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

December 2009

REVISION

Comment Period Closing Date: March 1, 2010
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Acknowledgements

The revised draft 2nd edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) is the distillation of hundreds of comments received in response to the December 2008 draft, both orally and in writing. The Interagency Advisory Panel on Research Ethics (PRE or the Panel) gratefully acknowledges the many members of the research community and the public, including research participants, who took the time to analyze, critique and suggest improvements to the first draft. Their comments have made a significant and positive contribution to this revision.

The Panel wishes to acknowledge the work of former Panel members and to express special appreciation for the continuous support from members of the Interagency Secretariat on Research Ethics, past and present. Their commitment to the evolution of the TCPS has made this draft a reality.
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INTRODUCTION

The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS or the Policy) is a joint policy of Canada’s three federal research agencies – the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada and the Social Sciences and Humanities Research Council of Canada (the Agencies).

This Policy expresses the Agencies’ continuing commitment to the people of Canada to promote the ethical conduct of research involving human participants. It has been informed, in part, by leading international ethics norms, all of which may help, in some measure, to guide the conduct of human research in Canada and by Canadian researchers abroad.

This edition represents the first substantive changes to the Policy since its adoption in 1998. It is a major revision, reflecting over a decade of experience with this Policy by the research community, applying it in response to existing and emerging ethical issues and new areas of research. It also distills the experience of the Interagency Advisory Panel on Research Ethics, which was created in 2001 primarily to steward the evolution and interpretation of this Policy, and to provide the Agencies with independent advice on issues related to the ethics of human research. This edition, which replaces the original TCPS, draws on the advice provided to the Panel by its working groups and committees. As well, it reflects the significant and valuable input from the research community and all those who provided feedback on the draft that the Panel circulated publicly, in December 2008.

**Mandate of the Agencies**

The people of Canada, through Acts of Parliament have created and funded the Agencies to promote and assist research within their respective legislative mandates. In discharging their mandates, the Agencies wish to promote research that is conducted according to the highest ethical standards. The Agencies have therefore adopted this Policy as a benchmark for the ethical conduct for research involving human participants. As a condition of funding, the Agencies require that researchers and their institutions apply the ethical principles and the articles of this Policy and be guided by the applications to the articles.

**Compliance with the Policy**

To be eligible to receive and administer research funds from the Agencies, institutions must agree to comply with a number of Agency policies set out as schedules to a Memorandum of Understanding (MOU) between the Agencies and institutions. (See Memorandum of Understanding on the Roles and Responsibilities in the Management of Federal Grants and Awards at www.nserc-crsng.gc.ca/NSERC-CRSNG/Policies-Politiques/MOURoles-ProtocolRoles/index_eng.asp). This Policy is Schedule 2 to that MOU. Institutions must therefore ensure that research conducted under their auspices adhere to this Policy. Researchers are expected, as a condition of funding, to adhere to the TCPS.
In addition to this Policy on the ethics of human research, institutions and their researchers must adhere to the other policies referenced in the MOU, which include policies on research integrity, peer review and conflicts of interest in research.\(^2\)

Organizations and entities not party to the MOU are welcome to adopt this Policy to guide the ethical aspects of the design, review and conduct of human research. Since the adoption of the original Policy in 1998, many bodies in Canada and abroad have adopted, adapted and been guided by this document. The Agencies hope that this Policy will continue to serve as a model and guide for the ethical conduct of human research.

The Agencies recognize that considerations around the ethical conduct of human research are complex and continually evolving. We therefore welcome comments and discussion, and commit to the continued evolution of this document.

**Endnotes**


\(^2\) Schedules 4, 6 and 14, respectively.
Chapter 1

ETHICS FRAMEWORK

A. The Importance of Research and Research Ethics

The search for knowledge about ourselves and the world around us is a fundamental human endeavor. Research is a natural extension of this desire to understand and to improve the world in which we live.

The scope of research is vast. On the purely physical side, it ranges from seeking to understand the origins of the universe down to 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. For the purposes of this Policy, research is defined as an undertaking designed to extend knowledge through a disciplined inquiry or systematic investigation.

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 human society. In order to maximize the benefits of research, researchers must have certain freedoms. These freedoms include freedom of inquiry and the right to disseminate the results of that inquiry, freedom to challenge conventional thought and freedom from institutional censorship. Collectively, these are generally referred to as “academic freedom.” Along with these freedoms comes the responsibility to make sure that research involving human participants meets high ethical standards that respect and protect the research participants.

Research is a step into the unknown. Because it seeks to understand something not yet revealed, research often entails risks to research participants and others. These risks can be trivial or profound, physical or psychological, individual or social. History offers unfortunate examples where research participants have been needlessly and at times profoundly harmed by research, sometimes even dying as a result. Ethical principles and guidelines play an important role in advancing the pursuit of knowledge while protecting and respecting human participants in order to try to prevent such occurrences.

People have also been gratified and have had their lives enriched by their participation in research, either because they may have benefited directly or because their participation has contributed to the expansion of knowledge. Given the fundamental importance of research and of human participation in research, we must do all that we can as a society to ensure that research is conducted in an ethical manner so as to build public confidence and trust. By promoting and guiding the ethical conduct of research involving humans, this Policy seeks to contribute tangibly to these goals.
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 aims 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

Respect for human dignity has been an underlying value of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS or the Policy) since its inception. Despite clear recognition of its centrality in research ethics, the term lends itself to a variety of definitions and interpretations that make it challenging to apply.

Respect for human dignity requires that research involving humans be conducted in a manner that is sensitive to the inherent worth of all human beings and the respect and consideration that they are due. In this Policy, respect for human dignity is expressed through three core principles – respect for persons, concern for welfare, and justice. These core principles transcend disciplinary boundaries and therefore, are relevant to the full range of research covered by this Policy.¹

Article 1.1 The guidelines in this Policy are based on the following three core principles:

- Respect for Persons
- Concern for Welfare
- Justice

These principles are complementary and interdependent. How they apply and the weight to be accorded to each will depend on the nature and context of the research being undertaken. Specific applications are addressed in the following chapters.

Respect for Persons

Respect for persons recognizes the intrinsic value of human beings and the respect and consideration that they are due. It encompasses the treatment of persons involved in research directly as participants and those who are participants because their data, or human biological or reproductive materials are used in research. Respect for persons incorporates the dual moral obligations to respect autonomy and to protect those with developing, impaired or diminished autonomy.

Autonomy includes the ability to deliberate about a decision and to act based on that deliberation. Respecting autonomy means giving due deference to a person’s judgement and ensuring that they are free to choose without interference. Autonomy is not exercised in isolation but is influenced by a person’s various connections to family, to community, and to cultural, social, linguistic, religious and other groups. Likewise, a person’s decisions can have an impact on any of these.
An important mechanism for respecting participants’ autonomy in research is the requirement to seek their free and informed consent. This requirement reflects the commitment that participation in research, including participation through the use of one’s data, or biological or reproductive materials, should be a matter of choice and that, to be meaningful, the choice must be informed. An informed choice is one that is based on an complete understanding as is reasonably possible of the purpose of the research, what it entails, and its risks and potential benefits, both to the participant and to others.

Certain factors may diminish a person’s ability to exercise their autonomy, such as inadequate information or understanding for deliberation, or a lack of freedom to act due to controlling influences or coercion. Such constraints may include the fear of alienating those in positions of authority, such as professional or personal caregivers, researchers, leaders, larger groups or a community to which one belongs. Other constraints may consist of barriers to accessing resources or knowledge outside the research context. Efforts should be made to eliminate or mitigate such constraints on autonomy where possible. However, in certain research contexts, incomplete disclosure of relevant information or deception may be necessary for the successful conduct of the research. (See Chapter 3, Section B for guidance on the ethical use of partial disclosure and deception).

Some people may be incapable of exercising autonomy because of immaturity, illness or certain mental health issues. While autonomy may be considered a necessary condition for participation in research, involving those who lack capacity can be valuable, just and even necessary. For those potential research participants, additional measures are needed to protect their interests and to ensure that their wishes (to the extent that these are known), are respected. These measures will generally include seeking consent from an authorized third party who is entrusted to make decisions on behalf of the prospective participant, based on knowledge of that person and their wishes or, if such wishes are unknown, consideration of their welfare. Even when the requirements of free and informed consent cannot be met, respect for persons requires involving the vulnerable person in decision-making where possible. This may include asking about their feelings regarding participation and/or for their assent. Where it is foreseeable that a participant may lose capacity during a research project, such as when studying dementia, it may be appropriate to ask research participants to express their preferences and ensure that they have authorized a trusted person to make decisions on their behalf should they lose the capacity to provide ongoing consent. (See Article 3.11 for guidance on research directives for individuals who lack capacity).

Welfare is a holistic concept that refers to how a person or group is faring. The welfare of a person is the quality of that person's experience of life in all its aspects. Welfare is constituted of the impact on persons of such factors as their physical, mental and spiritual health, as well as their physical, economic and social circumstances. Thus, determinants of welfare can include housing, employment, security, family life, community membership, and social participation, among other aspects of life. Other contributing factors to welfare are privacy and the control of information about the person, and the treatment of human biological and reproductive materials according to the expressed or reasonably expected wishes of the person who was the source of the information or materials. A person or group's welfare is also affected by the welfare of those who are important to them. Harm
includes any negative effects on welfare, broadly construed. (For the relationship between risk and harm, see Chapter 2, Section B).

Concern for welfare means that researchers and REBs should aim to protect the welfare of participants, and, in some circumstances, to promote that welfare. To do so, researchers and REBs must ensure that participants are not exposed to unnecessary risks. Researchers and REBs must attempt to minimize the risks associated with answering any given research question. They should attempt to achieve the best possible balance of risks and potential benefits in a proposed research study. Then, in keeping with the principle of respect for persons, participants or authorized third parties make the final judgement about the acceptability of this balance to them.

The welfare of groups can also be affected by research. Groups may benefit from the knowledge gained from the research, but they may also suffer from stigmatization, discrimination or damage to reputation. Engagement during the design process with groups whose welfare may be affected by the research can help to clarify the potential impact of the research and indicate where any negative impact on welfare can be minimized. Researchers must also consider the risks and potential benefits of their research and the knowledge it might generate for the welfare of society as a whole. Where research on individuals may affect the welfare of a group(s), the weight given to the group’s welfare will depend on the nature of the research being undertaken and the individuals or group in question. This consideration does not imply, however, that the welfare of a group should be given priority over the welfare of individuals.

Justice

Justice refers to the obligation to treat people fairly and equitably. Fairness entails treating all people with equal respect and concern. Equity requires distributing the benefits and burdens of research participation in such a way that no segment of the population is unduly burdened by the harms of research or denied the benefits of the knowledge generated from it.

Treating people fairly and equitably does not always mean treating people in the same way. Differences in treatment or distribution are justified when there are morally relevant differences between persons or groups. One important difference that must be considered for fairness and equity is vulnerability. Vulnerability is often caused by limited capacity or limited access to social goods, such as rights, opportunities and power. Vulnerable persons or groups have traditionally included children, the elderly, prisoners, those with mental health issues, and those with diminished capacity for self-determination. Ethnic and racial minorities and those who are institutionalized are other examples of groups who have, at times, been treated unfairly and inequitably in research or have been excluded from research opportunities. In order to treat vulnerable or marginalized persons or groups justly, they may need to be afforded special protections.

The recruitment process, both of participants who may become directly involved in research and those who participate as the source of information, or biological or reproductive materials to be used in research, is an important component of the fair and equitable conduct of research. Participants should be chosen based on inclusion criteria that are justified by the research question and not because they are easy to access or manipulate.
In addition, inequity is created when particular groups fail to receive fair benefits of research or when groups, or their data, or biological or reproductive materials, are excluded from research arbitrarily or for reasons unrelated to the research question.

An important threat to justice is the imbalance of power that often exists in the relationship between researcher and participant. Participants will generally not understand the research in the same way and in the same depth as does the researcher. Historically, there have been instances in which this power imbalance has been abused, with resulting harm to participants.

**Summary**

The respectful treatment that flows from the application of these principles can help to engender the trust of participants, as well as of the public, which is integral to 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 requires both researchers and REB members to navigate a sometimes difficult course between insufficient protection and overprotection of research participants. The three core principles that express the value of human dignity provide the compass for that journey.

**C. How to Apply this Policy**

**Proportionate review**

Proportionality is the approach to ethics review recommended throughout this Policy. (See in particular Articles 2.9 and 6.12). This Policy aims to strike an appropriate balance between recognizing the potential benefits of research and the need to protect participants from research-related harms, broadly construed. Given that research involving humans covers the full spectrum from minimal to significant risks, a crucial 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 risks presented by the research. A reduced level of scrutiny of a research project with minimal risks does not imply a lower level of adherence to the core principles. Rather, the intention is to reduce unnecessary impediments and facilitate the progress of ethical research.

**Research Ethics and Law**

In addition to the principles and guidelines in this Policy, researchers are responsible for ascertaining and complying with all applicable legal and regulatory requirements with respect to consent and the protection of privacy of research participants. (See Chapter 5). These legal and regulatory requirements may vary depending on the jurisdiction in Canada in which the research is being conducted and who is funding and/or conducting the research, and may be comprised of constitutional, statutory, regulatory, common law, and/or international or legal requirements of jurisdictions outside of Canada. Where the research is considered to be a governmental activity, for example, standards for protecting...
privacy flowing from the Canadian Charter of Rights and Freedoms and federal privacy legislation and regulatory requirements would apply.

The law affects and regulates the standards and conduct of research involving humans in a variety of ways, such as privacy, confidentiality, intellectual property, the capacity of research participants as well as in many other areas. Human rights legislation prohibits discrimination on a variety of grounds. In addition, most documents on research ethics prohibit discrimination and recognize equal treatment as fundamental. REBs should also respect the spirit of the Canadian Charter of Rights and Freedoms, particularly the sections dealing with life, liberty and the security of the person as well as those involving equality and discrimination.

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 strive to comply with the law while complying with ethical principles. Researchers should consult with colleagues, the REB or any relevant professional body to help resolve any conflicts between law and ethics, and guide an appropriate course of action. This may include the institution or professional association providing the researcher with access to legal advice, if needed.

This legal context for research involving humans is constantly evolving and varies from jurisdiction to jurisdiction. For this reason, REBs and researchers should be aware of applicable laws to identify legal issues that may occur in the conduct of research. REBs may satisfy this obligation through expertise among their members or through wider consultation. The researcher may seek independent legal advice where necessary.

The perspective of the participant

In designing and conducting research or reviewing the ethics of research, researchers and REBs must be mindful of the perspective of the participant. It may be necessary to consider the context – social, economic, cultural or other – that shapes the participant’s life, to properly evaluate the implications of the research in terms of the core principles.

Appropriate expertise for review

It is also 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. This Policy provides more direction concerning appropriate expertise in Articles 6.4 and 6.5.

Interpreting this Policy

This Policy contains both guidance for the interpretation of the principles of research ethics, as well as a number of mandatory requirements for researchers, institutions and members of REBs. Mandatory provisions are signalled by the use of the term “shall.” Guidance for the interpretation of the core principles are generally indicated by use of the term “should.”

Evaluating the ethics of human research is not, and cannot be, an exact science. The interpretation and application of the articles and principles to particular circumstances will
always be a part of the exercise. The articles in this Policy are intended to provide
guidance, and in some cases, to set out certain requirements. The application sections are
intended to supplement the articles with further explanation and examples. While they
cannot guarantee identical decisions across REBs, they can ensure that researchers and
REBs employing this Policy are operating within the same parameters and taking into
account the same considerations as they design and evaluate human research.

At the end of certain chapters, a section entitled “References” provides links to documents
that contain further guidance on specific topics addressed in the chapter. These references
are not meant to be exhaustive, but are offered to assist the reader who wishes to explore
certain topics in greater detail.

This Policy will continue to evolve in response to the emerging needs and suggestions of all
those whom this Policy is intended to serve, including the research community, participants
and the public.

Definitions

The definitions provided in this Policy are intended specifically and solely for the purposes
of this Policy.

Endnote

1 The three core principles incorporate within them the eight principles set out in the 1998
TCPS. Respect for human dignity is expressed through the three core principles. Respect
for free and informed consent and respect for vulnerable persons are both reflected in the
principle of Respect for Persons, while respect for vulnerable persons is also reflected in
the principle of Justice. Respect for privacy and confidentiality is an element of Concern
for Welfare. Respect for Justice and Inclusiveness is covered in the core principle of
Justice. Balancing Harms and Benefits, Minimizing Harm and Maximizing Benefit are in
fact not principles, but are the means by which the principle of Concern for Welfare is put
into effect. Each of these elements is addressed in greater detail in a chapter or section of
this Policy.

By using these broader and more encompassing core principles, this Policy seeks to provide
a more focused framework for the ethical guidance that follows. It is also a framework that
harmonizes with other national and international ethics policies.
Chapter 2

SCOPE AND APPROACH

The purpose of this Policy, as set out in Chapter 1, 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 – respect for persons, concern for welfare, and justice. 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.

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 Policy.

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

(a) research involving living human participants;

(b) research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells.

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

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

A determination that research is the intended purpose of the undertaking is key for differentiating activities that require review by an REB and those that do not.

For the purposes of this Policy, “human participants” (also referred to as “research...
participants,” or simply, “participants”) are those individuals whose data or responses to interventions, stimuli, or questions by the researcher are relevant to answering the research question.

Human participants are unique among the many parties involved in research, because they bear the primary risks of the research. These individuals are often referred to as “research subjects.” This Policy prefers the term “participant,” because it better reflects the spirit behind the core principles – that individuals who choose to participate in research play a more active role than the term “subject” conveys. As well, it reflects the range of research covered by this Policy, and the varied degree of involvement by participants that different types of research offer.

The core principles of this Policy – respect for persons, concern for welfare, and justice – help to shape the relationship between researchers and research participants.

Where researchers seek to collect, use, share and access different types of information or data about research participants, they are expected to determine whether the information or data proposed in research is identifiable or non-identifiable. Privacy concerns are strongest in regard to information that identifies a specific individual. For the purposes of this Policy, information is identifiable if it, alone or when combined with other information available to the person who receives it, can reasonably be expected to identify an individual. The term “personal information” generally denotes identifiable information about an individual. For further details about the types of information and the spectrum of identifiability, refer to Section A in Chapter 5 of this Policy.

In some cases, research may involve interaction with individuals who are not themselves the focus of the research in order to obtain information. For example, one may collect information from authorized personnel in the ordinary course of their employment about organizations, policies, procedures, professional practices or statistical reports. Such individuals are not considered research participants for the purposes of this Policy.

For the purposes of this Policy, human biological materials include tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva, and other body fluids. Embryo means a human organism during the first 56 days of its development following fertilization or creation, excluding any time during which its development has been suspended, and includes any cell derived from such an organism that is used for the purpose of creating a human being. Fetus means a human organism during the period of its development beginning on the 57th day following fertilization or creation, excluding any time during which its development has been suspended, and ending at birth. Fetal tissue includes membranes, placenta, umbilical cord, amniotic fluid and other tissue that contains genetic information about the fetus. Human reproductive materials mean a sperm, ovum or other human cell or a human gene, and includes a part of any of them. Further details on the above are provided in Chapter 12 of this Policy.
Where in doubt about the applicability of this Policy to a particular research project, the researcher shall seek the opinion of the REB. The REB makes the final decision on exceptions from ethics review.

