceed a time limit of three to six months after the close of the trial. Such policies should also address restrictions on the dissemination of particular kinds of information, such as information that may be considered proprietary or trade secrets. Restrictions on information that participants would reasonably consider relevant to their welfare (see Article 11.6), or that are required to give appropriate context to a manuscript or other publication, are seldom if ever justified.

**Clinical Trial Registration**

Clinical trial registries permit web-based access to information about ongoing clinical trials so that anyone may have information about trials and their results.

**Article 11.12** All clinical trials should be registered with a recognized and easily web-accessible public registry.7

**Application** Clinical trial registries are one way to help ensure that negative trial results are widely available. These, in addition to editorial policies, ethical policy reforms, and revised national and institutional ethics policies, contribute to a multi-faceted approach to combating non-disclosure, publication bias, and the suppression of data in clinical research.

**Endnotes**


6 These conditions are drawn from the recommendations of the National Placebo Working Committee on the Appropriate Use of Placebos in Clinical Trials in Canada, 2004. http://www.cihr-irsc.gc.ca/e/25139.html with minor amendments approved by the CIHR Standing Committee on Ethics.

7 The CIHR requires that randomized clinical trials be registered with an International Standard Randomized Controlled Trial Number (ISRCTN) at www.controlled-trials.com.

Chapter 12

HUMAN TISSUE

The use of human tissue for research contributes greatly to the advance of biomedical science. Ethical considerations raised by such research centre on acceptable access and consent to the use of tissue and potential privacy concerns arising from the disclosure of information derived from donor tissue.

Human tissue here refers to any biological material and includes blood or other body fluids. The status accorded the human body and its parts varies among individuals and cultures. This variation, in part, reflects how people perceive, identify with, and relate to their bodies. It is important, then, to assess the ethics of research involving human tissue with an awareness of, and sensitivity to, the relevant cultural context.

A. Identifiability of Tissue

Five categories of human tissue can be distinguished, based on the extent to which they are identifiable. These categories, with minor variations, are also found in Chapter 5 (“Privacy and Confidentiality”) with respect to the identifiability of personal information:

- **Identified tissue**: Tissue donors can be identified through direct identifiers associated with the sample (e.g., name, address, social insurance number or personal health number);

- **Identifiable tissue**: Tissue donors can be identified by a combination of indirect identifiers (e.g., date of birth, place of residence, or unique personal characteristic) using reasonably foreseeable means;

- **De-identified/coded tissue**: Identifiers are removed from tissue samples and replaced with a code that permits individual donors to be identified only by use of that code, access to which may be restricted;

- **Anonymized tissue**: Tissue is irrevocably stripped of any means of identification and a code is not kept to allow future re-linkage; and

- **Anonymous tissue**: Information that never had identifiers associated with it.

These categories, however, are not fixed. Identified, identifiable and de-identified tissue can be anonymized by well-accepted technical or administrative means. For purposes of assessing privacy, identified and identifiable tissue may be treated in much the same way,
since these categories of tissue can be straightforwardly associated with a particular individual. Likewise, anonymous and anonymized tissue also may generally be treated the same, since they cannot be associated with an individual.

However, due to continuing technological development in genetics, individuals with access to stored tissue are increasingly able to discover the identity of individual donors using genetic markers. For this reason, genetic testing has made it more difficult to categorize tissue as anonymous or anonymized. Researchers and research ethics boards (REBs) should be aware of, and guard against, this potential threat to donors’ privacy.

From the perspective of confidentiality, it may seem desirable to anonymize or de-identify collected tissue to the extent possible. However, there are considerations that may justify retaining some identifiers, which include the scientific requirements of some studies and the need to avoid using different samples from the same donor. Anonymity may not always be desirable for other reasons as well. Rendering tissue anonymous has the disadvantage of making it impossible to offer the benefits of research findings to donors and their families or to alert them to relevant clinical findings. This is particularly significant when research may disclose a previously undiagnosed condition, such as HIV infection or an inherited predisposition to breast cancer, for which potentially effective treatments are available.

B. Tissue Collection

Tissues samples may be obtained in different ways:

1. They may be collected expressly for a specific research purpose;
2. They may be collected incidentally to medical or diagnostic procedures with no initial intent to be used in research; or
3. They may be collected for research or medical or diagnostic purposes with some expectation that they may or will also be used in future research, although the precise research project(s) may not be known at the time.

The first category above refers to the initial collection of tissue for research, which is described in this section. The latter two categories are relevant to subsequent, secondary uses of tissue for research that may not have been conceived at the time the tissue was taken. These are described in Section D (“Secondary Use of Previously Collected Tissue”), below.

Article 12.1 Research proposing the initial collection and use of human tissue requires ethics review by a research ethics board and consent of the tissue donor.

(a) The collection and use of human tissue for research purposes should be undertaken with the free and informed consent of the donor;
(b) In the case of donors who lack capacity, consent may be given by advance directive or by an authorized third party; and
(c) In the case of deceased donors, consent may be given by advance directive or by an authorized third party.
Article 12.1 applies prospectively – that is, prior to the collection of tissue intended for research purposes. It applies the general elements of free and informed consent in Chapter 3 (“Free and Informed Consent”) to tissue donation. The consent process permits individuals to protect themselves against unwanted or potentially harmful invasions of privacy. Individuals who do not wish to contribute tissue to particular research projects should be free to withhold consent without penalty and without prejudicing access to any treatment they would otherwise receive. For individuals unable to give consent, the principles developed in Chapter 3 regarding third-party authorization should be observed.

When informed consent to the research use of tissue is being discussed, a clear distinction should be made between consent to research use and that for any clinical procedure or test. In practice, this may mean separate consent forms, but in any event, the different uses must be clearly explained and understood by donors.

Advance directives may include instructions relating to the future donation of tissue, and they should be respected. However, post-mortem donation of tissue can be an extraordinarily sensitive topic in some families. In such cases, if serious objections or divisions within a donor’s family become known, researchers should be aware of family members’ concerns, and they should respond in a way that respects that sensitivity. REBs and researchers should be aware that provincial human tissue gift laws often make specific provision for research use and should be consulted.

To facilitate the appropriate subsequent use of human tissue, consent forms should provide potential participants with a range of choices relating to the future use of their tissue.

Where secondary use of donated tissue is anticipated, it is desirable that individuals approached to donate be given a realistic opportunity to express the specific nature and scope of the consent they wish to give. Accordingly, offering a variety of choices, as suggested in Article 12.2, permits donors flexibility in shaping the acceptable secondary use of their tissue. Options might include, for example:

- Refusing any future use of their tissue in research;
- Permitting only anonymous or anonymized use of their tissue in research;
- Permitting identified, identifiable or coded use of tissue for one particular study only;
Permitting identified, identifiable or coded use of their tissue for any study relating to the condition for which the sample was originally collected;

Permitting future contact by researchers to seek consent for other studies; or

Permitting coded use of their biological materials for any kind of future study.

At the same time, donors should be advised that, once given, their consent may be difficult to withdraw. They should also be advised of the potential for subsequent identification, including identification by means of increasingly sophisticated genetic technologies.

**Article 12.3** For the purpose of obtaining free and informed consent, the full range of information set out in Article 3.2 in Chapter 3 (“Free and Informed Consent”) should be provided. In addition, researchers who seek to collect human tissue for research should provide potential donors or authorized third parties with the following information:

(a) The type and amount of tissue to be taken;

(b) The manner in which tissue will be taken, and the safety and invasiveness of the procedures for acquisition;

(c) Potential uses of the tissue, including any commercial uses;

(d) Measures to protect the privacy of individual donors, ensure confidentiality of the data, and minimize harms to donors;

(e) The length of time the tissue will be kept, how it will be preserved, and any limits on its use; and

(f) Where applicable, the researchers’ plan for disclosure of clinically relevant information derived from the tissue.

**Application** Free and informed consent to tissue donation requires that all currently known relevant information be provided to potential donors. In general, consent must be based on an understanding of the specific uses of tissue for research anticipated at the time. Potential research participants should also be advised if there is the possibility that future studies, the nature of which is currently unknown, may be undertaken using the donated tissue. Researchers should submit to the REB an acceptable plan for maintaining the duty of confidentiality in regard to tissue donors. Reasonably anticipated harms, such as the possibility of future identification, must also be disclosed. This includes information on any identifying information to be attached to the tissue, its potential traceability, and how the use of the tissue could affect the donor’s privacy.
In general, tissue samples should be used only for the agreed-on research project. The law in some jurisdictions requires that research be restricted to these purposes. Subject to Articles 12.5 and 12.6, if tissue is to be used for any other research purpose, the individual’s prior consent should be obtained.

The research protocol and consent form should describe any incidental findings that may be anticipated, as well as the way they will be managed. Incidental findings are unanticipated discoveries, which may not have been within the original focus of the research, that may have clinical, psychological, social or other health-related significance. If incidental findings are made, the question may arise whether, and how, they should be communicated to the affected donor. The management of incidental findings is more fully discussed in Article 3.4 in Chapter 3 (“Free and Informed Consent”).