Research Exempt from REB Review

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

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

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

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

Application For the purposes of this Policy, publicly available information is any existing stored documentary material, records or publications, which may or may not include identifiable information, and that the law treats as publicly accessible or legally accessible to the public with appropriate protections.

Some types of information are legally accessible to the public in a certain form and for a certain purpose, often specified by law or regulations. For example, registries of deaths, court judgments, or public archives and publicly available statistics (e.g. Statistics Canada public use files). All publicly available archives (national, provincial or municipal) have policies governing access to their records. An archival record or database that is subject to restrictions, for example those under access to information and privacy legislation or contractual restrictions imposed by the donor of the records, may nevertheless be considered publicly available for the purposes of this Policy.

To the extent that researchers use this information that is publicly available or legally made publicly accessible REB review is not required. Exemption from REB review is based on the “exclusive” reliance of research on the publicly available information, and where the information is legally accessible to the public a legally designated custodian/steward appropriately guards this information and protects its privacy and proprietary interests.

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

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

There are, however, publicly accessible digital sites where there is a reasonable expectation of privacy. When accessing identifiable information in publicly accessible digital sites, such as Internet chatrooms, and self-help groups with restricted membership, the privacy expectation of contributors of these sites is much higher. Researchers shall submit their proposal for REB review. (See Articles 10.3 and 10.4).

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

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

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

- (a) it does not involve any intervention staged by the researcher or direct interaction with the individuals or groups;
- (b) it does not involve collecting personal information that will be disseminated through photographic, film or video footage in the research results; and
- (c) where individuals or groups targeted for observation have no reasonable expectation of privacy.

**Application** For the purposes of this article, observational research is used to study acts or behaviour in a natural environment. It does not refer to observational methods used in epidemiological studies.

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

Refer to Chapter 10, Articles 10.3 and 10.4, that address the use of
observational methods in qualitative research, including projects involving
digital data collection on the Web.

**Article 2.4** REB review is not required for research that relies exclusively on secondary
use of anonymous information.

**Application** Secondary use refers to the use in research of information originally
collected for a purpose other than the current research purpose. For the
purposes of this Policy, anonymous information is a form of non-identifiable
information that never had identifiers associated with it (e.g. anonymous
surveys).

Rapid technological advances facilitate identification of information and make
it harder to achieve anonymity. Where the researcher seeks data linkage of two
or more anonymous sets of information and there is a reasonable prospect that
this can generate identifiable information, then REB review is required.

Guidance related to other categories of identifiable and non-identifiable
information and secondary use of identifiable information is provided in
Chapter 5.

**Activities Not Requiring REB Review**

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

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

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

Data collected from such activities but used later as part of a research project
would be considered secondary use of information not originally intended for
research. Refer to Section D of Chapter 5 for guidance concerning secondary
use of identifiable information for research purposes.

Article 2.6 Creative practice activities in and of themselves do not require REB review.

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 governed by ethical practices established within
the cultural sector.

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

Relationship between Ethics Review and Scholarly Review

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

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

Traditions for scholarly review vary among disciplines or fields of research,
including the stage at which scholarly review occurs, and this needs to be
taken into account by REBs. The extent of the scholarly review that is
required for biomedical research that does not involve more than minimal
risk will vary according to the research being carried out. Research in the
humanities and the social sciences that poses, at most, minimal risk shall not
normally be required by the REB to be peer reviewed.

REBs should normally avoid duplicating previous professional peer-review
assessments unless there is a good and defined reason to do so. Researchers
have a role to play in demonstrating to their REB whether, when and how
appropriate scholarly review has been or will be undertaken for their
research. REBs may request that the researcher provides them with the full
documentation of reviews already completed.

Where scholarly review is required,

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

- if the scholarly review has not yet been undertaken and is indicated by
  the relevant disciplinary tradition, the REB should consider the
  following mechanisms in satisfying itself that scholarly review of the
  research has been undertaken:

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

**REB Review Shall be Continuing**

**Article 2.8** REB review shall start with an initial review of research that falls within the
scope of this Policy. Ethics review shall continue throughout the life of the
project.

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

Continuing ethics review by an REB provides those involved in the research
process (in particular, researchers, REBs, and participants) with multiple
opportunities to reflect on the ethical issues surrounding the research. This
reflection can show whether the stated risks, or other unknown risks, were
incurred and how they affected the individual and collective welfare of
participants. This reflective practice is intended to enable both researchers
and REBs to be more effective in protecting 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 should involve a continuing dialogue between the
participants, REBs and researchers, as appropriate, to enable the principles
and practices surrounding research ethics to evolve.

In the conduct of their approved research, researchers shall report to their
REB, in a timely manner, departures from the initially approved research,
and events or issues that have ethical implications or that change the risk to
participants.

Further details related to the application of continuing ethics review and the
REB review of departures to approved research are outlined in Articles 6.14
and 6.15.
Chapter 2 – Scope and Approach

B. Approach to REB Review

This section introduces the concepts of risks and potential benefits of research (including a definition of minimal risk), as well as their balance in the conduct and ethics review of research. It addresses the preferred approach where the degree of scrutiny applied to ethics review should be proportionate to the level of risk that the research presents.

Concepts of Risks and Potential Benefits

Potential Benefits

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

Risks

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

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

- The magnitude or seriousness of the harm

Potential harms in research may span the spectrum from minimal (e.g. inconvenience of participation in research) through substantial (e.g. a major physical injury or an emotional trauma). Harms may be transient such as a temporary emotional reaction to a survey question, while other types of harm may be longer lasting, such as the loss of reputation following a breach of confidentiality. Research in certain disciplines, such as epidemiology, genetics, sociology or cultural anthropology, may present risks that go beyond the individual and may involve the interests of communities, societies or other defined groups.

- The probability of occurrence of the harm

This refers to the likelihood of participants actually suffering the relevant harms. An assessment of such probability may be based on the researcher’s past experience conducting such studies, or the review of existing publications that provide rates of the relevant harms in similar issues. And while researchers should attempt to estimate the occurrence of the relevant harms, this may be more difficult, or not possible for new or emerging areas of research where no prior experience, comparable research, or publications exist.
Certain accepted research paradigms bring inherent limitations to the prior identification of risk. For example, when research in the social sciences employs emergent design, the manner in which the study will proceed and any associated risks may be known only as the study unfolds. (See Chapters 3 and 10).

**Minimal Risk**

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

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

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

**Balancing Risks and Potential Benefits**

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

Risks and potential benefits may be perceived differently by different individuals and groups in society. Researchers and REBs should take this into account in designing and reviewing research. They should also recognize that researchers and research participants may not always see the risks and potential benefits of a research project in the same way. In assessing risks and potential benefits for specific populations, researchers and REBs should understand the role of the culture, values and beliefs of the populations to be studied, as well as any guidelines that exist for conducting research with these populations. (See Chapters 8, 9 and 10). Researchers should demonstrate to their REBs that they have a reasonable understanding of the likely effects of their research on the population being studied. This could be demonstrated, for example, by referring to previous experience with conducting research with a similar population, or published research on the effects of that type of research on the population being studied, or the presence of a community advisory group where it exists.

REBs should also be aware that some research, particularly in the social sciences, when conducting critical assessments of, for example, political or corporate institutions, may be legitimately critical and/or opposed to the welfare of those who are the focus of the research, and may cause them some harm. Such research should be carried out according to professional standards of the relevant discipline(s) or field(s) of research, but it should not
be blocked through the use of risk-benefit analysis. In such cases, the balance of risks to
those who are the focus of the research is mainly weighed against the potential benefit of
new knowledge to society and the indirect benefits to the population to which the
participant belongs.

**Article 2.9** The REB shall adopt a proportionate approach to ethics review such that the
lower the level of risk, the lower the level of scrutiny; the higher the level of
risk, the higher the level of scrutiny. The expertise involved in the ethics
review process should be proportionate to the risk of research to participants.

**Application** While all research shall be reviewed in adherence with the core principles,
proportionate review is intended to direct the most intensive scrutiny, time and
resources, and correspondingly, the most protection, to the most ethically
challenging research. A proportionate approach to ethics review starts with an
assessment of the magnitude and probability of harms, and potential 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.

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

**Risks to Researchers**

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

While it is not a formal part of its responsibilities, an REB may raise concerns about the
safety of student researchers as part of its communication to the student researchers, and to
their supervisors. Based on the level of risk, the REB may consider flagging such concerns
for review by an appropriate body within the institution.
Chapter 3

CONSENT

This chapter sets out the ethical requirements for consent in research involving humans. Throughout this Policy, the term “consent” means “free, informed and ongoing consent.” In general, participation should be based on consent that is voluntary, informed, and ongoing throughout the duration of the research. For the purpose of this Policy, “free” and “voluntary” are used interchangeably.

Respect for persons 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. Where a person has the capacity to understand this information, and the ability to act on it voluntarily, the decision to participate is generally seen as an expression of autonomy.

Equally, respect for persons implies that those who lack the capacity to decide for themselves should nevertheless have the opportunity to participate in research that may benefit themselves or others, through the intervention of authorized third parties who decide whether participation would be appropriate. For the purposes of this Policy, the term “authorized third party,” (also known as “authorized third party decision makers”) refers to any person with the necessary legal authority to make decisions on behalf of an individual who lacks the capacity to consent to participate or to continue to participate in a particular research project. These decisions involve considerations of welfare and justice.

Certain types of research require alternate processes for consent. These are also described in this chapter. Where elements of the consent process may need to be adapted to the requirements of a particular research project, the research ethics board (REB) can play an educational and consultative role in determining the appropriate process for seeking and maintaining consent.

The principal researcher is responsible for ensuring that the consent process is respected. This includes responsibility for the actions of the research team who are involved in the consent process.

In addition to this Policy, researchers are responsible for ensuring that all applicable legal and regulatory requirements with respect to consent are met. In some circumstances, researchers may have further legal obligations that may be determined in part by the nature of the research and the jurisdiction in which the research is being conducted.

A. General Principles

Consent Shall Be Given Voluntary

Article 3.1 (a) Consent shall be given voluntarily.
(b) Consent may be withdrawn at any time.

(c) If a participant withdraws consent, he or she can also request the withdrawal of his or her data or biological materials.

Application  
(a) The voluntariness of consent is important because it means that an individual has chosen to participate in research according to his or her own values, preferences and wishes.

The approach to recruitment is an important element in assuring voluntariness. In particular, how, when and where participants are approached and who recruits them are important elements in assuring (or undermining) voluntariness. In considering the voluntariness of consent, REBs and researchers should be cognizant of situations where undue influence, coercion, or the offer of incentives may undermine a participant’s voluntariness to consent to participate in research.

Undue Influence

Undue influence and manipulation may arise when potential participants are recruited by individuals in a position of authority. The influence of power relationships on the voluntariness of consent should be judged from the perspective of prospective participants, since the individuals being recruited may feel constrained to follow the wishes of those who have some form of control over them (e.g. employer and employees, teachers and students, commanding officers and members of the military or correctional officers and prisoners). This control may be physical, psychological, financial, or professional, for example, and 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. At the extreme, there can be no voluntariness if consent is secured by the order of authorities.

REBs should also pay particular attention to elements of trust and dependency in relationship (e.g. between physician and patient or between professor and student). These relationships can impose undue influence on the individual in the position of dependence to participate in research projects. Any relationship of dependency, even a nurturing one, may give rise to undue influence, even if it is not applied overtly. There may be a greater risk of undue influence in situations of ongoing or significant dependency.

Pre-existing entitlements to care, education and other services should not be prejudiced by the decision of whether or not to participate in or to withdraw from a research project. Accordingly, for example, a physician should ensure that continued clinical care is not linked to research participation.

Coercion

Coercion is a more extreme form of undue influence, involving a threat of harm or punishment for failure to participate. Coercion would negate the voluntariness of a decision to participate or to remain in a research study.
Incentives

Incentives are anything offered to participants, monetary or otherwise, for participation in research (incentives differ from reimbursements and compensation for injury, which are discussed in Article 3.2[j] below). Because incentives are used to encourage participation in a research project, they are an important consideration in assessing voluntariness. Where incentives are offered to participants, they should not be so large or 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 11.6. The offer of incentives in some contexts may be perceived by potential participants as a way to gain favour or improve their situation. This may amount to undue inducement and thus negate the voluntary aspect of the consent of participants.

This policy neither recommends nor discourages the use of incentives. The onus is on the researcher to justify to the REB the use of a particular model and the level of incentives. In considering the possibility of undue influence in research involving financial or other incentives, researchers and REBs should be sensitive to issues such as the economic circumstances of those in the pool of prospective participants, the age and capacity of participants, the customs and practices of the community and the magnitude and probability of harms. (See Chapter 4, Section D). Guardians and authorized third parties should not receive incentives.

(b) To maintain the element of voluntariness, the participant shall be free to withdraw their consent to participate from the research at any time and need not offer any reason for doing so. In some cases, however, the physical practicalities of the study may prevent the actual withdrawal of the participant partway through – for example, if the study involves only a single intervention or the termination of the research procedure may compromise the safety of the participant.

The participant should not suffer any disadvantage or reprisal for withdrawing nor should any payment due prior to the point of withdrawal be withheld. If the study used a lump-sum incentive for participation, the participant is entitled to the entire amount. If a payment schedule is used, the participant should be paid in proportion to his or her participation.

(c) Once they have withdrawn their consent to participate, participants may request the withdrawal of their data or biological materials\(^2\). In some research studies, the withdrawal of data or biological materials may not be feasible – for example, when personal information is de-identified and added to a data pool. As part of the consent process, participants should be informed when they are entering a study that it may not be feasible to withdraw data or biological materials.
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Consent Shall Be Informed

Article 3.2 Researchers shall provide to prospective participants or authorized third parties full disclosure of all information necessary for making an informed decision to participate in a research project.

Application At the commencement of any process of consent, researchers or their qualified designated representatives shall provide prospective participants with the information set out in the following list, as appropriate to the particular research project. Not all the listed elements are required for all research. However, additional information may be required in particular types of research or under particular circumstances.

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 listed or additional elements are necessary in a given research project.

The information generally required for informed consent includes:

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

(b) a statement of the research purpose in plain language – 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 plain language description of reasonably foreseeable risks and potential benefits, both to the participants and in general, that may arise from research participation;

(d) an assurance that prospective participants:

- are under no obligation to participate; are free to withdraw at any time without prejudice to pre-existing entitlements;

- will be given, throughout the course of the research, in a timely manner, information that is relevant to their decision to continue or withdraw from participation; and

- will be given information on the participant’s right to request the withdrawal of data or biological materials including any limitations on the feasibility of that withdrawal;

(e) information concerning the possibility of commercialization of research findings, and the presence of any real or potential conflict of interests 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;
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845  (g) the identity of the qualified designated representative with contact
846  information who can explain scientific or scholarly aspects of the
847  research;
848  
849  (h) information identifying the appropriate individual(s) with contact
850  information outside the research team to contact regarding possible
851  ethical issues in the research;
852  
853  (i) an indication of who will have access to information collected on the
854  identity of participants, descriptions of how confidentiality will be
855  protected, and anticipated uses of data; and information on who may
856  have a duty to disclose information collected and to whom;
857  
858  (j) information on any payments, including incentives for
859  participants, reimbursement for participation-related expenses and
860  compensation for injury;
861  
862  (k) a statement to the effect that, by consenting, participants have not
863  waived any rights to legal recourse in the event of research-related
864  harm; and
865  
866  (l) in clinical trials, information on stopping rules and when researchers
867  may withdraw participants.
868  
869  For consent to be informed, prospective participants should have adequate
870  time and opportunity to assimilate the information provided, pose any
871  questions they may have and discuss and consider whether they will
872  participate. The time required for this initial phase of the consent process will
873  depend on such factors as the magnitude and probability of harms, the
874  complexity of the information conveyed and the setting where the
875  information is given.
876  
877  The key to informed consent is that potential participants understand the
878  information being conveyed to them by researchers. Researchers and REBs
879  should consider how best to convey that information to facilitate
880  understanding. For example, written documentation may be supplemented
881  with visual aids or accompanied by video presentations.
882  
883  When language barriers necessitate the use of an intermediary for
884  communication between the research team and participants the researcher
885  should use an intermediary who has the necessary language skills to ensure
886  effective communication. (See Article 4.1).
887  
888  Paragraphs (a) to (c) require researchers to clearly explain the nature and goals
889  of the research and other essential information, in a manner that best promotes
890  understanding on the part of potential participants.
891  
892  Paragraph (b) requires disclosure of those who support a particular research
893  project, through funding or sponsorship. It is unethical for researchers to engage
894  in covert activities for intelligence, police or military purposes under the guise
of research. Conducting clandestine research or deliberately misrepresenting one’s research goals and impact to research participants is a clear violation of this policy. There are circumstances where deception may be a legitimate part of the research. (See Article 3.7 and its application, Research Involving Partial Disclosure or Deception).

Paragraph (c) requires researchers to consider all reasonably foreseeable risks that may result from participation. For example, when research is conducted on an organization or a community, researchers should inform potential participants within that organization or community the extent to which the organization or community is collaborating with the research and any risk this may pose to the participant.

Paragraph (d) helps to ensure the effectiveness of Article 3.1 – that a prospective participant’s choice to participate is voluntary. Paragraph (d) also supports the requirement that the consent process continue throughout the research.

Paragraph (e) aims at managing real or potential conflicts of interests. 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 interests matters are further elaborated in Chapter 7.

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, to the extent that it is feasible and in a manner that is appropriate. Beyond the ethical obligation to do so in such areas as 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 (addressed further in Articles 11.12 and 11.13).

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 (i) touches on issues of privacy and confidentiality, and secondary use of data, which are addressed in Chapter 5.

Paragraph (j) ensures that participants are informed of the payments they will receive, if any, for their participation. Reimbursement for participation-related expenses is intended to ensure that participants are not put at a direct or indirect financial disadvantage for the time and inconvenience of participation in research. Direct expenses are costs incurred because of research participation (e.g. paying for transportation to or parking at the research site) while indirect expense refers to losses that arise from participation (e.g. taking unpaid leave from work). Participants should also be informed about any compensation they
may be entitled to for research-related injuries.

Paragraph (l) is intended to inform the prospective participant in clinical trials of circumstances under which the researcher may end the participant’s involvement in a research project. Clinical trials have stopping rules – statistical points determined in advance, which, once reached, dictate that the trial must be terminated. As well, researchers may withdraw participants when the participants are not following the procedures of the clinical trial. These are discussed further in Chapter 11.

Consent Shall be an Ongoing Process

Article 3.3 Consent shall 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 consent to participate in the research. The researcher has an ongoing ethical and legal obligation to bring to the participant’s attention changes that have ethical implications or that may be germane to their continued participation in the research or to the particular circumstances of the participant. In particular, researchers should disclose changes to risks or potential benefits of the research. This gives the participant the opportunity to reconsider the basis for his or her consent in light of the new information.

Incidental Findings

Article 3.4 Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research.

Application “Incidental findings” is a term that describes unanticipated discoveries made in the course of research but that are outside the scope of the research. Material incidental findings are findings that have been interpreted as having significant welfare implications for the participant, whether health-related, psychological or social. If, in the course of research, material incidental findings are discovered, researchers have an obligation to inform the participant.

In some areas of research, such as medical and genetic research, there is a greater likelihood of material incidental findings. For research where material incidental findings are likely, researchers should develop a plan indicating how they will disclose such findings to participants and submit this plan to the REB. If there is uncertainty as to whether a research project warrants a plan, the researcher and REB can make such a determination on a case-by-case basis.

If researchers are unsure of how to interpret findings, or uncertain whether findings are material, they should consult with colleagues or refer to standards in the discipline. If researchers are unsure of the most appropriate method for disclosing material incidental findings to participants, they should consult with their REB or with colleagues. In some cases, incidental findings may trigger legal
reporting obligations – researchers should be aware of these obligations. (See Article 5.1).

Consent Should Precede Collection of or Access to Research Data

Article 3.5 In general, research should begin only after the participants or their authorized third parties have provided their consent.

Application In keeping with the principle of respect for persons, participants should provide their consent prior to engaging in research. This is the clearest demonstration that their participation is based on consideration of the risks and potential benefits of the research and other principles in this Policy. There are exceptions to this general ethical requirement, however, set out below in Articles 3.7 and 3.8.

This article does not apply to conversations that researchers 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, Article 6.11, Articles 9.3 to 9.6, and 10.1).

Critical Inquiry

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

Application Research in the form of critical inquiry, that is, the analysis of social structures or activities, public policies or other social phenomena, requires an adjustment in the assessment of consent. Where the goal of the research is to adopt a critical perspective with respect to an institution, organization or other entity, the fact that the object of the research may not endorse the research should not be a bar to the research receiving ethics approval. Where social sciences or humanities researchers seek knowledge that critiques or challenges the policies and practices of institutions, governments, interest groups or corporations may require that researchers not seek the organization’s permission to proceed with the proposed research. 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. Specific requirements pertain to Aboriginal organizations, the details of which are discussed in detail in Articles 9.4 - 9.8.

REBs should not prohibit research simply because the research is unpopular or looked upon with disfavour by a community or organization, in Canada or abroad. Similarly, REBs should not veto research on the grounds that the government in place or its agents have not given approval for the research project or have expressed a dislike of the researchers.
However, individuals who are approached to participate in a research project about their organization should be fully informed about the views of the organization regarding the research, if these are known, and of the possible consequences of participation. 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.

REBs should, however, legitimately concern themselves with the welfare of research participants and the security of research materials in such circumstances. When copies of field material are provided to participants in situations in which participants are vulnerable to risks from third parties on account of their participation, researchers should concern themselves with commitments concerning anonymity and confidentiality of participants to ensure that the human rights of participants and the ethical principles set out in this Policy are not compromised. In general, regardless of where the researchers conduct their research, researchers and REBs should concern themselves with safeguarding information while in transit. (See Articles 5.1 through 5.4).

B. Departures from General Principles of Consent

Alteration and Waiver of Consent in Minimal Risk Research

Article 3.7 The REB may approve a consent procedure that does not include or that alters some or all of the elements of consent or may waive the requirement to seek informed consent, provided that the REB finds and documents that all of the following apply:

(a) the research involves no more than minimal risk to the participants;
(b) the alteration or waiver is unlikely to adversely affect the welfare of the participants;
(c) it is impossible to carry out the research and to answer the research question properly, given the research design, without the alteration or waiver;
(d) whenever possible and appropriate, the participants will be debriefed and provided with additional pertinent information after participation or at a later time during the study; and
(e) the altered or waived consent does not involve a therapeutic intervention, or other clinical or diagnostic interventions.

Application In the circumstances described under Article 3.7, the nature of the research may justify a limited or temporary departure from the general requirement for 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
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the research justifies a limited or temporary exception to the general requirements in a particular case.

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 third parties 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. Some types of research can be carried out only if the participants do not know in advance the true purpose of the research. For example, some social science research that critically probes the inner workings of publicly accountable institutions might never be conducted without limited recourse to partial disclosure. 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 research and/or its purpose. For such techniques to fall within the exception to the general requirement of full disclosure for consent, the research must meet the requirements of Article 3.7.

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 3.7(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 consent has been allowed, it may still be possible for participants to express their consent or refusal at the conclusion of the study, following debriefing. In cases where a participant expresses concerns about participation in a study, the researcher may give the participant the option of removing his or her data from the project. 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, and justify why these conditions are essential for conducting the research. Where under the terms of the research proposal the participants are not permitted to withdraw their data, the identity of the participant shall be protected. Participants who express concern about the conduct of the study at the time of debriefing or who contest the limits imposed on withdrawing their data should be given contact information for the REB that approved the research.

Consent in Individual Medical Emergencies

This section addresses the exception to consent in situations where an individual who requires urgent medical care is unable to provide consent due to loss of consciousness or capacity, and the delay to seek 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. For guidance on research ethics review during a publicly declared emergency see Articles 6.21 and 6.22.

Article 3.8 Subject to all applicable legal 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 REB. The REB may allow research that involves medical emergencies to be carried out without the 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 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 the risks, methods and purposes of the research;

(e) third-party authorization cannot be secured in sufficient time, despite
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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, 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 3.8 outlines an exception, in addition to that in
Article 3.7, to the general obligation of seeking consent from those
participating in research.

It is the responsibility of researchers to justify to the REB the need for recourse
to this exception. The underlying assumption of Article 3.8 is that the
participant could not receive the direct benefits of the research without
foregoing the consent of the participant or of his or her authorized third party.
Article 3.8 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.

It is unethical to expose participants to any additional risk without their 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 3.8 indicate that researchers and
REBs must satisfy the requirements of clinical equipoise and assess the risks and
potential benefits of proposed research against existing standard efficacious care.

To respect the autonomy of the research participant, Article 3.8(e) requires
researchers to undertake diligent efforts to contact authorized third parties, if
reasonably feasible, and to document such efforts for the benefit of both the
participant and for the continuing review functions of the REB. The article also
requires that research participants who regain capacity be promptly afforded the
opportunity to consent concerning continued participation. Concern for the
patient’s welfare is paramount and should be informed by ethical and
professional judgment.

Because their incapacity to exercise consent makes them vulnerable, prospective
participants for emergency research are owed special ethical obligations and
protection commensurate with the risks involved. Their 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 seek 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 or actual 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 determination of capacity to participate in research, then, is not a static determination but a process that may change over time, depending on the nature of the decision the potential participant needs to make and changes in the participant’s condition. Assessing capacity is a question of determining, at a particular point in time, whether a research participant (or potential 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. Researchers should be aware of all applicable legal and regulatory requirements with respect to capacity. These vary among jurisdictions. Authorized third parties should also be aware of their legal responsibilities.

In keeping with the principle of justice, ethical considerations around research involving those who lack the capacity to 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 potential benefits of research. (See Chapter 4).

As indicated in Chapter 1, respect for persons and concern for welfare 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 consent to participate in particular research projects.

Article 3.9 For research involving individuals who lack the capacity, either permanently or temporarily, to decide for themselves whether to participate, the REB shall ensure that, as a minimum, the following conditions are met:

(a) the researcher should seek 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’ welfare will be protected;

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

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

(d) when authorization for participation was granted by an authorized third party, and the participant acquires or regains capacity during the course of the research, the researcher shall promptly seek the participant’s consent as a condition of continuing participation.

Application The decision of authorized 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 interests when making their decision.

Article 3.9 outlines other safeguards to protect those who lack the capacity to consent to participation in research. The article details various considerations relevant to the use of third-party authorization. Beyond the legal and regulatory requirements for seeking consent from authorized third parties, family members and friends may provide information to the authorized third party about the interests and previous wishes of prospective participants.

**Article 3.10** Where an authorized third party has consented on behalf of a person who lacks legal capacity, but that person has some ability to understand the significance of the research, the researcher shall ascertain the wishes of that person with respect to participation. The potential participant's dissent will preclude his or her participation.

**Application** Many individuals who lack legal capacity to make decisions may still be able to express their wishes in a meaningful way, even if such expression may not fulfill the requirements for 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 autonomous decision regarding consent but whose capacity is diminishing or fluctuating; 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 or signs suggesting dissent must be respected.

**Research Directives For Individuals Who Lack Capacity**

Although advance directives for treatment are recognized as a legitimate tool in health care, the use of directives in the context of research is not well developed and have no legal status. For the purposes of this Policy, research directives should be understood to express an individual’s preferences for participation in future research in the event that the individual loses capacity. Research directives are written instructions to be used by the authorized third party as information on a potential participant’s preferences when the third party is asked to provide substitute consent.

The efficacy of research directives is unknown and their legal status has not yet been recognized or tested. Research directives, nevertheless, are congruent with this Policy’s core principle of respect for persons. The use of research directives respects the right of individuals to express their preference regarding participation in research and respects privacy by allowing individuals to control information about themselves and materials from...
their bodies. Authorized third parties should consult with an individual’s research directive when making decisions about their involvement in research.

**Article 3.11** Research directives allow individuals with capacity to express preferences about their future participation in research should they ever lose capacity. Researchers and authorized third parties should take these directives into account during the consent process, but only if the individual who provided the research directive lacks capacity at the time the research is initiated.

**Application** Research directives are useful to individuals who are already participating in research as well as those who are not participating but may wish to participate in research at a later date. They give individuals a range of options regarding future participation in research. The use of research directives is particularly relevant for research involving participants with diminishing capacity, fluctuating capacity, or degenerative conditions and research that collects information or human biological materials.

The use of research directives does not alter the requirements for consent as articulated by the provisions of this Policy. In particular, in accordance with Article 3.9, researchers are required to seek the consent of authorized third parties before individuals who lack capacity can participate in research. If an individual regains capacity the researcher should promptly seek the consent of the individual as a condition of continuing participation.

Researchers, institutions and organizations may suggest the use of research directives in order to give participants an opportunity to express preferences about the use of information or material that has already been collected. Researchers who collect information or human biological materials for a specific research project may anticipate subsequent research uses. Some types of research initiatives (research platforms) involve long-term retention and use of information or human biological materials for research purposes (e.g. longitudinal studies that involve biobanking). These platforms typically cannot specify at the time of initial collection every study that could be carried out using the participants’ information or human biological materials. Research directives may be used in these contexts to give participants the opportunity to express their preference about future research should they lose capacity.

In long-term studies, research directives may be used to allow participants to make choices about other aspects of research participation. For example, participants could specify preferences about receiving findings or continuing use of information or samples if the participant loses capacity or upon death.

Individuals can also use research directives to express preferences concerning participation in future research. For example, individuals in an early stage of dementia may use a research directive to express their preferences for future participation in research that, due to diminishing capacity, they would not otherwise be able to consent to on their own. They also allow existing participants to express their preference to continue to...
participate in research should they lose capacity. Research directives should be as specific as possible and in the event of ambiguity or imprecision, should be interpreted narrowly.

D. Consent Shall Be Documented

Article 3.12 Evidence of consent shall be contained either in a signed consent form or in documentation by the researcher of other means of consent.

Application Written consent through a signed statement from the participant is a common means of demonstrating consent, and in some instances, is mandatory (e.g. Health Canada regulations under the Food and Drugs Act, the Quebec Civil Code). There are other means of providing consent that are equally ethically acceptable however. In some types of research, and for some groups or individuals, written consent may be perceived by some research participants as an attempt to legalize or formalize the consent process and thus may be interpreted as a violation of trust. In these cases, oral consent, a verbal agreement or a handshake may be required, rather than signing a consent form. In some cultures, the giving and receiving of gifts symbolizes the establishment of a relationship comparable to consent.

Where consent is not documented in a signed consent form, researchers use a range of consent procedures, including oral consent, field notes, and other strategies, for documenting the consent process. Consent may also be demonstrated solely by the actions of the participant – for example, through the return of a completed questionnaire. Where there are valid reasons for not recording consent in writing, the procedures used to seek consent must be documented. (See Article 10.2).

Whether or not a consent form is signed, it may be advisable to leave a written statement of the information conveyed in the consent process with the participant. For the participant, it is evidence of the fact that he or she has agreed to participate in a particular research project. 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. However, researchers should not leave any documentation with a participant if it may compromise their safety or confidentiality. Additionally, 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.

Endnotes

1 For example, see Article 21 of the Civil Code of Québec, which sets conditions for the conduct of research involving minors or adults who lack the capacity to consent.

2 The term “human biological materials” may be considered, for the purposes of most of this Policy, to include materials related to human reproduction. The last Section of Chapter 12 discusses ethical issues specific to such materials.
Chapter 4

FAIRNESS AND EQUITY IN RESEARCH PARTICIPATION

A. Introduction

The principle of justice holds that particular individuals, groups, or communities 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 an important consideration for researchers, research ethics boards (REBs), research institutions and sponsors. Issues of fair and equitable treatment arise in deciding whether and how to include individuals, groups or communities in research, the basis for exclusion of some, and social justice issues such as how research differentially impacts groups and communities in society.

This chapter addresses inclusion in research of individuals and groups that might be inappropriately excluded on the basis of attributes such as culture, language, gender, race, ethnicity, age and disability. It provides guidance relevant to inclusion in research of certain groups such as women, children, the elderly, and those who lack capacity to consent to participate in research. Historically, these groups have been inappropriately excluded from research. This chapter also addresses the fair inclusion and equitable treatment of individuals and communities whose situation or circumstances makes them vulnerable in the context of a specific research project. Such individuals run the risk of being included in research in ways that may be unfair and inequitable.

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. In a community hosting the research, benefits may take the form of information sharing, training for local personnel, the establishment of health care or similar services. Benefits may be indirect, where an individual’s research participation or a study involving a community contributes to advancement in knowledge that may lead to improved conditions for a group to which the participant belongs. Such knowledge may inform other communities or society in general.

Over-protectionist attitudes or practices of researchers or REBs, whether intentional or inadvertent, exclude some members of society or communities from participating in research, and may therefore fail to treat those individuals or communities justly. 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 to ensure treatments that are frequently given to the young and the elderly are effective and safe in these populations.

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.
Researchers and REBs must navigate between the dangers of imposing unfair burdens on particular research participants, groups, and communities and overprotecting them.

B. Appropriate Inclusion

Article 4.1 Taking into account the scope and objectives of their research, researchers should be inclusive in selecting research participants. Researchers shall not exclude individuals from the opportunity to participate in research on the basis of attributes such as culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender or age, unless there is a valid reason for the exclusion.

Application Article 4.1 is based on the principle of justice. It imposes a duty on researchers not to exclude individuals or groups from participation for reasons that are unrelated to the research. Groups have been inappropriately excluded from participation in research on the basis of attributes such as gender, race, ethnicity, age and disability.

The focus, objective, nature of research and context in which the research is conducted inform the inclusion and exclusion criteria for a specific research project or study. Some research may be focused on a certain individual (such as in a biography) or 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, or research focused on certain cultural traditions or languages). Such research should not be precluded so long as the selection criteria for those to be included in the research are germane to answering the research question. Researchers who plan to actively exclude particular groups should clarify to their REBs the grounds for the exclusion.

Where a language barrier exists between the researcher and the potential participant, various measures may be used to ensure effective communication between them in recruitment and consent discussions. For example, an intermediary who may not be part of the research study or team, but who is competent in the language used by the researchers as well as that preferred by the research participant, may assist with communication between potential participants and researchers. The selection of the intermediary and the intermediary’s activities will depend on the nature, context, and risks of the research.

C. Inappropriate Exclusion

Research Involving Women

Women have historically been inappropriately excluded from participating in some research. This exclusion of women, where unwarranted, has delayed the advancement of knowledge, denied potential benefits to women, and exposed women to harm when research findings from male-only studies have been generalized inappropriately to women,
as has often been the case in clinical drug trials, for example. The inclusion of women in research advances the commitment to justice, 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 4.2** Women shall not be inappropriately excluded from research solely on the basis of gender or reproductive capacity.

**Application** While some research is properly focused on particular research populations that do not include women or include very few women, women should generally be represented where there is a reasonable expectation that the results of the research will be generalized to women.

Article 4.2 rejects discriminatory and unethical use of inclusion or exclusion criteria that presumptively or inappropriately exclude women because of their gender or reproductive capacity. In considering research on pregnant or breastfeeding women, researchers and REBs shall, however, take into account risks and potential benefits for the woman and her embryo, fetus or infant.

**Research Involving Children**

Children have varying degrees of maturity, metabolically, immunologically and cognitively, which presents important challenges for research design and consent, depending on the nature and complexity of the research. In addition to vulnerability that arises from their developmental status, children may also lack capacity to consent to participate in research. (See Article 4.5). As well, physical or psychological harms a child may experience in a research setting may have long-lasting consequences. As a result, researchers have often simply avoided the inclusion of children in some research, especially in clinical trials testing new treatments, so as to eliminate any risks. The result is a generally poor understanding of how the results of clinical trials conducted with adults only apply to children.

As is the case with women, the inclusion of children in research advances the commitment to justice in research by improving our knowledge of, and ability to respond to, the unique needs of children throughout their development.

**Article 4.3** Children shall not be inappropriately excluded from research solely on the basis of their age or development status.

**Application** Researchers should not automatically exclude children from research, unless there is a valid reason for doing so. When considering the inclusion of children in research, researchers and REBs shall consider a child’s stage of physical, physiological, psychological and social development to ensure adequate protections for the child’s welfare. Where children have not yet attained the capacity to consent for themselves to participate in research, researchers shall seek consent from an authorized third party while ascertaining the child’s assent or dissent, as outlined in Chapter 3. Note that Article 4.5 equally applies to children.
As the population ages, the proportion of elderly people is increasing and so is their life-expectancy. Research designed to improve our understanding of a wide range of aspects of aging and the lives of elderly people is important for ensuring that they stay fully integrated into society and maintain a continuing high quality of life. Medically, elderly patients are the highest consumers of drugs, yet many of these treatments have not been tested adequately on elderly patients. Research that takes into account the differential effects on the elderly and how best to accommodate their needs provides scientific evidence that can inform changes to policies and standards of care for the elderly.

**Article 4.4** Elderly people shall not be inappropriately excluded from research solely on the basis of their age.

**Application** REBs and researchers should ensure that elderly people are not automatically excluded from research unless there is a valid reason for doing so. When considering the inclusion of elderly people in research, researchers and REBs shall consider their physical and social needs to ensure adequate protections. Depending on their social circumstances, elderly people may require some reasonable accommodation for mobility, transportation support, and other types of assistance that would otherwise preclude their participation in research. The principle of justice requires that such accommodations for the natural processes of aging be considered by REBs and researchers to ensure that exclusion of the elderly is not based on easily remediable issues that are not germane to the research question.

**Research Involving Participants Who Lack the Capacity to Consent for Themselves**

The core principles of justice and concern for welfare entail special ethical obligations toward individuals who lack capacity to consent to participate in research. This section sets out conditions that apply to research involving those who cannot consent for themselves. It should be read in conjunction with Section C of Chapter 3.

**Article 4.5** Subject to conditions in Articles 3.9 and 3.10, individuals who lack capacity to consent to participate in research shall not be inappropriately excluded from research. Where a researcher seeks to involve individuals in research who do not have capacity to consent for themselves, the researcher shall satisfy the REB that:

(a) the research question can be addressed only with participants within the identified group; and

(b) the research involves minimal risk or a minor increase above minimal risk with appropriate justification; and

(c) the research maintains an appropriate balance of risks commensurate with the potential to provide direct benefits to the participants or the relevant group to which they belong.
Application

Individuals with cognitive impairments or intellectual disabilities and children may lack capacity to consent to participate in particular research initiatives. As a result, they have, historically, experienced both over-inclusion as populations of convenience for some research, and also unjustified exclusion from other research. Yet the advancement of knowledge about their social, psychological and health experiences and needs may depend on their appropriate participation in research. Their inclusion in research requires special considerations as outlined in this article.