While all the basic guidelines of Chapter 3 regarding free and informed consent apply to research involving human tissue, some deserve special attention. Explaining the purpose of the research is of particular importance, since the tissue donor will not be directly involved in the research. Explaining the potential for financial conflict of interest is also important, as there may be the potential for significant commercial gain.

C. Tissue Storage and Banking

This section applies to any storage of tissue. It includes tissue stored only for the duration of a study as well as that which is stored or banked for future research use.

Collection and retention of tissue in biological banks (“biobanks”) creates an increasingly important resource for research. Biobanks vary widely in their characteristics. Different types of biological materials may be stored in biobanks, including blood and tissue samples, such as tissues from tumours or organs. Biobanks may include or be linked with databases of identifiable or non-identifiable information; they may be disease-specific or contain genetic material from a wide population base; they may be established prospectively for use in a specific research study or to provide biological materials for numerous studies.

The creation of biobanks presents risk to individuals whose genetic and other personal information may be accessed, used, retained and disclosed, and they also present risk to those individuals’ biological relatives and others with whom they have shared genetic characteristics.

Article 12.4 Institutions and researchers that maintain collections or repositories of tissue:

(a) Should ensure that they have or use appropriate facilities, policies and procedures to ensure that tissue is stored safely and in accordance with applicable standards; and

(b) Should establish appropriate physical, administrative and technical safeguards to ensure that the privacy of tissue donors is protected.
Application

Institutions and researchers must ensure that their facilities, equipment and procedures permit tissue to be stored safely so that its scientific value is maintained. Procedures for storage and record-keeping must include effective measures to ensure that donors’ identities are protected. Such measures include the security of facilities and effective procedures for data handling, record-keeping and regulating access to tissue and associated information by outside researchers and others.

Organizations that maintain biobanks may have their own policies on privacy, confidentiality and access to materials. Researchers should be aware of requirements for compliance with such policies. For example, researchers may be required to apply to the organization for permission to access biological samples, and they may be required to enter into an agreement with the organization that sets out conditions for research access and use of materials in the biobank.

Identified data derived from tissue may be linked to other research or public databases. Such data linking can be a powerful research tool and valuable resource for monitoring the health of populations, understanding factors influencing disease, and evaluating health services and interventions. Data linkage raises separate privacy issues, discussed in Section E (“Data Linkage”) of Chapter 5 (“Privacy and Confidentiality”).

D. Secondary Use of Previously Collected Tissue

A researcher may want to use tissue left over from earlier research, from a diagnostic examination or surgical procedure, or from an established tissue repository. At the time tissue was collected, individuals may have consented to a particular research purpose or otherwise expressed a preference about future uses, such as an advance directive made in accordance with laws governing gifts of human tissue for research or other purposes, or by an instruction contained in a consent form, as described in Article 12.2. Researchers and REBs should respect known preferences or instructions. Alternatively, future use of tissues may not have been discussed with or even contemplated by the individual. It can be difficult then to determine individual wishes regarding future uses of tissue for research. A proportionate assessment of risks and benefits will help guide the research ethics process in these cases.

Chapter 5 (“Privacy and Confidentiality”) provides detailed guidance on secondary use of personal information for research purposes (in particular, see Articles 5.5 and 5.6). The following section adapts the provisions in Chapter 5 to the specific context of research involving secondary use of tissue.

Article 12.5 Researchers should seek research ethics board (REB) approval for the secondary use of tissue. Researchers must satisfy the REB that:

(a) Use of the tissue is essential to the research;

(b) They will take appropriate measures to protect the privacy of and minimize
harms to the individuals from whom tissue was collected, and to ensure confidentiality; and

(c) Individuals from whom the tissue was collected did not object to secondary use at the initial stage of collection or otherwise make known their objection.

**Application**  For research involving the secondary use of tissue that is anonymous, anonymized, and de-identified or coded where no member of the research team has access to the code that permits re-identification of individuals, the REB may proceed by delegated review. (Under some circumstances, delegated review may be available for secondary use of identifiable tissue.) Researchers and REBs should be aware, however, that risks may arise even in research involving anonymized or anonymous tissue. The research may reveal potentially harmful information about groups or communities, even though it may not be possible to identify the individuals who provided the tissue. For example, as more fully described in Section E (“Genetic Research Involving Communities”) of Chapter 13 (“Human Genetic Research”), research on human tissue may involve an exploration of genetic variation within specific groups or communities. Such research may raise ethical concerns about stigmatization and exploitation of groups and social disruption in communities. For this reason, researchers may have an obligation to seek the engagement of community members or leaders in the design, conduct and reporting of such research (see Article 12.6, below). Should any of these concerns arise during the conduct of a study, the researchers should bring such concerns to the REB for guidance and direction.

Subject to Article 12.6, if a researcher satisfies the conditions in Article 12.5 (a) to (c), the REB may approve the research without requiring the consent of individuals from whom tissue was collected. Established tissue repositories may have their own policies and procedures governing access to tissue for research purposes. For example, repositories may release only anonymized samples and may require researchers to sign material transfer agreements or secure REB approval. Researchers should be aware of and abide by such policies and procedures and obtain any other required permission.

**Article 12.6**  In highly sensitive situations involving secondary research use of tissue, the research ethics board (REB) may require that a researcher’s secondary use of the tissue be dependent on the informed consent of the individuals from whom the tissue was collected or from authorized third parties, unless it is impossible or impracticable to obtain consent. If the REB is satisfied that consent is impossible or impracticable, access for secondary use may require either:

(a) An appropriate strategy for notifying individuals or groups that tissue is intended to be used for a specified research purpose; or
(b) Consultation with representatives of individuals or groups from whom tissue was collected.

**Application** In considering the applicability of this article, REBs should apply a proportionate approach to ethical assessment of research that considers the likelihood and magnitude of harms for individuals from whom tissue was collected, as well as the potential benefits of the research. Highly sensitive situations may arise when identifying or identifiable results of the research will be published or when the tissue was originally collected from individuals or groups who may have special interests in regard to tissues, such as groups with specific medical conditions or who attribute particular cultural or religious significance to tissue. For this reason, according to the Canadian Institutes of Health Research Guidelines for Health Research Involving Aboriginal People, secondary research use of tissue samples known to have originated with Aboriginal people requires the specific consent of the individual donor and, where appropriate, consultation with the community if the sample can be traced back to the individual or the community. REBs should also be particularly cautious when individuals or groups from whom the tissue was collected may be significantly harmed by accidental or intentional disclosure.

Article 12.6 provides that the REB may require researchers to seek consent from individuals or their authorized third parties. It may, however, be impossible or impracticable to contact all individuals or authorized third parties to obtain informed consent, particularly when the group is large or its members are likely to be deceased, geographically dispersed or difficult to track. Attempting to locate and contact members of the group may raise additional privacy concerns, especially when a relationship with individuals has not been maintained. Seeking consent from only a partial set of group members may introduce undesirable bias into the research. Financial, human and other resources required to contact individuals and obtain consent may be so burdensome as to impose undue hardship that jeopardizes the research.

Where an REB is satisfied that consent is impossible or impracticable, Article 12.6(a) requires that the researcher propose an appropriate strategy for giving notice to individuals or groups about the proposed research or, where such notification is impossible or impracticable, that there be consultation with representatives of the individuals or group, in accordance with Article 12.6(b). For example, researchers may develop a way to sample the opinions of a subset of individuals in the group or contact one or more organizations that are likely to represent the views and interests of the individuals from whom tissue was collected. The goal of notice or consultation is to provide an opportunity for input regarding the proposed research.

If researchers seek access to tissue in an established repository, the organization that manages the repository may have already taken steps to obtain consent from or notify individuals or authorized third parties, or to engage in consultation with representative groups. The researcher should
inform the REB of the extent to which the repository organization has
addressed these issues. If the REB is satisfied that issues of consent,
notification or consultation have already been addressed by the repository
organization, it may be unnecessary for the researcher to duplicate steps that
have already been undertaken.

**Article 12.7** In the context of secondary research with tissue, researchers who wish to contact
individuals from whom tissue was previously collected must obtain research
ethics board approval prior to contact.

**Application** Sometimes a research goal may be achieved only by follow-up contact with
individuals to collect additional information or biological samples. However,
contact with individuals whose previously collected tissue is sought for use in
secondary research raises privacy concerns, especially if a relationship with
these individuals has not been maintained. Individuals might not want to be
contacted by researchers. The research benefits of follow-up contact must clearly
outweigh the potential harms to individuals of follow-up contact, and the REB
must be satisfied that the proposed manner of follow-up contact is respectful and
minimizes potential harms to individuals.