To be ethically acceptable, the participation of those who lack capacity to consent for themselves shall be necessary and appropriate to address the research question. Researchers and REBs shall consider the level of risk to which participants who lack capacity to consent are exposed, and the potential for benefits accruing directly to the participants or to a group to which they belong. Their participation should generally be limited to research of minimal risk as defined in this Policy (see Chapter 2 for the definition of minimal risk). The prospect of benefits for participants should be commensurate with the level of risk entailed by the research.

Where the research entails only minimal risk, it should at least have the potential to provide benefits to participants or to a group to which they belong. Where the research presents a minor increase above minimal risk, it should have appropriate justification and the potential for direct benefits for the participants themselves. Where the research presents a minor increase above minimal risk but no prospect for direct benefits to the participants themselves, it should have the potential to yield generalizable knowledge that is likely to benefit the population from which the participants are recruited.

The research design should take into account factors that may affect the capacity of potential research participants to receive information, to consent to the research at some stage or to participate in it. These factors may be permanent or may vary over time. The participant’s capacity to consent may fluctuate over time. Articles 3.9 and 3.10 in Chapter 3 establish other conditions regarding research that involve individuals who lack capacity to consent. This includes the involvement of an authorized third party to consent on their behalf, and adequate provisions to ascertain the wishes of the individuals concerning their participation.

D. Inappropriate Inclusion

The core principles of respect for persons and concern for welfare entail special ethical obligations toward individuals or groups whose circumstances may lead to their vulnerability in the context of a specific research project or study and limit their ability to fully safeguard their own interests. These may include individuals who are institutionalized, those in dependent situations, or those whose circumstances, such as poverty or poor health status, may render even modest incentives to participate so attractive as to constitute an inducement to take risks they would otherwise not take. Their situation may also compromise the voluntariness of consent in other ways. However, such individuals should
not automatically be considered vulnerable simply because of assumptions about the vulnerability of the group to which they belong. Their particular circumstances shall be considered in the context of the proposed research project.

**Article 4.6** Individuals or groups whose circumstances may make them especially convenient for researchers to recruit into research projects shall not be included in research solely on the basis of these convenient circumstances.

**Application** REBs and researchers shall carefully examine the relationship between the circumstances of the individuals and communities they aim to recruit and the research questions they aim to answer. They should not presume that these circumstances will either automatically preclude or qualify individuals or communities for participation. Researchers and REBs should recognize and address changes in a participant’s circumstances that may create, heighten or attenuate their vulnerability and provide special protections or consideration. This may be the case for individuals or communities who are vulnerable to abuse, unfair treatment or discrimination.

In general, researchers should be familiar with the cultural, social and economic circumstances of prospective individual research participants or host communities. Researchers should anticipate, to the best of their ability, needs of participants and their communities that might arise in any given research project. Especially when participants and their communities have a wide range of pressing needs as a result of their low socioeconomic circumstances, these needs can present significant ethical challenges for researchers.

Researchers should also be sensitive to the expectations and opinions of participants regarding potential benefits of the research, and, where possible, they should arrive at agreements with the community about the scope and nature of the potential 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 to better ensure balance in the relationship between researchers and participants and mutual benefit in researcher-community relations. (See Article 9.13 on mutual benefits in collaborative research as it pertains to research involving Aboriginal peoples in Canada).

Researchers shall ensure that any potential benefits for participants or their communities are not only commensurate with the risks of participation, but also fair in terms of the overall distribution of benefits between participants and researchers. A fair distribution of benefits can help ensure that individuals and communities are not included in research merely because their circumstances make their recruitment more convenient or efficient for researchers.

Benefits may, for example, take the form of information sharing, training for local personnel, or health care or similar services. Where applicable, these
research agreements outlining expectations and other considerations, whether
formal or informal, should be submitted to the REB under the auspices of
which the research is being conducted and by the REB or other responsible
body or bodies where such exists at the host research site or country for review.
(See Article 8.3).

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 normally provide copies of publications or other research
reports or products arising from the research to the institution or organization –
normally the host institution – that is best suited to act as a repository and
diseminator of the results within the participating communities. This may not
be necessary in jurisdictions when the results are readily available in print or
electronically. In all cases, researchers should ensure that participating
communities are informed of how to access the results of the research that
should be made available to them in a culturally appropriate and meaningful
format, such as reports in plain language in addition to technical reports.

Respect for Communities and Minimizing Social Disruption

Researchers should recognize that communities, as well as individuals within those
communities, can be put at risk or their vulnerability may be exacerbated by research
activities. They should be aware of the implications of their research for local communities
and should be attentive to social changes that might be introduced by their research
projects. Researchers should also take care not to create unrealistic expectations among
participants within those communities with respect to the potential benefits of the research.
They should demonstrate respect for the communities they engage in research by exercising
due diligence to anticipate and minimize any risk and social disruption that might be
created by the research.
There is widespread agreement about the interests of research participants in protection of 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. Fundamental rights and freedoms in the Canadian Constitution have been interpreted by courts to include privacy protections. Privacy rights are also protected in federal and provincial/territorial legislation. Model voluntary codes have also been adopted to govern access to, and the protection of, personal information. Some professional organizations have also established codes that establish the conditions and obligations of their members regarding collection, use and disclosure of personal information.

Privacy risks in research relate to the identifiability of participants and the potential harms they, or groups to which they belong, 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, storage and retention of information, and disposal of records or devices on which information is stored.

This Policy is based on a proportionate approach to ethical assessment of research. Researchers and research ethics boards (REBs) should identify and mitigate privacy risks, keeping in mind that a matter that is not sensitive or embarrassing for the researcher may be so for the participant.

In addition to guidance provided in this Policy, researchers are responsible for compliance with all applicable legal and regulatory requirements with respect to protection of privacy and consent for the collection, use or disclosure of information about participants. These requirements may vary by jurisdiction and, depending on who is funding/conducting the research, may consist of obligations under the Constitution (including the Canadian Charter of Rights and Freedoms), and federal or provincial privacy legislation, among other legal and regulatory requirements.

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. (See Chapter 3 for further discussion of consent).

Confidentiality

The ethical duty of confidentiality refers to the obligation of an individual or organization to safeguard information entrusted to it by another. The ethical duty of confidentiality includes obligations to protect information from unauthorized access, use, disclosure, modification, loss or theft. Fulfilling the ethical duty of confidentiality is essential to the trust relationship between researcher and research participant, and to the integrity of the research enterprise.

Security

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 the use of locked filing cabinets and the location of computers containing research data away from public areas. Administrative safeguards include the development and enforcement of organizational rules about who has access to personal information about research participants. Technical safeguards include use of computer passwords, firewalls, anti-virus, encryption and other measures that protect data from unauthorized access, loss or modification.

Types of Information

Researchers may seek to collect, use, share and access different types of information about research participants. Such information may include personal characteristics, such as age, culture, educational background, employment history, health care, life experience, religion, social status or other matters where an individual has a reasonable expectation of privacy.

Information may be categorized along a spectrum of identifiability. For the purposes of this Policy, researchers and REBs must consider if information proposed for use in research is identifiable or non-identifiable.

Information is identifiable if it, alone or when combined with other information available to the person who receives it, can reasonably be expected to identify an individual. The term “personal information” generally denotes identifiable information about an individual.

The following categories help explain the spectrum of identifiability for the purposes of this Policy:

- Directly identifying information – the information identifies a specific individual through direct identifiers (e.g. name, social insurance number, personal health number).
Indirectly identifying information – the information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g. date of birth, place of residence or unique personal characteristic).

De-identified/coded information – direct 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).

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).

Ethical concerns regarding privacy decrease as it becomes more difficult or impossible to associate information with a particular individual. These concerns also vary with the sensitivity of the information and the extent to which access, use or disclosure may harm an individual or group by exposing them to embarrassment, stigmatization, discrimination or other detriments.

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 or de-identify the data at the earliest opportunity. While these measures often protect participants from identification, use of de-identified/coded or anonymized information for research may present risks of re-identification.

Technological developments increase the ability to access, store, and analyze large volumes of data. These activities may heighten risks of re-identification, such as when researchers link datasets, as discussed in Section E of this chapter, or where a dataset contains information about a population in a small geographical area or individuals with unique characteristics (e.g. uncommon field of occupational specialization, diagnosis with a very rare disease). Various factors affect the risk of re-identification and researchers and REBs should be vigilant to consider and reduce risks of re-identification.

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 ethical duty of confidentiality and appropriate measures to safeguard information become paramount. This Policy generally requires more stringent protections in research involving identifiable information. Researchers should consult their REB if they are uncertain about whether information proposed for use in research is identifiable – for example, when proposing to link de-identified datasets.

**B. The Ethical Duty of Confidentiality**

Article 5.1 Researchers shall safeguard information entrusted to them and not misuse or wrongfully disclose it.

Application When researchers obtain information with a promise of confidentiality, they
assume an ethical duty that is central to respect for research participants and the integrity of the research enterprise. Breaches of confidentiality may harm the participant, the trust relationship between the researcher and the participant, other individuals or groups, and/or the reputation of the research community. Research that probes sensitive topics (e.g. illegal activities) generally depends on strong promises of confidentiality to establish trust with participants.

The ethical 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 confidentiality.

The ethical duty of confidentiality must, at times, be balanced against legal or professional requirements, or competing ethical considerations, that call for disclosure of information obtained or created in a research context. For example, in exceptional and compelling circumstances, researchers may be subject to obligations to report 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. In other situations, a third party may seek access to information obtained and/or created in confidence in a research context. An access request may seek voluntary disclosure of information or may seek to compel disclosure through force of law (e.g. by subpoena). Chapter 1, Section C elaborates on research ethics and law.

Certain areas of research (such as research involving children at risk of abuse or study of criminal behaviour) are more likely to put researchers in positions where they may experience tension between the ethical duty of confidentiality and disclosure to third parties. Researchers shall maintain their promise of confidentiality to research participants within the extent permitted by law and/or ethical principles. This may involve resisting requests for access, such as opposing court applications seeking disclosure. Researchers’ conduct in such situations should be assessed on a case-by-case basis and guided by consultation with colleagues, any relevant professional body, the REB, and/or legal counsel. Institutions should support their researchers in maintaining promises of confidentiality.

In some instances, participants may waive confidentiality, for example, if they wish to be identified for their contributions to the research. In such situations, researchers should negotiate agreement with participants about how participants may be identified to recognize their contribution. Where an individual participant waives confidentiality but other members of the participant group object because identification may cause harm to the group, researchers shall maintain confidentiality. (See Articles 3.2 (f) and 10.5).

Researchers shall describe measures for meeting confidentiality obligations and explain any reasonably foreseeable disclosure requirements:
(a) in application materials they submit to the REB; and

(b) during the consent process with potential research participants.

**Application**

This article recognizes that some research investigations are more likely to put researchers in a position where they may have a requirement to disclose information to third parties. The reasonable foreseeability of disclosure requirements can be assessed by considering the nature and objectives of the research inquiry. For example, research that involves interviewing high risk families about inter-generational violence raises a reasonably foreseeable prospect that researchers may acquire information that a child is being abused. Researchers who reasonably foresee that their inquiries may give rise to a legal or ethical reason to disclose information obtained in the research context shall advise the REB and potential participants about the possibility of compelled disclosure. Advising participants of reasonably foreseeable disclosure requirements is an important aspect of consent.

Situations may arise where researchers unexpectedly acquire information that gives rise to a reason for disclosure to a third party, or researchers may receive a disclosure demand from a third party. In such cases, advising a participant about the disclosure may be important to respect the trust relationship with the participant and to ensure the participant's ongoing consent. Decisions about whether, how and when to advise a participant of disclosure should be guided by any applicable disciplinary standards and consultation with the REB, colleagues, professional body and/or legal counsel.

Researchers shall also inform participants and seek consent from participants if personal information might be provided to government departments or agencies, community partners in the research, personnel from an agency that monitors the research, a research sponsor (such as a pharmaceutical company), the REB or a regulatory agency.

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 seek consent, researchers should advise potential participants if aggregated data from a study may be disclosed, particularly where such disclosure may pose a risk to the participants. For example, aggregate data provided to authorities about research on illicit drug use in a penitentiary may pose risks to the prisoners, even though they are not identified individually.

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.
Chapter 5 – Privacy and Confidentiality

C. Safeguarding Information

Article 5.3 Researchers shall provide details to the REB regarding their proposed measures for safeguarding information, for the full life cycle of information – that is, its collection, use, dissemination, retention and/or disposal.

Application Researchers shall 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. Safeguarding information helps respect the privacy of research participants and helps researchers fulfill 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, type and state of data (e.g. paper records or electronic data stored on a mobile device, whether information contains direct or indirect identifiers, whether data is in transit and more vulnerable to unauthorized access). Measures 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, and purpose of any secondary use of identifiable information;
(c) limits on the use, disclosure and retention of the information;
(d) risks of re-identification of individuals;
(e) appropriate security safeguards for the full life cycle of information;
(f) any recording of observations (e.g. photographs, videos, sound recordings) in the research that may allow identification of particular participants;
(g) any anticipated uses of personal information from the research; and
(h) 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).

In considering the adequacy of proposed measures for safeguarding information during its full life cycle, REBs should not automatically impose a requirement that researchers destroy the research data. Stored information may be useful for a variety of future purposes. Appropriate data retention periods vary depending on the research discipline, research purpose and kind of data involved. 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. Researchers should address how the participant's information will be handled if participants choose to withdraw from research.

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.

Consideration of future uses of personal information refers not just to research, but also to other purposes, such as the future use of research materials for educational purposes.

Research data sent over the Internet may require encryption or use of special denormalization software to prevent interception by unauthorized persons or other risks to data security. In general, identifiable data obtained through research that is kept on a computer and connected to the Internet should be encrypted.

Institutions or organizations where research data are held have a responsibility to establish appropriate institutional security safeguards. Such data security safeguards should include physical, administrative and technical measures and should address the full life cycle of information. This includes institutional or organizational safeguards for information while it is currently in use by researchers and for any long-term retention of information.

Secondary use refers to the use in research of information originally collected for a purpose other than the current research purpose. Common examples are social science or health survey datasets that are collected for specific research or statistical purposes, but then re-used to answer other research questions. Information initially collected for program evaluation may be useful for subsequent research. Other examples include health care records, school records, biological specimens, vital statistics registries or unemployment records, originally created or collected for therapeutic, educational or administrative purposes, but later sought for use in research. Chapter 12 provides further guidance on research involving secondary use of previously collected human biological materials.

Secondary use avoids duplication in primary collection and therefore reduces burdens and costs for participants and researchers. Privacy concerns and questions about the need to seek consent arise, however, when information provided for secondary use in research can be linked to
individuals and when the possibility exists that individuals can be identified in published reports or through data linkage. Privacy legislation recognizes these concerns and permits secondary use of identifiable information under certain circumstances.

**Article 5.5** Researchers who seek a waiver of consent for secondary use of identifiable information in research shall satisfy the REB that:

(a) identifiable information is essential to the research;
(b) the waiver is unlikely to adversely affect the welfare of individuals to whom the information relates;
(c) the researchers will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable information;
(d) the researchers will comply with any known preferences previously expressed by individuals about uses of their information;
(e) it is impossible or impracticable to seek consent from individuals to whom the information relates; and
(f) The researchers have obtained any other necessary (e.g. legal) permission for secondary use of information for research purposes.

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

**Application** This Policy does not require that researchers seek consent from individuals for the secondary use of non-identifiable information. However, consent must be sought where researchers propose to use identifiable information, unless the researcher satisfies all the requirements in Article 5.5.

The waiver of consent in this article is specific to secondary use of identifiable information. The terms of Article 3.7 addresses alteration and waiver of consent in other circumstances and does not apply here.

Secondary use of information identifiable as originating from a specific Aboriginal community, or a segment of the Aboriginal community at large, is addressed in Article 9.20.4

“Impracticable” refers to undue hardship or onerousness such that the conduct of the research is jeopardized; it does not mean mere inconvenience. Consent may be impossible or impracticable when the group is very 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. Financial, human and other resources required to contact individuals and seek consent may impose undue hardship. In some jurisdictions, privacy laws may preclude researchers from using personal information to contact individuals to seek their consent for secondary use of information.

Privacy laws may also impose specific rules regarding disclosure of information.
for secondary use in research. 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 disclosure conditions. Such conditions may include the requirement that the researcher not publish identifiable information or contact individuals to whom the information relates. Researchers should be aware of relevant laws that regulate disclosure of information for research purposes.

At the time of initial collection, individuals may have had an opportunity to express preferences about future uses of personal information, including research uses. Researchers and REBs shall respect any known preferences. For example, where possible, identifiable information about individuals who have expressed objection to future use should be removed from the dataset before researchers use it for approved research.

An REB may require that researchers engage in discussion with representatives of individuals or groups to whom the information relates where the proposed research involves information of greater sensitivity (e.g. genetic information, information about persons who seek help through domestic violence shelters, or information about sexual practices). Discussion is not intended as proxy consent. Rather, a goal of discussion is to seek input regarding the proposed research, such as the design of the research, measures for privacy protection and potential uses of research findings. Discussion may also be useful to determine that the research will not adversely affect the welfare of individuals to whom the information relates. Researchers should advise the REB of outcomes of such discussion and the REB may require modifications to the research proposal based on the feedback.

**Article 5.6** When secondary use of identifiable information without consent has been approved under Article 5.5, researchers who propose to contact individuals for additional information shall, prior to contact, seek REB approval of the plan for making contact.

**Application** In certain cases, a research goal may be achieved only through follow up contact with individuals to collect additional information. Under Article 5.5, the REB may have approved secondary use without consent based, in part, on the impossibility or impracticability of seeking consent. Where contact with a sub-group is feasible, researchers may subsequently wish to attempt to make contact with some individuals to obtain additional information. Contact with individuals whose previously collected information has been approved for secondary use in research raises privacy concerns. Individuals might not want to be contacted by researchers or might be upset that identifiable information was disclosed to researchers without their consent. The research benefits of follow-up contact must clearly outweigh the risks to individuals of follow-up contact, and the REB must be satisfied that the proposed manner of follow-up contact minimizes risks for individuals. The proposed plan should explain who will contact individuals to invite their
participation in the research (e.g. a representative of the organization that holds the individual’s information) and the nature of their relationship with those individuals. Researchers will need to seek consent from these individuals for any new data collection. Article 3.1 provides further guidance on consent and approaches to recruitment.

E. Data Linkage

Researchers who propose to engage in data linkage shall obtain REB approval prior to carrying out the data linkage, unless the research relies exclusively on publicly available information as discussed in Article 2.2. The application for approval shall describe the data that will be linked and the likelihood that identifiable information will be created through the data linkage.

Where data linkage involves or is likely to produce identifiable information, researchers shall satisfy the REB that:

(a) the data linkage is essential to the research; and
(b) appropriate security measures will be implemented to safeguard information.