**E. Human Reproductive Tissue**

This section sets out ethical guidelines relating to research involving human fetuses and fetal
tissue, embryos, stem cells and gametes. While research involving human reproductive tissue
has great promise for assisting the development of healthy pregnancies, curing illness, and
repairing or rebuilding tissue, some such research is objectionable to many. Accordingly, this
research has provoked vigorous debate. Discussion and reflection should continue as our
scientific understanding develops.

Significant ethical issues include consent to research involving reproductive tissue, privacy
concerns of donors and research participants, and the potential for harm to an embryo or fetus.
Researchers and REBs have a continuing duty to remain mindful of the public interest in these
issues, and to respect policy, legal and regulatory requirements. In particular, researchers and
REBs should be aware of the detailed requirements and prohibitions found in the *Assisted
Human Reproduction Act.*

**Article 12.8** In addition to Articles 12.1 to 12.7 that apply to all research involving human
tissue, the following guidelines apply to research involving human
reproductive tissue.

(a) Research using reproductive tissue or cells, in the context of an
anticipated or ongoing pregnancy, should not be undertaken if the
knowledge sought can reasonably be obtained by alternative methods.

(b) No reproductive tissue should be obtained, for research use, through
commercial transaction.
Application  Because of the potential for harm to the woman or the fetus, Article 12.8(a) recommends that the use of such reproductive tissue should be avoided where pregnancy is anticipated or ongoing, if research goals may be accomplished in some other way.

Article 12.8(b) reflects concerns about the commercialization or commodification of human reproduction. The purchase or sale, directly or indirectly, of any human tissue for the purpose of creating a human being, including any gamete or in vitro human embryo, is ethically unacceptable.

Research Involving Human Embryos

An embryo is a human organism during the initial period of its development following fertilization or creation. It includes any cell derived from such an organism that is used for the purpose of creating a human being. Any research in which fertilization occurs should be regarded as research on embryos. The Assisted Human Reproduction Act prohibits the creation of a human embryo specifically for research purposes.

Article 12.9 Research on embryos intended for implantation to achieve pregnancy is acceptable if intended to benefit the embryo or to advance knowledge if:

(a) Research interventions will not compromise the care of the mother, or the subsequent fetus; and

(b) Researchers closely monitor the safety and comfort of the mother and the safety of the embryo.

Application Research potentially altering the embryo by chemical or physical manipulation should be distinguished from research directed at ensuring normal fetal development. For example, the evaluation of potential teratogens and their effects on certain cell lineages may use early embryos, but those embryos must not be implanted for an ongoing pregnancy.

Article 12.10 Research involving human embryos that have been created for reproductive purposes, but are no longer required by their donors for this purpose, may be ethically acceptable if:

(a) The ova and sperm from which they are formed were obtained in accordance with Article 12.8;

(b) Where the embryo was created using donor gametes, free and informed consent was provided by the gamete donors; and

(c) Embryos exposed to manipulations not directed specifically to their ongoing normal development will not be transferred for continuing pregnancy.
Research on embryos requires the consent of the gamete donors. The REB may not waive the requirement for such consent. In particular, researchers and REBs should be aware of the Consent Regulation under the Assisted Human Reproduction Act.  

Research Involving Fetuses and Foetal Tissue

The term “fetus” applies to the developing human being from fertilization to delivery, whether alive or dead at delivery. Fetal tissue includes membranes, placenta, umbilical cord, amniotic fluid and other tissue that contains the genetic information of the fetus.

Research may be undertaken on methods to treat, *in utero*, a fetus that is suffering from genetic or congenital disorders. Because the fetus and the woman cannot be treated separately, any intervention to one involves an intervention to the other.

**Article 12.11** With respect to fetal research:

(a) Consistent with the requirements of Chapter 3 (“Free and Informed Consent”), research involving a human fetus requires the free and informed consent of the woman.

(b) Research interventions should not compromise the woman’s ability to decide whether to continue her pregnancy.

**Application** Research involving a human fetus requires the free and informed consent of the woman. Accordingly, research involving the use of fetal tissue should be guided by respect for the woman’s dignity. Research methods on the treatment of fetuses *in utero* thus pose no issues that are not addressed elsewhere in this Policy. Researchers should ensure that a clear distinction is made between consent to research use and consent for any clinical procedures or testing. In practice, this may mean separate consent forms, but in any event, the different uses must be clearly explained and understood by participant-donors.

**Pluripotent Stem Cell Research**

**Article 12.12** Researchers who intend to conduct research to derive or use pluripotent stem cells should follow the Canadian Institutes of Health Research Guidelines for Human Pluripotent Stem Cell Research, as amended from time to time.