Growing numbers of databases and advancing technological capacity to link databases create new research opportunities, but also new privacy risks. In particular, linkage of de-identified or anonymized databases may permit re-identification of individuals. This article provides guidance for researchers who propose to carry out data linkage and requires that they assess and mitigate risks of re-identification. Only a restricted number of individuals should perform the function of merging databases. Researchers should use enhanced security measures to store the merged file.

Where researchers seek access to datasets held by another organization, it may be preferable for the data holder to carry out the data linkage and remove identifiers before disclosing the merged dataset.

Legislation and organizational policies may regulate data linkage in specific circumstances. For example, some personal information protection legislation require data sharing agreements that regulate conditions under which data linkage may be carried out. Data holders, such as statistics agencies, may also have policies on data linkage.

Where researchers propose to access and link datasets of identifiable information for the secondary purpose of research, the requirements of Section D apply.
Endnotes

1 See, for example, the Canadian Standards Association’s Model Code for the Protection of Personal Information, (1996).


4 See also the Canadian Institutes of Health Research Guidelines for Health Research Involving Aboriginal People, (May 2007), www.cihr-irsc.gc.ca/e/29134.html

5 For discussion of factors relevant to assessing impracticability of consent, see, for example, the Canadian Institutes of Health Research Best Practices for Protecting Privacy in Health Research (September 2005), Section 3.3 “Secondary Use,” pp. 38 – 41.

6 See, for example, Statistics Canada’s Policy on Record Linkage: www.statcan.gc.ca/record-enregistrement/policy4-1-politique4-1-eng.htm
Chapter 6

GOVERNANCE OF 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, authority, and accountability, 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 this Policy – respect for persons, concern for welfare and justice – to their ethics review of research projects. These operational guidelines are meant to be flexible enough to apply in various contexts, at institutions of various sizes, and to the full range of research disciplines, fields and methodologies.

A. Establishment of REBs

Authority, Mandate and Accountability

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

Application

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

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.

Members of an institution, that is its faculty, staff and students, may be
affiliated with other institutions, or may be engaged in consulting or other
professional activities in a separate enterprise. To enable the consistent
application of this Policy, members of the institution should obtain REB
approval of the ethical acceptability of their research if they engage in research
involving humans related to one of their other organizational affiliations or to
their supplemental professional activities. Should the institution assess that
some situations warrant an exception, the basis and conditions for case-by-case
exceptions shall be clearly documented in their institutional policies. Case-by-

...
Institutional policies and procedures shall also support and promote the effective and independent operation of REBs. REBs should have the independence to conduct ethics reviews free of inappropriate influence, including situations of real, potential or perceived conflict of interests. (See Chapter 7).

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

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

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

Institutions shall respect the authority delegated to the REB. An institution may not override REB decisions simply to promote or prevent a particular research project.

REB Composition

Basic REB Membership Requirements

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

Article 6.4 The REB shall consist of at least five members, of whom:

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

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

(c) at least one member is knowledgeable in the law (but that member should not be the institution’s legal counsel or risk manager); and

(d) at least one community member who has no affiliation with the institution.
Chapter 6 – Governance of Research Ethics Review

Each member shall be appointed to formally fulfill the requirements of only one of the above categories. To ensure the independence of REB decision making, institutional senior administrators shall not serve on the REB.

**Application** This minimum requirement for REB membership brings to bear the necessary basic background, expertise and perspectives to allow informed independent reflection and decision making on the ethics of research involving humans. While each member shall be formally appointed to provide the perspective of one of the above categories as the member’s primary responsibility, they can contribute to the review based on their experience, expertise or knowledge in more than one of the categories above (Article 6.4[a] to [d]).

The size of an REB may vary based on the diversity of disciplines, fields of research and methodologies to be covered by the REB, as well as on the needs of the institution. In appointing REB members, institutions should strive for appropriate diversity. Institutions may need to exceed the minimum REB membership requirements in order to ensure an adequate and thorough review, or to respond to other local, provincial/territorial or federal legal or regulatory requirements. 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. Institutions are encouraged to establish a pool of substitute members (see below).

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

**Knowledgeable in ethics:** Knowledge of ethics of research involving humans is key within the REB membership as a whole. A member knowledgeable in ethics (Article 6.4[b]) needs to have sufficient knowledge to guide an REB in identifying and addressing ethics issues. A balance of ethics theory, practice and experience offers the most effective path to knowledge in ethics for REB membership. The kind and level of knowledge or expertise needed on the REB will be commensurate with the types and complexities of research the REB reviews. For example, a member knowledgeable in ethics serving on a social sciences and humanities REB may 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, for
example – privacy issues, not to provide formal legal opinions or to serve as legal counsel for the REB. To avoid undermining the independence and credibility of the REB, the institution’s legal counsel or risk manager should not be a member of the REB. In-house legal counsel might be seen to identify too closely with the institution’s financial interest in having research go forward or, conversely, may be unduly concerned with protecting the institution from potential liability. Any external legal counsel hired on a case-by-case basis by the institution should not serve as a member of that institution’s REBs while working for the institution.

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:** The community member shall not be affiliated with the institution and should not be currently engaged in scientific, legal or academic work. 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.

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. Institutions should provide training opportunities to community members. (See Article 6.7).

In addition to a broad-based representation from the community, it is highly desirable that institutions seek to appoint former research participants on REBs. Their experience as research participants provides the REB with a vital perspective and important contributions to the ethics review process.

**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 composition 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 REB 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.
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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 shall maintain 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, knowledge 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 In appointing REB members, institutions shall establish their terms to 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 In appointing and renewing REB members, the institution should consider the qualifications and expertise the REB needs, and should provide REB members with necessary training to review the ethical issues raised by research proposals that fall within the mandate of the REB.

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

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 includes training all members in core principles and understanding of this Policy, basic ethics standards, applicable institutional policies, and legal or regulatory requirements. It includes an understanding of the role and mandate of REBs and responsibilities of REB members. Training
should be tailored to the types and complexities of the research the REB reviews. This training should be offered both 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 REB Chair is responsible for ensuring that the REB review process conforms to the requirements of this Policy.

**Application** The role of the REB Chair is to provide overall leadership for the REB and facilitate the REB review process, based on institutional policies and procedures and this Policy. The Chair should monitor the REB’s decisions for consistency and ensure that these decisions are recorded accurately and that they are clearly communicated to researchers in writing as soon as possible.

Institutions shall provide the necessary resources to enable the REB Chair to fulfil his or her responsibilities.

**REB Quorum**

**Article 6.9** Institutions shall establish quorum rules for REBs subject to the range of competence and knowledge required by this Policy to ensure the soundness and integrity of the ethics review process.

**Application** REB quorum shall be at least five members, shall meet the minimum requirement of membership representation outlined in Article 6.4, and shall take into account the presence at a given meeting of the specific expertise, relevant competence and knowledge necessary to provide an adequate ethics review of the proposals under consideration at that meeting.

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

**REB Meetings and Attendance**

**Article 6.10** REBs shall have regular meetings to discharge their responsibilities, and shall normally meet face-to-face to review proposed research that is not assigned to delegated review.

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

Planning regular meetings is essential to fulfilling REB responsibilities. A schedule of REB meetings should be communicated to researchers for the
planning of ethics review of their research. 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, teleconferencing and use of other technologies may be regarded as necessary for meetings when REB members are geographically dispersed and there is no other way of holding an effective REB meeting or when exceptional or exigent circumstances significantly disrupt or limit the feasibility of face-to-face REB meetings, 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. Use of such technologies requires the Chair to ensure active participation of members not physically present. Respecting the principles of this Policy, institutions should consider developing written procedures for the occasional use of videoconferences or other technologies by an REB.

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

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

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 shall submit their research project for REB review and approval of its ethical acceptability prior to the start of recruitment of research participants or access to data. Subject to Article 10.1, REB review is not required for the initial exploratory phase involving contact with individuals or communities intended to establish research partnerships or the design of a research study.
REB review and approval of the ethical acceptability of research is required before recruitment or the formal data collection involving research participants. Similarly, as an integral component of their research design, researchers may undertake pilot studies involving research participants whose data will be used in the full implementation of a larger study. For the conduct of such pilot studies, researchers should seek consent from prospective participants and obtain REB approval before recruitment or the formal data collection involving research participants.

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

REBs shall follow a research ethics review process proportionate to the level of risk in research under review.

REBs shall 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. (See Article 2.9).

With the support of their institutions, REBs may develop their own mechanisms under which delegation of the conduct of review, decision making, and the associated reporting process will occur. Those mechanisms and procedures should be made public. It is the REB, through its chair, that decides on the level of review to be utilized.

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 (defined in Chapter 2 of this Policy), an REB generally may authorize a delegated ethics review and decision making, 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
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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. In selecting delegated reviewers and in the process of delegation, special attention should be given to situations of real, potential or perceived conflict of interests as outlined in Article 7.3.

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

- research that is confidently expected to involve minimal risk;
- minimal-risk changes to approved research;
- annual renewals of approved minimal risk research;
- annual renewals of more than minimal risk research where the research will no longer involve new interventions to current research participants, does not involve the recruitment of new research participants, and the remaining research activities are limited to data analysis;
- evidence that conditions or other requirements laid down by the REB in an initial review have been met.

An institution may decide that ethics review of research that is carried out by undergraduate students as part of their course work may be reviewed by a delegated review process that complies with this Policy. The REB should set out criteria for determining which categories of research proposals are suitable for consideration through this means, and establish procedures, such as who is responsible for implementing and overseeing the approval mechanisms. Where an undergraduate student is carrying out research that is part of a faculty member’s own research program, such research should be reviewed by the regular REB procedures.

An REB that implements a delegated review process shall require that the actions and decisions of the delegated reviewer(s) be well documented and formally reported to the full REB, through its chair, in a timely and appropriate manner, thus permitting the REB to maintain oversight over the decisions made on its behalf so as to protect the interests of participants. Accountability requires that, regardless of the review strategy, the REB continues to be responsible for the ethics of all research involving human participants within its jurisdiction.

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

**Application** The REB shall accommodate reasonable requests from researchers and may
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2414 initiate invitations to researchers to participate in discussions about their
2415 proposals, but researchers shall not be present when the REB is making its
2416 decision. When an REB is considering a negative decision, it shall provide the
2417 researcher with all the reasons for doing so and give the researcher an
2418 opportunity to reply before making a final decision. (See Article 6.17).

2419 In the event that a minority within the REB membership considers a research
2420 project unethical, even though it is acceptable to a majority of members, an
2421 effort should be made to reach consensus. Consultation with the researcher,
2422 external advice, or further reflection by the REB may be helpful. If
2423 disagreement persists, a decision should be made in accordance with the
2424 process mandated by the institution. In such instances, the minority position
2425 may be communicated to the researcher.

2426 Participation by the researcher in such discussions is often very helpful to both
2427 REBs and researchers. Such discussions may result in a deferral of the REB’s
2428 decision until the researcher has considered the discussions and possibly
2429 modified the proposal. Such discussions are an essential part of the educational
2430 role of the REB.

2431 Continuing Ethics Review

2432 Article 6.14 The REB shall make the final determination as to the nature and frequency
2433 of the continuing ethics review in accordance with a proportionate approach
2434 to ethics review. At minimum, continuing ethics review shall consist of an
2435 annual status report on the research, followed by an end-of-study report.

2436 Application Research is subject to continuing ethics review from the date of initial REB
2437 approval until completion of the study. (See Article 2.8) At the time of first
2438 review, the REB has the authority to determine the term of approval and the
2439 level at which continuing ethics review occurs in accordance with a
2440 proportionate approach to research ethics review. For research projects
2441 lasting longer than one year, researchers should submit at minimum an
2442 annual report with sufficient details to enable the REB to make an informed
2443 judgment about the ethical acceptability of the research. For research lasting
2444 less than one year, an end-of-study report may suffice.

2445 For some types of research (e.g. qualitative research or longitudinal
2446 research), there may be some difficulty in establishing start or end dates. For
2447 these cases, the REB should work with researchers to determine a reasonable
2448 timeline for continuing ethics review and for determining the completion
2449 date dependent on the discipline and method of study. The reporting
2450 schedule for continuing ethics review may be adjusted throughout the life of
2451 the project. This would be necessary, for example, if the risk level of the
2452 research increases as a result of the addition of new procedures.

2453 Research that involves minimal or no risk to the research participant should
2454 be held to the minimum requirements for continuing ethics review, that is, a
2455 short annual report. Following a proportionate approach, an REB has the
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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 standards. For example, researchers have a responsibility to 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. Institutions should provide necessary resources to REBs to assist them in fulfilling their continuing ethics review responsibilities.

Departures from Approved Research

Article 6.15 REBs 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 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 shall 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. An REB may stipulate a timeframe for the reporting of such events.

In the case of clinical trials, unexpected or unanticipated events and reporting requirements are defined and addressed in Chapter 11 of this Policy. 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 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 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 welfare of the research participants. In case of doubt on the potential impact of the departure from approved research on the level of risk to participants, researchers should consult with their REBs. Researchers and REBs may work together to develop a list of types of reportable events.

**Record Keeping of REB Documents**

**Article 6.16** REBs shall prepare and maintain comprehensive records, including all documentation related to the studies submitted to the REB for review, attendance at all REB meetings, and accurate minutes reflecting research ethics decisions. Where the REB denies ethics approval for a research proposal, the minutes shall include the reasons for this decision.

**Application** REBs need to act, and to be seen to be acting, fairly and reasonably. Institutions shall provide REBs the necessary resources to enable them to maintain complete study files, including the original application, as well as...
annual and end-of-study reports. This should be guided by their institutional
record-keeping policies and other relevant legal or regulatory requirements
when deciding the retention period of their files. Minutes and other relevant
documentation shall be accessible to authorized representatives of the
institution, researchers, sponsors and funders 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 for REB decisions is optional when ethics approval is
granted.

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 research ethics administration 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

Where researchers do not receive ethics approval upon initial review, or receive approval
with conditions that they find compromise the feasibility or integrity of the proposed
research, they are entitled to reconsideration by the REB. If that is not successful, they may
appeal to a separate review board.

Reconsideration of REB Decisions

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

REBs should follow principles of natural and procedural justice in their decision
making. This includes providing a reasonable opportunity to be heard; reasoned
grounds for the decisions, and the opportunity for rebuttal. (See Article 6.13).
Researchers and REBs should make every effort to resolve disagreements they
may have through deliberation, consultation or advice. If a disagreement cannot
be resolved by the researcher and REB, the researcher shall have the option of
appealing the REB decision through the established appeal mechanism. (See
Article 6.18).

In the case of protocols reviewed by delegated review, requests by the
researcher for reconsideration of a delegated review decision should be
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forwarded by the researcher for review by the full REB. The onus is on researchers to justify on what grounds they request 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 6.18 Institutions shall have an established mechanism and a procedure in place for entertaining appeals from researchers when they cannot reach agreement with REBs through discussion and REB reconsideration.

Application In cases when researchers and REBs cannot reach agreement through discussion and reconsideration, an institution shall provide access to an established appeal process for the review of an REB decision.

By nature of its role and lack of frequency of meeting, an appeal body is typically 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). An appeal body shall be established by the same body that created the REB. Members of the REB whose decision is under appeal shall not serve on that appeal body.

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

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.

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 6.19 The appeal body shall have the authority to approve, reject or request modifications to negative decisions made by an REB. An appeal body can overturn negative decisions made by an REB. Its decision shall be final.

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. The onus is on the researchers to justify on what grounds – for example, content, procedures, conflict of interests of REB member(s), or disagreement on interpretation of this Policy – 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 body shall function impartially, provide a fair hearing to those
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 lives.

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 respect for persons, concern for welfare, and justice when reviewing the ethics of research to be conducted in such emergencies. It should be noted that the following articles and the requirement for consent will not apply to research undertaken by federal, provincial and territorial public health officials operating under statutory powers during public health emergencies.

Institutional Emergency Research Ethics Preparedness Plans

Article 6.20 In concert with their researchers, institutions and their REBs 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 research ethics review in institutions; 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,
REBs should try to work collaboratively with researchers who would likely
be involved in emergency-type research such as researchers in relevant
biomedical, environmental and social science areas, and what special
consent provisions may be made in emergency research. (See Chapter 3).
Institutions might consider the use of an instrument to identify and triage the
types 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:

- what constitutes “essential” research during the emergency;
- 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);
- continuing ethics review of research undertaken prior to the occurrence
  of the emergency; and
- the review process for departures from approved research, because new
  information may become available very rapidly during emergencies.
  (See Article 6.15).

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 (see Articles 6.4 and 6.5), negotiate reciprocity agreements with
other institutions for REB reviews (see Article 8.1), and revisit how
scholarly review 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 the core 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 6.21 The application of research ethics policy and procedures for emergencies is
limited to the duration of officially declared public emergencies and should
cease as soon after the declared emergency as is feasible.

Application Research ethics review policies and procedures for declared emergencies
should be applied only to compelling public necessities occasioned by a
public emergency. 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.

Respecting Core Principles: Limiting Exceptions

Article 6.22 REBs should give special care to requests for exceptions to
the principles
and procedures outlined in this Policy during publicly declared emergencies.

Application Especially during times of emergency, researchers, REBs and institutions
need to be vigilant and exercise due diligence in respecting ethical
principles, procedures, and the law in effect during such emergency. 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 procedure should fall on those claiming
the exception.

To guide fair and reasonable implementation for emergency circumstances,
any exception to or infringement of ethics principles and procedures need to
be demonstrably justified by those urging the infringement. Sometimes a
proposed infringement or exception will not be justified for research
purposes. Justified exceptions to or infringement of ethics principles and
procedures should correspond directly, and be calibrated, to the benefit
targeted by the goal of the policy. Exceptions 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 justice means that research ethics review policies and procedures for publicly declared emergencies shall be used in a manner that is not discriminatory or arbitrary. The commitment to justice advances a fair and balanced distribution of risks and potential benefits even in the face of public emergencies.

REBs and researchers should be aware that individuals, 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 welfare 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 respect participants and be concerned about their welfare shall be accordingly addressed. (See Article 4.6).

Endnote

Chapter 7

CONFLICT OF INTERESTS

This chapter addresses ethical issues that can arise when research activities and other activities conflict. A conflict of interests may arise when activities or situations place a person or institution in a real, potential or perceived conflict between their duties or responsibilities related to research and their personal, institutional or other interests. Conflict of interests may occur when individuals’ judgments and actions or institutions’ actions in relation to research are, or could be, affected by personal, institutional or other interests, including, but not limited to, business, commercial or financial interests, pertaining to these individuals, their family members, their friends, or their former, current or prospective professional associations – or of the institution itself.

Conflicts of interests must be assessed when conducting research involving humans to ensure protection of the potential participant and integrity of the research. Conflicts of interests that jeopardize these protections are contrary to the core principles on which this policy is based. In light of this, the first step is to avoid or prevent being in a condition of conflict of interests, if possible. When it is not possible to avoid such a condition, then the next step is to disclose the conflict to the appropriate persons which will then result in appropriate efforts to minimize or manage the conflict of interests.

Researchers and students hold trust relationships, either directly or indirectly, with research participants, research sponsors, institutions, their professional bodies and society. These relationships based on trust between parties can be put at risk by conflicts of interests that may compromise independence, objectivity or ethical duties of loyalty. Although the potential for such conflicts has always existed, pressures on researchers, for example, to suspend dissemination of research outcomes or use inappropriate recruitment strategies, heighten concerns regarding ethical behaviour.

Institutions involved in research, too, hold trust relationships with research participants, research sponsors, researchers and society. These institutions may have financial or reputational interests that conflict with the institution’s obligations that may include provision of education, the promotion of research, as well as their obligation to protect and respect human dignity as characterized by the core principles of this Policy. For example, institutions may experience pressures to attract particular research funding or certain types of research activities that are self-sustaining, which may compromise their independence and public trust. Institutions have an obligation to ensure that the ethical conduct of research is not compromised by real, potential or perceived conflicts of interests.

The research ethics board (REB), as an entity, or as the members that make up the board, also hold trust relationships with research participants, research sponsors, researchers and society. The REB can also find itself in a conflict of interests.
Conflicts of interests may jeopardize the integrity of research and the protection offered participants. Conflicts that create divided loyalties may distract researchers, REBs and institutions from concern for the welfare of participants and are contrary to the core principles on which this Policy is based. Failures to disclose and manage conflicts may impede the informed and autonomous choices of individuals to participate in research. Potential participants need to know about real, potential or perceived conflicts of interest in order to consent. (See Article 3.2 [e]). Conflicts of interests may also undermine the respect for participants that is fundamental to the principle of justice.

Researchers, their institutions and REBs should identify and address conflicts of interests – real, potential or perceived – to discharge professional and institutional obligations, maintain public confidence and trust, and ensure accountability. In some cases, the conflict (real, potential or perceived) cannot be managed and the institutions, the researcher or the REB member may need to abandon one of the interests in conflict. Where necessary, the researcher may have to manage the conflict of interests either by disclosing it to participant or removing himself/herself from the research.

This chapter addresses Conflict of Interests for Institutions in Part A, for REB members in Part B, and for Researchers in Part C.

### A. Institutions and Conflicts of Interests

**Article 7.1** Institutions shall develop and implement conflicts of interests policies including procedures to identify, prevent, disclose and manage conflicts of interests that may affect research involving humans. All parties should act in a transparent manner in identifying and addressing conflicts of interests. Institutions should make their written conflict of interests policies and procedures publicly available to all members of the research enterprise, including research participants, REBs, researchers, administrators, research sponsors and others.

**Application** 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.

When developing institutional policies and procedures on conflicts of interests, 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 interests. (See Articles 6.1, 6.2 and Article 7.2).

Measures to manage conflicts of interests should reflect the inherent threat of conflict of interests to research participants, as well as to the scientific and scholarly integrity and credibility of research. Measures to manage conflicts of interests should be proportionate to the risks. Institutions should consider the
following measures to address conflicts of interests at the institutional level that are germane to research involving human participants:

- Create central institutional mechanisms, such as a competent institutional authority, a conflict of interests committee, or other delegated bodies within the institution to help identify, evaluate and manage conflicts of interests;
- Refine or redesign roles, responsibilities and reporting lines to avoid, minimize or manage the potential for conflicts;
- Prevent or minimize conflict of interests in institutional design and structuring when creating new roles, responsibilities or relationships;
- Apply barriers to insulate potentially conflicting roles and responsibilities;
- Institute requirements that individuals involved in the conduct of research withdraw from, or do not participate in, roles or functions unduly compromised or disabled by any real, potential or perceived conflict.

Conflict of interests policies and procedures should be developed in a transparent manner.

The goal of such policies is to avoid conflict of interests where possible, or alternatively, to identify and disclose real, potential or perceived institutional conflicts of interests, to make them transparent and open to scrutiny and to provide mechanisms to evaluate and manage them. Institutions must respect the autonomy of the REB decision making processes and ensure the REB has ongoing and adequate financial and administrative resources to fulfil its duties. (See Articles 6.1 and 6.2).

Article 7.2 Institutions should ensure that real, potential or perceived institutional conflicts of interests that may affect research involving humans are reported to the REB through the established conflict of interest mechanisms. The REB shall consider whether the institutional conflict of interests should be disclosed to potential participants as part of the consent process.

Application An institutional conflict of interests involves a conflict between at least two substantial institutional obligations that cannot be adequately fulfilled without compromising one or both obligations. Conflicts may occur when pursuing particular goals, for instance, the pursuit of two different “goods.” For example, seeking to expand its donors’ base for the development of the infrastructure of the university may conflict with the conduct of research. Conflicts may be real, potential or perceived. Institutional conflicts of interests 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.

Institutions may be in conflict of interests, for example, when (a) they sponsor
a research study; (b) they manage the intellectual property that forms the basis of a study or they stand to benefit from intellectual property resulting from the research; (c) the institutions hold equity holdings in companies and/or receive major donations, or (d) through the roles or responsibilities of the institutional official responsible for research development (e.g. vice-president responsible for fundraising with industry) and for oversight of research involving research participants.

Acting in a professional role within the institution, an individual is in a conflict of interests when this individual (e.g. university president, vice-president, dean of a faculty or department head) is subject to competing incentives or functions. These may significantly interfere with the impartial exercise of duties, including legal and ethical obligations within the institutional structure. An institutional conflict of interests may, thus, directly divide one’s professional duties and loyalties when the incentive structure of the institution places individuals who have responsibilities for functions or actions that may be in conflict with one another in conflicts of loyalty and function. The conflict may be chronic, relating to recurring situations resulting from by the institutional structure, or it may be triggered by a unique situation that is not likely to recur.

Any member of an institution, a senior administrator, researcher, REB member or any other individual who is aware of potential sources of institutional conflicts of interests that may affect research involving humans should refer to the institutional policy for proper steps to inform the REB of such conflicts. Institutional policies shall address when the disclosure of the conflict to the REB is appropriate. The disclosure of the institutional conflict of interests prior to the actual review may jeopardize the independent decision making of the REB. For example, it might be better that an REB not know prior to its review of a research proposal that the sponsor of the research is considering an endowment or major donation to that institution. In other instances, prior disclosure to the REB will be necessary for the REB deliberations and decision making regarding disclosure of such a conflict in the consent process. Identification, disclosure, evaluation and management of the institutional conflict should be resolved in accordance with the institutional conflict of interests policies.

Likewise, when a significant, real, potential or perceived institutional conflict of interests is disclosed and brought to its attention, the REB should be guided by and defer to, the prescribed institutional mechanisms for consulting with the relevant body to manage the conflict. The REB should record the fact that the issue has been forwarded to the appropriate body through relevant institutional mechanisms. To that end, effective communications processes should be established between REBs and institutions they serve.

Community-based 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
Chapter 7 – Conflict of Interests

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 risks, such as disclosure of the possible conflicts between multiple
roles, may be sufficient to manage the conflict. (See also Chapter 9).

B. REB Members and Conflicts of Interests

Article 7.3 When reviewing research proposals, REB members shall disclose real or
potential conflicts of interests to the REB, and, where necessary, the REB may
decide that some of its members must withdraw from REB deliberations and
decisions.

Application To maintain the independence and integrity of ethics review, members of the
REB must avoid, disclose and/or manage real, or potential conflicts of interests.
For example, REB members are in a conflict of interests when their own
research projects are under review by their REB, when they are the co-
investigator, or when they are in a supervisory or mentoring relationship with a
graduate student applicant. REB members may also be in a conflict of interests
type when they have interpersonal relationships or personal or financial
interests in a company, labour union or not-for-profit organization that may be
the sponsor of the research study, or may be substantially affected by the
research.

When REB members are, or have been, in direct conflict with researchers on
academic or scientific issues, or when they have engaged in research
collaborations and/or commercial transactions with the researcher whose
proposal is under review, REB members should disclose and fully explain to
the REB the conflict of interests 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 interests. To
manage such conflicts, the REB as a whole, first in consultation with the REB
member and then in that person’s absence, should discuss and determine
whether the REB member should withdraw from the committee when such
projects are under consideration.

Conflict of interests policies should determine a reasonable time period during
which an REB member is not allowed to review a proposal from a close
colleague to ensure adequate and continued access to competent expertise. In
some cases, the scientific expertise of the REB member may still be sought
when no other individuals with the scientific expertise relevant to the proposal
under review are available to the REB. In such instances, the REB will record
this explicitly in the minutes. The member should not be present when the REB
makes its decision. In exceptional circumstances guaranteeing unbiased,
competent and independent decision making by the REB may require reducing
the quorum. The REB minutes should record whether with the withdrawal of
the REB member, the REB was unable to maintain its quorum for decision
While the presence of administrative staff dedicated to research ethics functions (e.g. the research ethics office administrator or director) may be relevant and appropriate to support REB procedures, an institutional senior administrator (e.g. a vice-president research or business development) should not serve on an REB, attend meetings, or influence the REB decision making process. (See Articles 6.2, 6.4 and 6.10). The mere 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.

REBs and non-voting senior administrators should consider other venues to discuss policy issues, general issues arising from the REB’s activities, revisions of policies or training or educational needs, to the benefit of the overall operations and mandate of the REB. In the discharge of their interdependent roles and duties to research participants, effective communications processes should be established between REBs and the relevant officers of institutions they serve.

In cases where senior administrators interfere with the REB decision-making process, REBs should invoke the institutional conflict of interests policies.

Institutional conflicts of interests may give rise to professional conflicts or divided loyalties for individuals working in affected institutions. Reasonable compensation by institutions for work done by REB members is appropriate. However, in some instances, individual members of the REB may have a conflict of interests in accepting undue or excessive honoraria for their participation in the REB. Institutions should define appropriate levels of compensation.

C. Researchers and Conflicts of Interests

Researchers shall disclose to the REB real, potential or perceived individual conflicts of interests, as well as any institutional conflicts of interests of which they are aware that may have an impact on their research. Upon discussion with the researcher, the REB shall determine the appropriate steps to manage the conflict of interests.

Individual conflicts of interests may arise from interpersonal relationships (e.g., family or community relationships), financial partnerships, other economic interests (e.g. spin-off companies in which researchers have stakes, or private contract research outside of the academic realm), academic interests or any other incentives that may compromise integrity, 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 interests, researchers are expected to recognize, disclose, limit and manage their individual conflicts in a manner that is satisfactory to the REB.
Managing conflict of interests is a process, of which the first step is identification followed by disclosure. Upon disclosure to the REB, the steps taken by the REB to manage the conflict should be context-based and proportionate to the risks. For example, in some cases, the REB might conclude that the identified conflict of interests does not warrant specific actions. Generally, the REB should require, consistent with Article 3.2(e), that the researcher disclose any real, potential or perceived conflict of interest to the research participant. When disclosure to the REB is not enough to manage the conflict of interests, the REB, guided by established institutional policies, may require that the researcher withdraw from the research or that others who are not in conflict of interests make research-related decisions. Where appropriate, disclosure to the sponsor, the institution and any relevant professional body may also be necessary. In exceptional cases, the REB has the discretion to refuse approval of a study where the REB decides that the conflict of interests has not been avoided or cannot appropriately be managed.

If there is a need to involve the researcher in some aspect of the research for which this individual is in conflict of interests, such involvement should be justified and disclosed to the research participant by the researcher, and reviewed and endorsed explicitly by the REB in its minutes. In line with the proportionate approach, and through the continued ethics review process, REBs may impose additional control mechanisms in such cases.

Dual roles of researchers and associated obligations (e.g. acting as both a researcher and a therapist, health care provider, 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 (e.g. free and informed consent of participants). Article 3.2(e) reminds researchers of relevant ethical duties that govern real, potential or perceived conflicts of interests as they relate to the consent of participants. To preserve and not abuse the trust on which many professional relationships rest, researchers should be fully cognizant of conflicts of interests that may arise from their dual or multiple roles, being entirely aware of their rights and responsibilities, and they shall manage the conflict. When acting in dual roles, the researcher shall disclose this fact to the participant.

In some instances, the perceived or real conflict of interest may arise after the research has been conducted. For example, when after the completion of a clinical trial conducted in a clinical practice, the physician is invited to participate in a seminar organized by the sponsor of the trial in an interesting location or when a company offers to ghost-write a scientific article only to be signed by the physician-researcher.

Care should also be exercised in developing relationships between researchers and authorities, so as not to compromise the consent and privacy of participants and the confidentiality obligations of researchers, and to maintain public confidence and trust. Article 3.1 provides additional information on coercive situations and how they may impact on consent.
As part of the research plan for REB review, researchers must provide details on the research project, payments to the researchers by sponsors, commercial interests, consultative relationships and other relevant information (e.g. donation to an institution by a research sponsor) and documentation, and identify strategies to prevent, disclose and manage conflicts properly. Disclosure of the kinds and amounts of payments to researchers, 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 interests and will help the researcher in resolving them. (See Articles 11.9 and 11.10).

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

In addressing conflicts of interests, disagreements between the REB and the researcher 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 respect for persons and concern for welfare of participants. If the researcher and the REB cannot resolve their disagreement they should use the institutional conflict of interest mechanisms.

Reference

Chapter 8

MULTI-JURISDICTIONAL RESEARCH

This chapter sets out options, procedures and considerations for the ethics review of multi-jurisdictional research either entirely within Canada, or in Canada and other countries. It is intended to facilitate the ethics review and conduct of such research while ensuring that participants are afforded the same respect and protection in accordance with the core principles of this Policy.

Contemporary 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 institutions and/or 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 this Policy – respect for persons, concern for welfare, and justice. These core principles should be balanced with a proportionate approach to the research ethics review process for research being undertaken in Canada or abroad.

A. Review Mechanisms for Research Involving Multiple Institutions and/or Multiple REBs

This section primarily addresses the ethics review mechanisms for research involving multiple institutions and/or multiple REBs. It is not intended to apply to ethics review mechanisms for research involving multiple REBs within the jurisdiction or auspices of a single institution – addressed in Article 6.3.

Research involving humans that may require the involvement of multiple institutions and/or 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). (See Article 6.1);

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

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

Adoption of Alternative Review Models is an Institutional Responsibility

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

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

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 agree to adhere to the requirements of this Policy, formalize the cross-institutional agreement, and document the existence of such agreement in their institutional policies;
- the highest institutional level, the body that originally defined the jurisdiction of the REB and its relationship to other relevant bodies or authorities within the institution, makes the decision to allow an REB to recognize decisions made by another institution’s REB (in accordance with Article 6.2); 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 and REBs should use the review models defined by their institution (see Article 8.2) and facilitate coordination of ethics review. Whatever model is chosen, roles and responsibilities of all involved in the process should be defined and agreed to at the outset. Continuing ethics review for such research should follow the same process outlined in Article 6.14.

**Review Models**

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

1. **Independent Review by Several Single REBs**

This follows the same review process for research that does not require the involvement of multiple REBs and/or institutions. The REBs involved at each participating institution conduct their independent research ethics review and provide their separate decisions, either concurrently or sequentially. The level of ethics review of research that may involve multiple REBs and/or institutions should be proportionate to the risk involved in the research. (See Article 6.12).

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

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

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

Institutions may allow research on specialized content or research methods to be reviewed by an external, specialized or multi-institutional REB, where such a body exists. In the official agreement between the selected REB and the institutions submitting research for review, the specialized or multi-institutional REB shall 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 creating a single joint REB to which 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 or policies that designate one or more REBs for the review of certain types of research within the province (see References below).

Roles and responsibilities should be clearly defined in the official agreement between the institution(s) delegating the review and the institution of the REB that will review the research, or in the relevant legislation or policies. 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. Review by a specialized or multi-institutional REB need not be preceded or followed by local REB review unless warranted to help ensure that local issues and values are taken into account.

3. Reciprocal REB Review

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

In either case, 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. The reviewing REB might call upon local REBs to provide information in addition to that provided by the researchers.

Selection of a Review Model Relevant to the Research Project

In accordance with their institutional policies and procedures, researchers and REBs should, together, determine which review model is the most appropriate for the proposed research involving multiple institutions and/or REBs.

When planning for research involving multiple institutions and/or multiple 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 the alternative review models at the planning and design stage of their research, and should consult with their REB to facilitate the selection and coordination of the appropriate review model.

Sensitivity to context is a key issue in the application of the core principles of this Policy to the ethics review of research involving multiple institutions.
and/or REBs. In choosing the appropriate review model, the researcher and the REB should pay attention to the research context and the characteristics of the populations targeted by the research.

Where the choice of review models is available, researchers and REBs should consider the following:

- the discipline and content area of the research and the availability of appropriate experience and expertise within, or available to, the reviewing REB;
- the scope of the project to be reviewed and appropriateness of the proposed review model;
- the vulnerability of the study population overall and/or the particular characteristics of the local population at individual sites, differences in values and cultural norms, and the level of risk associated with the research under review;
- any relevant differences in laws and/or guidelines pertaining to the research in question if the institutions are in different provinces/territories/countries;
- relationships between institutions and REBs, and conflict resolution mechanisms related to REB decisions;
- the potential for conflict of interests and undue influence, including from funding sources;
- 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 might affect the research.

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

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

National and international standards for research involving 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 shall satisfy itself that the requirements of this Policy are
Article 8.3
(a) 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 and/or REBs consistent with this Policy, the terms of that model apply.

(b) Subject to Article 8.3 (a), research conducted under the auspices of a Canadian research institution and conducted outside its jurisdiction, whether elsewhere in Canada or outside Canada, shall undergo prospective ethics review both by (i) the REB at the Canadian institution under the auspices of which the research is being conducted and (ii) the REB or other responsible review body or bodies, if any, at the host research site.

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, if any. 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 [see Chapter 9], 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).

Researchers should inform the REB about the absence of established review mechanisms at the research site, and about their efforts to identify any other suitable review mechanisms in the host country. When no appropriate mechanisms for research ethics review exist at the research site, researchers and REBs should apply the core principles outlined in this Policy. (See Chapter 1).
REBs should not prevent research from proceeding solely because the research cannot be reviewed and approved through a formal REB review process in the foreign country or other jurisdiction. Under these circumstances, researchers should be aware of relevant cultural practices, such as those normally followed to seek entry into the relevant communities, and be respectful of them. Researchers should inform the REB of their strategies to familiarize themselves with the relevant norms and cultural practices and to minimize risks to individuals and communities participating in, or potentially affected by, the research, including the risk of any social disruption that the research might cause or exacerbate. Additional guidance may be found in Chapter 4, Section D, and Chapter 9 of this Policy.

Researchers and REBs should afford the prospective participants no less protection and respect than what this Policy requires. Respect for persons, concern for welfare, and justice considered in the context of the particular research project and setting should guide researchers in the design of their research, and REBs in their review.

**Article 8.4**  
(a) The information to be provided to the home REB will be determined by the provisions of the review model.

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

- the relevant information on the rules governing human research and the ethics review requirements at the host site, where such exist;
- 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 researchers’ home REB.

**Application**  
Researchers and REBs should be aware of the research ethics requirements and the types of protection afforded to research participants at proposed research locations. Researchers and REBs should consult relevant resources for details about governing laws or policies, and for information regarding appropriate REBs at the proposed research site in Canada or in the host country. (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, at a minimum, the provisions of this Policy for the particular research project are followed at such sites, within the host country or in Canada.

Subject to Article 8.4(a), 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
researchers and the REBs or equivalent review bodies involved. (See also Section A 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 site or country. In the absence of formal reciprocity agreements between countries or institutions with respect to initial and continuing ethics review, 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 8.1).