**Hybrids and Chimeras**

Research involving the creation of hybrids and chimeras raise serious ethical concerns, and federal legislation prohibits certain activities relating to their creation. Researchers and REBs are referred to the Assisted Human Reproduction Act for guidance in this area.
Endnotes

1  http://www.cihr-irsc.gc.ca/e/29134.html
3  Assisted Human Reproduction (Section 8 Consent) Regulations (SOR 2007-137)  
4  The Guidelines for Human Pluripotent Stem Cell Research can be found at  
Chapter 13

HUMAN GENETIC RESEARCH

Human genetic research involves the study of genetic factors responsible for human traits and the interaction of those factors with each other and with the environment. Research in this area includes identification of genes that comprise the human genome; functions of genes; and characterization of normal and disease conditions in individuals, biological relatives, families and groups; as well as studies involving gene therapy. Participants in clinical trials are increasingly being asked to participate in genetic studies in addition to the primary clinical trial. With the increasing prevalence of genetic research, researchers, research ethics boards (REBs) and participants should be aware of the ethical issues that this research raises.

Genetic research may have profound social impacts, both positive and negative. As genetic research advances, genes and their alleles (versions) are being identified, but the function of each gene and its relationship to disease conditions or other characteristics may not be clear. In single-gene disorders, for example, an allele of a single gene is directly related to hereditary disease. More commonly, diseases or personal characteristics are influenced by multiple genes and environmental factors.

Research may help us better understand the human genome and genetic contributions to health and disease. It may lead to new approaches to preventing and treating disease. Individuals may benefit from learning about their genetic predispositions if intervention strategies are available to prevent or mitigate disease onset and symptoms, or otherwise promote health. Genetic research also has the potential, however, to exploit or stigmatize individuals or groups, who may experience discrimination or other harms because of their genetic status.

A. Application of Core Principles to Genetic Research

Genetic information has implications beyond the individual, because it may reveal information about biological relatives and others with whom the individual shares genetic ancestry. The participation of an individual in genetic research may therefore have ramifications for these other persons or groups. In some cases, researchers specifically seek to conduct genetic research with members of families or communities. Such research requires particular attention to the social and cultural contexts in which participants live. Research with families or communities may raise special considerations regarding recruitment of participants, consent processes, privacy and confidentiality, and community engagement.

Article 13.1 Guidelines for informed consent, protections for privacy and confidentiality, policies for research with human tissues, and other ethical guidance described in earlier chapters of this Policy apply equally to human genetic research.

Application In developing and reviewing proposals involving genetic research, researchers and
REBs should refer to earlier chapters in this Policy, including Chapter 3 (“Free and Informed Consent”), Chapter 5 (“Privacy and Confidentiality”) and Chapter 12 (“Human Tissue”). Other chapters relevant to the specific research proposal, such as Chapter 9 (“Research Involving Aboriginal Peoples”) or Chapter 11 (“Clinical Trials”) should also be consulted. This chapter does not reiterate principles set out in earlier chapters. Rather, it focuses on issues that arise specifically in the context of human genetic research and sets out ethical principles in regard to handling of information revealed through genetic research, provision of genetic counselling, participation of families and communities in genetic research, banking of human biological materials, and research involving gene transfer.

B. Plans for Handling Information Revealed through Genetic Research

Article 13.2 Researchers conducting genetic research must:

(a) In their research proposal, develop a plan for handling information that may be revealed through their genetic research;

(b) Submit their plan to the research ethics board; and

(c) Advise potential participants of the plan for handling information revealed through the research, in order to obtain free and informed consent.

Application The types of information that may be revealed through genetic research – and implications of this information for participants and their biological relatives – requires that researchers and REBs ensure that an appropriate plan is in place for handling both anticipated and unanticipated information. In some cases, genetic research may reveal known gene-disease associations or other information, including incidental findings, that may be clinically relevant for individuals or their biological relatives in treating or alleviating health conditions or risks. In other cases, research may reveal information that is inconclusive in its scientific, clinical or other implications. Genetic research may also reveal information about family relationships, including non-paternity.

This range of information varies in its possible implications for individuals. In some cases, follow-up clinical testing and counselling may be recommended. Information may also have implications for biological relatives and raise disclosure considerations, as discussed in Articles 13.3(b) and 13.4. Genetic information may also affect an individual’s eligibility for employment or insurance, for example, if an individual who gathers genetic information is required to disclose disease predisposition risks to participants’ employers or insurers.