Endnote

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

References

Chapter 9

RESEARCH INVOLVING ABORIGINAL PEOPLES IN CANADA

Note: A draft of Chapter 9 was released in November 2009. The version below was revised. To view the November 2009 version as well as a version showing where changes were made, please click on the following link: www.pre.ethics.gc.ca/eng/policy-politique/initiatives/reports-rapports/arei-iera/.

Introduction

The Aboriginal and treaty rights of Aboriginal peoples of Canada, including the Indian, Inuit and Métis peoples of Canada, were recognized and affirmed in the Constitution Act, 1982. This affirmation implies an ethical duty for those involved in research to acknowledge and support the desire of Aboriginal Peoples to maintain their collective identities and the continuity of their cultures.

This chapter acknowledges the unique status of the Aboriginal peoples of Canada. It interprets how the value of respect for human dignity and the core principles of respect for persons, concern for welfare, and justice, as articulated in Chapter 1 apply to research involving Aboriginal peoples. It accords respect to Indigenous knowledge systems by ensuring that distinct world views are represented wherever possible in planning and decision making, from the earliest stages of conception and design of projects through to analysis and dissemination of results. It affirms Aboriginal rights, interests and responsibilities as reflected in community customs and codes of research practice in order to better ensure balance in the relationship between researchers and participants and mutual benefit in researcher-community relations. The purpose of this chapter specifically, and the Policy in general, is to provide guidance to researchers on ethical conduct in research involving Aboriginal peoples. Neither this Policy nor this chapter are meant to reflect or introduce any change to current Government of Canada policy with respect to the issues discussed herein.

Indian peoples commonly identify themselves as “First Nations.” The desire to conserve and develop knowledge specific to First Nations, Inuit and Métis communities, and to benefit from contemporary applications of traditional knowledge, is a motivating force in community initiatives to assume a decisive role in research. The guidance provided in this chapter is based on the premise that engagement with community is an integral part of ethical research involving Aboriginal peoples. While continuing to respect individual autonomy, this Policy acknowledges the role of community in shaping the conduct of research, in particular, research that affects First Nations, Inuit and Métis peoples. In light of the diversity within and between First Nations, Inuit and Métis communities, and the ongoing development of community codes of research practice by these communities at the
local, regional and national level, ethical review of a proposed project must be attentive to
its specific context.

This chapter has drawn on prior work, both within Canada and internationally, that
recognizes the rights, interests and responsibilities of Aboriginal peoples participating in
and affected by research endeavours. Some of that work has been done by the three
gencies responsible for this Policy. In particular, the Canadian Institutes of Health
Research (CIHR) and its Institute of Aboriginal Peoples’ Health have engaged in extensive
dialogue with community partners to develop CIHR Guidelines for Health Research
Involving Aboriginal People (2007). The Social Sciences and Humanities Research Council
(SSHRRC) and the Natural Sciences and Engineering Research Council (NSERC), likewise,
have developed guidelines applicable to programs targeted at research involving Aboriginal
people and issues. Aboriginal entities at local, regional and national levels have published
and implemented codes governing research practice – including ethical protections – that
emphasize collective rights, interests and responsibilities.

This Policy provides guidance for research involving humans, as defined in Chapter 2.
Guidelines applicable to particular programs, research domains and community settings
may elaborate on processes set out herein, or may address ethical concerns of broader
scope. Researchers and research ethics boards (REBs) are advised to consult reference
documents that apply to their research undertaking. Examples of relevant resources are
listed at the end of this chapter.

A. Key Concepts and Definitions

For the purposes of this Policy, this chapter uses the following key concepts:

- Aboriginal peoples – a term referring collectively to Indian, Inuit and Métis
  peoples of Canada, whose existing Aboriginal and treaty rights are recognized and
  affirmed. Indian peoples commonly identify themselves by traditional names such
  as Mi’kmaq, Dene or Haida, and as First Nations. For the purposes of this Policy,
  the term “Aboriginal” includes persons of First Nations, Inuit or Métis origin –
  regardless of where they reside and whether or not they have status on an official
  register. The term “Aboriginal” glosses over the distinctions among First Nations,
  Inuit and Métis peoples, who have their own histories, cultures and languages, so an
  attempt has been made to limit use of the term in this Policy to instances where a
  global term is appropriate.

- Aboriginal rights, interests and responsibilities – for the purposes of this Policy,
  ethical obligations are more broadly construed than the legal definition of
  Aboriginal and treaty rights. The term “responsibilities” is consistent with
  Aboriginal worldviews that include multi-generational obligations to ancestors and
  future generations.

- Community – describes a collectivity with shared identity or interests that has the
  capacity to act or express itself as a group. In this Policy, a community may be
territorial, organizational or a community of interest. Territorial communities have
governing bodies exercising local or regional jurisdiction, for example, members of
a First Nation resident on reserve lands. Organizational communities have explicit
mandates and formal leadership. In both territorial and organizational communities, membership is defined and the community has designated leaders. Communities of interest may be formed by individuals or organizations who come together for a common purpose or undertaking, such as a commitment to conserving a heritage language. These are informal communities whose boundaries and leadership may be fluid and less well-defined. They may exist temporarily or over the long term.

An individual may belong to multiple communities, both Aboriginal and non-Aboriginal for example, as a member of a local Métis community, a graduate students’ society, and a coalition in support of Aboriginal rights. For the purposes of research, how an individual defines which of his or her community relationships are most relevant will likely depend on the nature of the particular research project being proposed.

- Community engagement – a process that establishes interaction between a researcher or research team and the Aboriginal community relevant to the research project. It signifies a collaborative relationship between researchers and communities, although the degree of collaboration may vary depending on the community context and the nature of the research. The engagement may take many forms including – consent from formal leadership to conduct research in the community, joint planning with a responsible agency, commitment to a partnership formalized in a research agreement, or dialogue with an advisory group expert in the customs governing the knowledge being sought. The level of engagement may range from information sharing to active participation and collaboration to empowerment and shared leadership of the research project. Communities may also choose not to engage actively in a research project, but simply to acknowledge it and register no objection to it.

- Indigenous knowledge – the knowledge held by Indigenous peoples who, in Canada, may be referred to as Aboriginal. 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, especially, in relationships. Indigenous peoples value their relationship with the land as a living entity that reveals the way to living a good life. Spirituality expressed in traditional or Christian practices, relationships with ancestors and responsibilities to future generations are integral to the world view of many Aboriginal peoples.

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. It includes traditional knowledge received from past generations and innovations transmitted to subsequent generations.
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B. Interpreting the Ethics Framework in Aboriginal Contexts

Chapter 1 identifies three principles as expressions of the core ethical value of respect for human dignity – respect for persons, concern for welfare, and justice. The three core principles are interpreted in this chapter as follows:

Respect for persons 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 cultures and identities have increasingly led to the development of codes of research practice that address concerns arising from their world views. Aboriginal codes of research practice thus go beyond the scope of ethical protections for individual participants, and extend to the interconnection between humans and the natural world, as well as obligations to maintain and pass on to future generations knowledge received from ancestors and innovations devised in the present generation.

Historically, the well-being of individual participants has been the focus of research ethics guidelines. In this Policy, the principle of concern for welfare is broader, requiring consideration of participants and potential participants in their physical, social, economic and cultural environments. This Policy acknowledges the important role of Aboriginal communities in promoting collective rights, interests and responsibilities that also serve the welfare of individuals.

Aboriginal peoples 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 and contribution to Canadian society. The interpretation of concern for welfare in First Nations, Inuit and Métis contexts may therefore place strong emphasis on collective welfare as a complement to individual well-being.

Justice may be compromised when a serious imbalance of power prevails between the researcher and participants. Resulting harms are seldom intentional but nonetheless real for the research participants. In the case of Aboriginal peoples, abuses stemming from research have included: misappropriation of cultural heritage such as songs, stories and artefacts; 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 misrepresented or stigmatized whole communities.

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 recruiting participants and maintained over the course of the research, can enhance ethical practice and the quality of research. Taking time to establish a relationship can promote mutual trust and communication, identify mutually beneficial research goals, define appropriate research collaborations or partnerships, and ensure that the conduct of research adheres to the core principles of justice, respect for persons and the concern for welfare of the collective, as understood by all parties involved.
“Indigenous peoples” is a term used in international discourse, roughly equivalent to the umbrella term “Aboriginal peoples” in Canada. For the purposes of this Policy, the following are considered to be among the characteristics that identify them. Indigenous people are the descendants of those who inhabited a country or a geographical region prior to the time when people of different cultures or ethnic origins arrived and established dominance through conquest, occupation or settlement. They display resolve to maintain and adapt their heritage and historical links to their territories and associated natural resources.

Although the present chapter addresses research involving Aboriginal peoples in Canada, researchers, REBs, research participants and the research community at large may find the guidance articulated here useful when undertaking research or reviewing a proposal involving Indigenous peoples in other countries or ethno-cultural groups who endorse collective decision making as a complement to individual consent. However, the importance of seeking local guidance in applying or adapting ethical guidelines articulated in this Policy must be emphasized.

For considerations that apply to research conducted in another country, see Chapter 8, Section B.

C. Applying Provisions of this Policy in Aboriginal Contexts

The Requirement of Community Engagement in Aboriginal Research

Article 9.1 Where the research is likely to affect an Aboriginal community or communities to which potential participants belong, and where any of the following conditions apply, researchers shall seek engagement with the relevant community:

(a) research is conducted on First Nations, Inuit or Métis lands;
(b) recruitment criteria include Aboriginal identity as a factor for the entire study or for a subgroup in the study;
(c) the research seeks input from participants regarding a community’s cultural heritage, artefacts, Indigenous knowledge or unique characteristics;
(d) Aboriginal identity or membership in an Aboriginal community is used as a variable for the purpose of analysis of the research data;
(e) the interpretation of the research results will refer to Aboriginal communities, peoples, language, history or culture.

Application While the legal basis for research oversight may vary depending on the community, the practical requirement of engaging community

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representatives and the ethical obligation to respect community views of welfare remain consistent.

Paragraph (a) refers to First Nations, Inuit and Métis lands that include Indian reserves, Métis settlements, lands allocated under an Inuit or First Nations land claim agreements and lands over which a claim has been asserted but not settled, as defined by the Aboriginal community prospectively engaged in research.

Paragraph (c) refers to cultural heritage, which includes but is not limited to First Nations, Inuit and Métis peoples’ relations with particular territories, material objects, collective knowledge and skills, and intangibles that are transmitted from one generation to the next – such as folklore, customs, representations or practices. Cultural heritage is a dynamic concept, in that materials, knowledge and practices are continuously adapted to the realities of current experience. For a further reference to cultural heritage see, for example, the United Nations Declaration on the Rights of Indigenous Peoples cited under References at the end of this chapter.

Cultural heritage research such as archaeological research and handling of artefacts may raise ethical obligations important to the Aboriginal community that may not be addressed in academic research protocols. Researchers and communities should agree in advance on how to reconcile or address these divergent perspectives. (See Article 9.12).

Paragraph (c) also refers to Indigenous knowledge. Appropriation of Indigenous knowledge, treatment of such knowledge as a commodity to be traded, or making unauthorized adaptations for commercial purposes may cause offence or harm to communities from which the knowledge originates. Such conduct has prompted initiatives in various countries and international agencies to address unethical, unfair and inequitable treatment of Indigenous knowledge and knowledge holders. (See Article 9.18).

**Forms of Engagement**

Community engagement as defined in this Policy can take varied forms. In geographic and organizational communities that have local governments or formal leadership, engagement would normally take the form of review and approval of a research proposal by a designated body prior to recruiting participants. In less structured situations (for example, a community of interest), a key consideration for researchers, prospective participants and REBs is determining the nature and extent of community engagement required. In some situations, the determination may be that the welfare of relevant communities is not affected, and consent of individuals is sufficient. Communities lacking infrastructure to support community engagement should not be deprived of opportunities to participate in guiding research affecting their welfare. (See Article 9.14).

**Article 9.2** The nature and extent of community engagement in a project shall be determined jointly by the researcher and the relevant community and shall be appropriate to community characteristics and the nature of the research.
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Application

First Nations, Inuit and Métis communities differ from one another, and they encompass increasing diversity within their own boundaries as a result of formal education, employment, mobility and intermarriage with non-Aboriginal persons. This diversity makes generalizations about the form of community engagement inappropriate. It also increases the importance of clarifying mutual expectations and obligations with the community and incorporating them in a research agreement.

The following list, which is not exhaustive, provides examples to illustrate the forms of Aboriginal engagement that might be appropriate in various types of research.

1) Research directly involving a community on First Nation, Inuit or Métis lands with a formal governance structure. For example, a project that examines the incidence of diabetes in Pond Inlet, Nunavut, or the impact of contaminants in animals and plants used for country food on Inuit health.

- 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) Research involving Aboriginal people who comprise a sizeable proportion of the study or community and where Aboriginal-specific conclusions are intended. For example, a comparative study of access to public housing in Prince Albert, Saskatchewan.

- First Nations in the district, represented by their tribal council, the local Métis association, urban Aboriginal and women’s organizations may partner with the Prince Albert city council to sponsor, implement and use the results of the housing study.

3) Research focusing on a larger community that is known to include Aboriginal people (regardless of their proportion), and where Aboriginal-specific conclusions are anticipated. For example, a study of student retention in high schools in the Sault Ste. Marie district of Ontario.

- 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) 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. For example, research on employment development programs serving residents of the inner city of Winnipeg in Manitoba.
5) Interviewing a sample of individuals of Aboriginal ancestry across Canada on the impact of a policy in their lives, where the results are not attributable to or likely to affect the community or communities with which they may identify. For example, survey research on the implementation of Indian Act provisions requiring ministerial approval of an “Indian’s” will.

- First Nations, Inuit and Métis individuals, whether or not they identify as members of an Aboriginal community, freedom of expression as does any citizen. They are free to consent and to participate in research projects that they consider of personal or social benefit. If the project is unlikely to affect the welfare of the individuals’ communities, local community engagement is not required under this Policy. The necessity or desirability of engaging regional or national representatives of Aboriginal communities in policy research may, however, be determined by other considerations.

6) Natural sciences research on First Nation, Inuit or Métis lands and treaty and land claims agreement areas where Aboriginal people may act as co-investigators or benefit from findings. For example, research focusing exclusively on contaminants in animals or plants in Nunavik that does not make inferences regarding food intake.

- Research that involves the collection and analysis of tissue samples from animals or plants and not involving human research participants is not covered within the scope of this Policy and does not require REB review. However, funding program guidelines and licensing requirements in the North may impose obligations to engage communities. Community laws, customs or codes of research practice may require securing regional and local permission and reporting findings to communities on whose traditional lands the research takes place. (See NSERC literature on Northern Research Program for professors and students/fellows and Article 9.8 below).

7) Research that incidentally involves a small proportion of Aboriginal individuals but is not intended to single out or describe characteristics of Aboriginal people in the study. For example, a study of the effectiveness of therapies to control high blood pressure in a sample of hospital outpatients not designed to collect Aboriginal-specific data.

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

8) Research exclusively based on publicly available information as defined by this policy. For example, historical, genealogical or analytical research based exclusively on publicly available records or data in accordance with legislation.

- Such research does not involve the collection of data from communities directly or from living persons and is not subject to REB review. (See Article 2.2). Community engagement is not required. However, findings of such research nevertheless may have an impact on the identity or heritage of persons or communities. Researchers should seek culturally informed advice before use of such data to determine if harms may result and if benefit-sharing should be explored with the original source community. (See Article 9.15).

**Respect for First Nation, Inuit and Métis Governing Authorities**

Where a proposed research project is to be conducted on lands under the jurisdiction of a First Nation government, an Inuit land claim organization or a Métis government, or on traditional lands subject to a claim as defined by the community, researchers shall seek the engagement of formal leaders of the community, except as provided under Articles 9.5, 9.6 and 9.7.

**Application**

Formal leaders with governance responsibilities on First Nations, Inuit or Métis lands are charged with protecting the welfare of the community. They may approve research or delegate responsibility for reviewing proposals to a local or regional body. Article 8.3 applies in such cases, requiring ethics review of research proposals both by “(i) the REB at the Canadian institution under the auspices of which the research is being conducted and (ii) the REB or other responsible review body or bodies, if any, at the host research site.” Ethics review by the institutional REB and the responsible community body are required in advance of recruiting and securing consent of individuals.

Research involving multiple geographic communities raises complex issues of review and approval. Regional bodies or national organizations may facilitate ethics review and make recommendations but the decision on participation normally rests with the local community.

**Engagement with Organizations and Communities of Interest**

Aboriginal organizations, including First Nations, Inuit and Métis representative bodies, service organizations and communities of interest shall
be recognized as communities for the purposes of collaboration in research undertakings and representation of their members in ethical review and oversight of projects.

Application  Research affecting First Nations, Inuit and Métis peoples is often initiated outside the Aboriginal community and carried out by non-Aboriginal personnel. Researchers have often neglected to inform participants and communities of results and they have afforded Aboriginal people little opportunity to correct misinformation or to challenge ethnocentric interpretations. In light of such experience, many Aboriginal people feel apprehensive about the activities of researchers and they are reluctant to participate in research.

A majority of persons who self-identify as Aboriginal live in rural and urban communities outside of designated Aboriginal lands. Issues affecting their welfare are under-researched. Political organizations, Friendship Centres, housing associations, healing circles and many other groups that have come together are potential partners in creating knowledge to enhance the welfare of their own communities and society at large.

Complex Authority Structures

Article 9.5  Where alternatives to securing the agreement of formal leadership are proposed for research on First Nations, Inuit or Métis lands or in organizational communities, researchers should engage community processes and document measures taken, to enable the REBs to review the proposal with due consideration of complex community authority structures.

Application  REBs should not assume that approval of a project by formal leaders is the only avenue for endorsing a project. In some communities and some domains of knowledge, authority to permit and monitor research rests with knowledge keepers designated by custom rather than election or appointment. In First Nations settings, a confederacy council spanning several communities may be recognized as having authority over its members’ traditional knowledge. In an Inuit community, the hamlet council, an Elders’ circle and a Hunters’ and Trappers’ society may have overlapping responsibility and expertise with respect to the knowledge being sought. Métis Elders dedicated to conserving Michif language may assert their autonomy from political leaders but choose to collaborate with educational or cultural agencies.

The preferred course is to secure approval for research from both formal leaders of a community and customary authority. This is especially important for outsiders to communities, whose presence or intentions might be challenged. Researchers should engage community processes, including the guidance of moral authorities such as Elders, to avert potential conflict. These measures should be documented to assist the REB in considering the community engagement processes proposed. (See Article 9.10).
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Recognizing Diverse Interests Within Communities

Article 9.6 In engaging communities, researchers should ensure, to the extent possible, that they take into consideration the views of all relevant sectors, including communities of interest who may not have a voice in the formal leadership of a geographical or organizational community. Vulnerable groups or individuals may need or desire special measures to ensure their safety or inclusion.

Application Vulnerable or marginalized subgroups within communities should be not be deprived of opportunities to participate in guiding research affecting their welfare. Covert research or direct challenges to legitimate authority risk increasing participants’ vulnerability, deepening rifts within the community and actually impeding the advancement of social justice. Strategies that have proven effective to accommodate diversity include: advocacy by moral authorities in the community; special measures to protect the identity of participants in small communities; identifying research questions that include rather than divide interest groups; or expanding the coverage of a project to multiple communities where personal interests are less prominent. In some cases, the risks to participants and communities involved with or affected by the proposed research outweigh the potential benefits likely to be gained and the research should not be undertaken.