The plan for handling information should take into account factors such as clinical relevance and anticipated benefits and harms for research participants and other people whose interests are implicated. Plans may include return of individual findings to participants or general notification of non-identifiable research results through newsletters, websites or other means. In regard to release or publication of research findings, the provisions of Chapter 5 ("Privacy and Confidentiality") should be consulted.

Confidentiality) apply. In some cases, researchers may consider that the most ethical course of action is not to return results of genetic research to participants (for example, where clinical significance is unknown due to novelty of the genetic investigation).

Article 13.3 Where researchers plan to return findings to individuals, participants in genetic research should have an opportunity to:

(a) Make informed choices about whether they wish to receive information about themselves; and

(b) To express preferences about whether information will be disclosed to biological relatives or others with whom the participants share a family or group relationship.

Application An individual’s right to privacy includes a right not to know information about himself or herself, and the principles on which this Policy is based emphasize autonomous choices regarding research participation. To permit participants to make informed choices about whether to receive information about themselves, researchers should explain the types of findings that may be revealed (as discussed in the Application of Article 13.2) and the potential implications of these findings for the participant, and should give the participant options for receiving different types of information. For example, a participant may want to receive clinically important information, but decline to receive information that is of unknown clinical significance.

Where individual results will be returned to participants, researchers must develop appropriate procedures for communicating results in accordance with the participant’s preferences or instructions. These procedures should be clearly described in the researcher’s plan. This may include direct communication of results to the participant, or communication to a specified health-care provider or other party authorized to receive the information. As discussed below, provision of research results to individuals may give rise to a need for genetic counselling.

Participants in genetic research should have an opportunity to express their preferences about disclosure of information to relatives or others, but these preferences are subject to the researcher’s duty to warn, as described in Article 13.4.

Article 13.4 Researchers may have an obligation to disclose information to biological relatives of the research participant in exceptional circumstances. This may include instances where genetic research reveals information about a serious or life-threatening condition that can be prevented or treated through intervention, even if the participant has expressed a preference against sharing information. Researchers should inform participants of this obligation in the plan for handling information.
As discussed in Chapter 5 (“Privacy and Confidentiality”), researchers have important obligations to maintain confidentiality of information. In genetic research, however, situations may arise where researchers become aware that a third party may be at high risk of a serious or life-threatening condition that can be prevented or treated. In such exceptional circumstances, legal or ethical imperatives may require that researchers disclose information they have obtained in a research context. Researchers should explain this to participants during informed consent discussions.

C. Genetic Counselling

Where researchers plan to return results of genetic research to participants, the research protocol should make genetic counselling available at that time, where appropriate.

Where the plan for handling information revealed in genetic research involves return of individual results to participants, genetic counselling may be required to explain the meaning and implications of the information. For example, genetic counselling can help explain the clinical significance of the information, whether health-care interventions or lifestyle changes are recommended, and implications of the information for biological relatives. Researchers should explain differences between genetic testing in a research context and testing in a clinical context. Clinical genetic testing may be needed to clarify or confirm results obtained in research. Where researchers disclose information to biological relatives or other family or group members, genetic counselling should be made available to them and the research participants. While the service provider need not necessarily be a genetic counsellor, he or she must have the experience or training to provide genetic counselling.

D. Genetic Research Involving Families

Where researchers seek to recruit members of a family to participate in genetic research, recruitment processes should be respectful of privacy and other personal interests of family members. In seeking consent from members of a family to participate in genetic research, researchers should ensure that consent from each individual is free and informed.

Recruitment of members of a family may take place in various ways. A family group, such as parents and a child or several adult siblings, may all together receive an invitation to participate in genetic research. Alternately, researchers may ask an individual who has agreed to participate for permission to contact family members who will receive a subsequent invitation to participate. Family members may have conflicting views about participation in research, and some may have specific sensitivities or objections. Researchers should recognize the potential for conflict within families and be respectful of any known sensitivities. They should also ensure that consent from each individual is free and informed. Where researchers seek participation from children or other members of a family who may lack capacity to give consent,
In some situations, researchers may seek permission from an individual participant to contact family members. Where appropriate to respect privacy interests or known sensitivities, it may be preferable for the participant to make initial contact with the family member. Alternately, the participant may identify a third party who may be asked to make initial contact with the family member to provide them with information about the opportunity to participate in genetic research. An approach by someone in a position of authority over the family member may raise concerns about undue influence or manipulation. Refer to Chapter 3 (“Free and Informed Consent”) for further guidance in regard to voluntariness of consent.

E. Genetic Research Involving Communities

Article 13.7 Where researchers intend to recruit participants for genetic research based on their membership in specific communities, it may be appropriate for researchers to consult with community leaders or representatives, in addition to seeking free and informed consent from individual participants. In these cases, researchers must provide details to the research ethics board about their proposed methods for seeking engagement or consultation.

Application Some genetic research seeks to explore genetic variations within specific groups or communities. Such research may raise ethical concerns regarding stigmatization or exploitation of groups, as well as social disruption in communities, especially if individual members disagree about participation in research. Researchers may have an ethical obligation to seek the engagement of leaders or representatives of the community or to consult with community members about the proposed research. This duty will depend on factors such as the objectives of the proposed research (in particular, the extent to which membership in, or characteristics of, the community are a key aspect of the research), the potential benefits and harms of the research to the community, the nature of the community from which participants will be recruited, and the community’s organizational structure.

Individuals within a community may have conflicting views about participation in research, including disagreements between leaders and members. Such conflicts may involve attempts by some to influence or coerce choices of others about whether to participate in research. Researchers should recognize the potential for conflict within groups and ensure that consent and consultation processes foster free and informed decisions by individual members of a community. Refer to Chapter 3 (“Free and Informed Consent”) for further guidance in regard to voluntariness of consent.

Chapter 9 (“Research Involving Aboriginal Peoples”) articulates specific applications of the principles relevant to research involving Aboriginal peoples, which arise from historical examples of inappropriate treatment of Aboriginal
people in research. Researchers who propose to conduct genetic research within Aboriginal communities or to use materials obtained from Aboriginal peoples and that have implications for Aboriginal peoples should refer to the detailed discussion in that chapter for further guidance.

**F. Genetic Material Banks**

**Article 13.8**  
(a) Researchers who propose research involving prospective collection and banking of genetic material must indicate in their research proposal, and inform potential research participants, how they plan to address the associated ethical issues, including confidentiality, privacy, storage, use of the data and results, withdrawal by the participant, and future contact of participants, families and groups.

(b) Researchers who propose research involving secondary use of previously collected and banked genetic material must, likewise, indicate in their research proposal how they plan to address associated ethical issues.

**Application**  
As discussed in Chapter 12 (“Human Tissue”), collection of human tissues and genetic material and their retention in biobanks provides an increasingly important research resource. Principles for research involving human tissue (see Chapter 12) apply to banking of genetic material. Section C (“Tissue Storage and Banking”) of Chapter 12 provides guidance for prospective creation of biobanks of genetic material, and Section D (“Secondary Use of Previously Collected Tissue”) addresses access to and use of previously collected genetic material. Researchers who intend to bank genetic material should inform participants of the potential for secondary use. Principles regarding secondary use set out in Chapter 5 (“Privacy and Confidentiality”) are also relevant.

**G. Gene Transfer**

Principles set out in Chapter 11 (“Clinical Trials”) apply to clinical trial research involving gene transfer. In the context of gene transfer research, researchers and REBs should pay careful attention to the need to assess safety, minimize risk, and avert therapeutic misconception. Researchers have obligations to share new information that may be relevant to continuing consent, and to follow up with participants to identify adverse events.

**Article 13.9**  
Gene transfer research that involves alteration of human germline cells is governed by statute in Canada under the *Assisted Human Reproduction Act* and its regulations. Researchers must be aware of how these apply to their work.

**Application**  
Gene alteration involves the transfer of genes into cells to induce an altered capacity of the cell. Viruses are commonly used vectors (carriers) to introduce the gene into the host genome. Gene alteration is irreversible: the cell and its descendants are forever altered and introduced changes cannot be removed. The possible use of germline alteration in the embryo implies changes that could be transmitted to future generations.
In other research situations, the special circumstances of gene transfer must be explained to potential research participants (or authorized decision-makers) during the process of free and informed consent. This includes providing information about uncertain and potentially latent risks of gene transfer and any processes for long-term follow up of participants. Principles regarding inclusion in research (see Chapter 4 [“Inclusion in Research”]) should be followed where gene transfer research involves children or others who may lack capacity to consent for themselves.

Scientific research in these areas – and associated ethical debate – is evolving rapidly, and researchers must be aware of current law and also be guided by the core principles of this Policy.

References

- The HumGen database provides a comprehensive source of literature, policies and laws regarding human genetics, including Canadian and international content.
- [http://www.humgen.umontreal.ca/int/](http://www.humgen.umontreal.ca/int/)