Critical Inquiry

Article 9.7 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.

Application Considerations in conducting critical inquiry are discussed more fully in Article 3.6. As in the case of research involving vulnerable subgroups within an Aboriginal community (see Article 9.6), critical inquiry will require creative approaches to ensure that cultural norms are respected, that the safety of participants is protected and that the welfare of the larger community is not disrupted.

For example, the Sisters in Spirit project of the Native Women’s Association of Canada (NWAC) launched in 2005 for a five-year period illustrates research of national scope that incorporates a critical dimension. The project involves interviewing families of missing and murdered Aboriginal women in urban and rural settings, on and off First Nations territory. It examines, among other matters, the adequacy of public institutions and services, Aboriginal and non-Aboriginal, to protect the women’s well-being and support families in their efforts to deal with their losses. The objective is to effect policy change and improve the safety and well-being of Aboriginal women in Canada. NWAC has published its commitment to participatory research and the principles and practices that protect the privacy and well-being of participants. The project builds on NWAC’s 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.

Respect for Community Customs and Codes of Practice

Article 9.8 Researchers have an obligation to become informed about and to respect the
relevant customs and codes of research practice that apply in the particular
community or communities affected by their research. Inconsistencies between
community custom and this Policy should be identified and addressed, where
possible, in advance of initiating the research.

Application First Nations, Inuit and Métis codes of research practice derive from laws and
customs of predominantly oral cultures. While some rules may be in written
form, their interpretation is dependent on experiential knowledge acquired
through interactions in the community. An example is the strict limitation on
making publicly available sacred knowledge that might be revealed within a
trusting relationship. In academic culture, rules regarding limits on disclosure
of information would reasonably be incorporated in a research protocol.

In Aboriginal communities, custom may restrict the observation, recording or
reporting of ceremonies or certain performances and require approval of
appropriate individuals. Article 10.3 addresses research involving observational
studies, the requirement for research ethics review and the ethical implications
associated with observational research approaches, which may infringe on
consent and privacy.

Many First Nations communities across Canada have adopted an ethics code
originally developed to govern practice in the First Nations Regional Health
Survey. It asserts ownership, control, access and possession of research
processes affecting participant communities and is generally referred to as
OCAP. It addresses issues of privacy, intellectual property, data custody and
secondary use of data, which are also covered later in this chapter. Researchers
should consult with their own institutions to ensure that the application of
OCAP or other community-based ethics codes is consistent with institutional
policies, particularly on issues of intellectual property. Where conflicts exist,
they should be addressed and resolved prior to the commencement of the
research. (See Article 9.18).

The ethical duty to respect community laws, customs and responsibilities and
to engage the relevant community applies equally to First Nations, Inuit and
Métis researchers conducting research in their own local or cultural
communities, if they are also members of research institutions adhering to this
Policy. First Nations, Inuit and Métis scholars attached to academic institutions
as faculty members, students or research associates are increasingly engaged in
research involving their own communities and sometimes their own family
members. They are generally exempt from restrictions on physical access to
territory or personal access to community members.
Life history and language research are examples of research areas where insider relationships and skills provide unique opportunities to extend the boundaries of knowledge. While it can be argued that recording the life history of an elderly relative is a family matter rather than a community matter, the potential impact of such research on the wider community, conflicts between the individualist norms of the academic environment and the norms of the community, and the possibility of unclear or mistaken assumptions on the part of participant and researcher make community engagement important. The relevant community to be engaged in such cases might be extended family members, peers of the participant with whom the researcher’s interpretations can be validated, or Elders knowledgeable about cultural rules governing disclosure of privileged information.

**Institutional Ethics Review Required**

Article 9.9 Ethics review by community REBs or other responsible bodies at the research site will not be a substitute for review by institutional REBs and will not exempt researchers affiliated with an institution from seeking REB approval at their institution, subject to Article 8.1.

Application Applying this Policy in a way that accommodates the diversity of First Nations, Inuit and Métis cultures and communities is complex. For example, the fit between institutional policies and community laws, customs and codes of research practice may be unclear, requiring researchers to adapt conventional practice or negotiate a resolution.

The presumption that community engagement is required in research involving Aboriginal participants is consistent with Article 8.3, which provides that research conducted outside the jurisdiction of the researcher’s institution shall undergo prospective ethics review both by “(i) the REB at the Canadian institution under the auspices of which the research is being conducted and (ii) the REB or other responsible review body or bodies, if any, at the host research site”.

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

In accordance with Article 8.4, communication between the institutional REB and the responsible agency in the community may assist in resolving inconsistencies between institutional policy and community laws, customs and codes of research practice. If a community ethics review is required in addition to the mandatory institutional REB review, reconciling differences may require re-submission to one or the other review body.

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

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 in Aboriginal cultures are
captured within its regular complement. For occasional review of Aboriginal
research appointment of ad hoc advisors or delegation to a specialized or
multi-institutional REB may be appropriate. (See Articles 6.4, 6.5 and
Article 8.1).

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

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

**Article 9.10** When proposing research expected to involve First Nations, Inuit or Métis
participants, researchers shall advise their REB how they have engaged or
intend to engage the relevant community or, alternatively, present a rationale as
to why an exception to the requirement is appropriate.

**Application** In order for REBs to consider whether the form of community engagement is
appropriate, they will require evidence in the form of (a) a preliminary or
formal research agreement between the researchers and the responsible body in
the research site; (b) documentation of a written or oral decision to approve the
proposed research in a group setting; (c) a written summary of advice received
from a culturally informed advisory group or ad hoc committee, for example in
an urban community of interest. Provision of a research agreement is
particularly emphasized in health research funded by CIHR. (See CIHR
*Guidelines for Health Research Involving Aboriginal People* in the Reference
section at end of this chapter).
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Where a researcher has an ongoing relationship with a community, a letter from formal or customary leaders in the relevant community may signal approval to proceed with the research.

Although researchers must offer the option of engagement, a community may choose to engage nominally or not at all, despite being willing to allow the research to proceed. A community may, for example, support a study carried out independent of community influence in order to use scientifically defensible results to validate a negotiating position. In instances where community engagement is not taken up, researchers must present to the REB the steps they took to invite and facilitate engagement by the community. Lack of engagement by communities may also be due to inadequate financial or human resources. Researchers should demonstrate what efforts they have made to assist in capacity-building to facilitate engagement.

Research Agreements

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

Application Research agreements serve as a primary means of clarifying and confirming mutual expectations and, where appropriate, commitments between researchers and communities. The scope of the agreement will depend on the level of engagement which the community desires, and the availability of resources to support community participation.

At a minimum, the agreement should address the ethical protections that would apply in securing individual consent for a comparable project and should specify any commitments regarding collective community participation and decision making, sharing of benefits and review and updating of the agreement. Expanding on information normally provided to an individual participant (see Article 3.2), agreements typically set out the purpose of the research and detail mutual responsibilities in project design, data collection and management, analysis and interpretation, production of reports and dissemination of results.

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

Research agreements are increasingly being recognized by academic institutions and the researchers associated with them as providing reference points for ethics review and approval on such elements as consent, confidentiality and intellectual property. 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. Researchers should check with their institutions regarding signing authority for research agreements that include undertakings beyond those normally included in a consent form.

Community agreement that a research project may proceed is not a substitute for securing the free and informed consent of individuals being recruited to participate in that project, in accordance with Chapter 3.

Building relationships, clarifying the goals of a project and negotiating agreements requires substantial investment of time and resources on the part of the community and researcher. Development and participation costs incurred by the community and the researcher should be factored into proposals to the extent possible within funding guidelines.

**Collaborative Research**

**Article 9.12** While community engagement is appropriate in any research that affects Aboriginal communities, researchers should consider applying a collaborative or participatory approach as appropriate to the nature of the research and the level of engagement desired by the community.

**Application** This Policy encourages collaborative research with First Nations, Inuit and Métis communities as a means of facilitating mutually respectful and productive relations.

Collaborative research is generally understood to involve respectful relationships among colleagues, each bringing distinct expertise to a project. Collaboration often involves one or other of the partners taking primary responsibility for certain aspects of the research, such as addressing sensitive issues in community relations or scientific analysis and interpretation of data.

Community-based research is research that takes place at community sites and involves collaboration between community agencies and scientific researchers. It often seeks to address a research topic of practical relevance to the community. The terms “community-based research” and “participatory research” are often used interchangeably or in combination.

Participatory research is a method that promotes research relevant to local concerns, action and social change, increased community skills, capacity building, sustainability, and knowledge translation. In its fullest expression, participatory research engages researchers and community members in an active partnership that shares decision making throughout the research process – identifying the issue to be researched, developing the research design, collecting, analyzing, and interpreting the data, developing conclusions and disseminating results.
An outcome of collaborative research highly valued by communities is increased capacity to carry out autonomous research that can more readily be conducted in Aboriginal languages and oral modes. The exploration, articulation and application of Indigenous knowledge in the local community is thus advanced, potentially benefiting other communities through knowledge transfer.

**Mutual Benefits in Collaborative Research**

**Article 9.13** Collaborative research should be relevant to community needs and priorities and should benefit the participating community as well as extend the boundaries of societal knowledge.

**Application** To benefit the participating community a research project should be relevant and have the potential to produce valued outcomes from the perspective of the community and its members.

Relevance and community benefit can take a number of forms depending on the type of research being conducted. For example, genetic research on diabetes in a First Nations community is unlikely to benefit the community in the short term, but collaboration may facilitate increased knowledge of the condition and change that improves health outcomes. Collaborative research can thus accommodate basic as well as applied research, short-term and long-term benefits. In another example, a study of housing and homelessness in an Inuit community was initiated at the request of the community. Using participatory research methods and social science tools, the nature, extent and consequences of the local housing shortage was documented, enabling the community to communicate its needs effectively to non-Inuit (Qallunaat) authorities. Training workshops provided employment and transferred skills to Inuit youth involved in data collection. The project provided field experience in community-based research for university student assistants and materials useful to other Inuit communities in subsequent research.

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. They also seek to share in the benefits of research activities in the form of direct research grants, release time for project personnel, overhead levies on shared projects and commercialization of research discoveries.

**Strengthening Research Capacity**

**Article 9.14** Research projects should support the enhancement of the skills of community personnel in research methods, project management and ethical review and oversight.

**Application** To the degree possible, researchers should foster education and training of community members to enhance their participation in research projects.
Employing Aboriginal research assistants and translators is already common practice in community-based projects. Extending skills transfer through a rational program of training will support collaboration with institutions and advance the capacity of communities to initiate and implement their own research.

Communities vary widely in the level of human and material resources they have available to collaborate with research initiatives. Small, remote communities and many urban communities of interest have limited organizational resources to advise or collaborate in research. The least organizationally developed communities are the most vulnerable to exploitation. Researchers, REBs and communities leaders should strive to protect the interests of such communities by undertaking research and supporting the enhancement of capacity to participate in research.

Funding programs that target the development of Aboriginal research and capacity building seek to generate significant research training opportunities for Aboriginal students, allowing researchers to include in their grant applications stipends for undergraduate, master’s degree or doctoral students or post-doctoral researchers, as appropriate, with priority given to Aboriginal people.

**Recognition of the Role of Elders**

**Article 9.15** Researchers should engage the community in determining appropriate recognition for the unique advisory role of Elders in the design and execution of research and interpretation of findings in the context of cultural norms and traditional knowledge.

**Application** Recognition of Elders may include adherence to customary prescribed procedures to solicit their involvement – feasting, gift-giving, providing honoraria, acknowledging contributions by name or, as directed, withholding the Elder’s identity in reports and publications. 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.

**Privacy and Confidentiality**

**Article 9.16** 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 individual consent process.

**Application** Researchers and community partners should consider early in the design of the research how community codes of research practice fit with provisions for privacy and confidentiality set out in Chapter 5. Where conflicts exist, they should be resolved in advance of starting the research.
In some First Nations communities, privacy and confidentiality of identifiable personal and community information may be affected by application of the principles of ownership, control, access and possession (OCAP). (See definition under Article 9.8). The Regional Health Survey administered by regional First Nations organizations has addressed 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.

Small Aboriginal communities are characterized by dense networks of relationships, with the result that de-identifying individual data is often not sufficient to mask identities, even when data are aggregated. Communities themselves have distinguishing characteristics, which in some cases have compromised efforts to disguise the site of research and led to the stigmatization of whole communities. Some Aboriginal research participants are reluctant to speak to interviewers from their own community because of privacy concerns.

On the other hand, in some social sciences and humanities research, the significance of information is tied to the identity of the source, and individual attribution, with consent, is appropriate. Communities partnering in research may wish to be acknowledged for their contribution.

Privacy protections in research are evolving. Respect for and accommodation of First Nations, Métis and Inuit priorities on joint ownership of the products of research and maintaining access to data for community use should guide research practices, with appropriate deference to federal, provincial and territorial legislation on privacy.

**Interpretation and Dissemination of Research Results**

**Article 9.17** Researchers should afford community representatives engaged in collaborative research an opportunity to react and respond to research findings before the completion of the final report, in the final report, and in all relevant publications resulting from the research.

**Application** 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 about interpretation arises between researchers and the community and cannot be resolved, 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.
Final reports shall be made available to the community participating in the research. Researchers and communities should clarify the extent to which research findings will require translation, plain language summaries or oral presentations in order to make the research findings accessible to the community.

An Aboriginal community and those who participated in the research should have the option to decide how collective or individual contributions to the research project will be acknowledged and credited in the dissemination of results, for example at conferences and seminars.

Intellectual Property

Article 9.18

In collaborative research, intellectual property rights including copyright should be discussed by researchers, communities and institutions and the assignment of rights or the grant of licences and interests in copyrighted material that may flow from the research should be specified in advance of the research in a research agreement, as appropriate.

Application

There is an ongoing international debate regarding misappropriation, commodification, and unfair or harmful commercial exploitation of Indigenous knowledge.

First Nation, Inuit and Métis laws and customs distinguish among knowledge that can be publicly disclosed, disclosed to a specific audience or disclosed under certain conditions. Determination of what information may be shared and with whom will depend on the culture of the Aboriginal community in question. Any restrictions on access to or use of traditional or sacred knowledge shared in the course of the research project should be addressed in the research agreement.

Researchers, institutions and communities may need to adopt a two-tiered approach: first to address issues regarding access to data and use or publication of findings; and second, to address issues related to commercial applications of the results from collaborative research.

Regarding the first issue (access and use of data) a research agreement may set out any limits on the disclosure of personal or privileged information, subject to applicable legal and regulatory requirements and the discussion in Chapter 5 of this Policy. It might include a right to review reports and publications regarding the research prior to publication or limits on the release of, or access to research results, subject to applicable laws. The agreement may also set out any interests, licences or assignments in copyright flowing from publications about or based on the research.

With respect to commercialization of results, the use, assignment or licensing of any intellectual property, such as patents or copyright, resulting from the research (if any) may also be addressed in an agreement.
Researchers should consult the research office of their institution before entering into a research agreement that includes intellectual property provisions. Researchers should consult the program literature or policies on intellectual property and copyright adopted by the federal research agencies NSERC, SSHRC and CIHR available on their websites and seek legal advice where appropriate.

It is widely recognized that some Indigenous knowledge may have commercial applications and lead to the development of marketable products, for example, traditional plant medicines. If the proposed research has explicit commercial objectives or direct or indirect links to the commercial sector, these should be clearly communicated to all parties as a requirement of consent.

**Prospective Collection of Human Biological Material Involving Aboriginal Peoples**

**Article 9.19** As part of community engagement, researchers shall address and specify in the research agreement the rights and proprietary interests of individuals and communities, to the extent such exist, in human biological materials and data to be collected, stored and used in the course of the research.

**Application** Canadian law does not provide clear recognition of property rights in human biological materials. Researchers should be aware, however, that Aboriginal people and communities express proprietary interests in data and biological samples collected for research. Consistent with Chapter 12, and Article 9.11 of this Policy, researchers and communities should address and specify in the research agreement:

- the objectives for collection, use and storage of human biological materials;
- the roles and responsibilities regarding custodianship of the data and the samples; and
- any future use of these samples and associated data, including material transfer agreements to third parties and any subsequent requirements for community engagement.

Individuals who are invited to donate biological materials shall give their consent in accordance with Articles 12.1 and 12.2.

**Consent and Secondary Use of Data or Human Biological Materials Originating from Aboriginal Peoples**

**Article 9.20** 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 re-consent from individuals, new or renewed agreement of communities, or seeking culturally informed advice about protection of cultural heritage or representations of Indigenous knowledge or society.
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Application

Misrepresentation of Aboriginal peoples, use of data or human biological materials without appropriate engagement with the source community or consent of participants, 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 unauthorized genetic research. In addition, there are fears in First Nation communities that access to health data for purposes other than treatment will facilitate unauthorized government surveillance.

The privacy of individual participants in research is normally protected by removing information that would identify them personally. De-identified data are added to a data pool and are available for analysis and sometimes for secondary use. Consistent with the general provisions set out in Chapter 5, secondary use of data collected initially for other purposes, from which personal identifiers have been removed, does not require REB review.

As discussed in Chapter 5, 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 impracticable to obtain it subsequently. Such secondary usage requires REB review (see Articles 5.5 to 5.7), and the REB may allow an alteration or waiver of consent under certain conditions. (See Section B, in Chapter 3).

Secondary use of data identifiable as originating from Aboriginal participants or communities shall be subject to REB review to avoid harms ensuing from inadvertent identification of communities, potential misuse of cultural heritage, or misrepresentation of Indigenous knowledge when interpretation of data is no longer guided by community engagement. 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.

A common example of secondary use of data that are identifiable as originating from a specific community without appropriate engagement with the community is the practice of accessing traditional plant knowledge from the published literature to inform commercial development of products. In fields such as ethnobotany there is a significant amount of traditional knowledge that was published without the awareness or consent of the original knowledge holders. Researchers should seek culturally informed advice before use of such data to determine if harms may result and if benefit-sharing should be explored with the original source community.
Article 9.21 Researchers who propose research involving secondary use of human biological materials originating from Aboriginal peoples shall:

(a) obtain REB approval for the proposed research; and

(b) engage the community from which the biological materials originated in accordance with any existing research agreement or the REB’s direction; and

(c) obtain consent of individuals from whom the biological materials originated unless:

(i) an existing research agreement permits secondary use based on individual consent given at the time biological materials were initially collected; or

(ii) the REB and the community agree that individual consent may be waived in accordance with Articles 12.3 or 12.4.

Application Where the researcher can satisfy the REB that secondary use is consistent with an existing research agreement, the REB may require that the researcher engage the community from which the biological materials and associated identifiable information originate in accordance with the terms of the research agreement. New individual consent to secondary use is not required where the original consent authorized future use. Where secondary use has not been specified in the research agreement and authorized by the original individual consent, researchers shall engage the community from which the biological materials and identifiable information originate prior to initiating secondary use. Individual consent for the secondary use is required unless the REB and the community agree that either Article 12.3 or 12.4 applies.

Endnotes

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2 See Chapter 1, regarding the scope of definitions used in this Policy.

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References

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- First Nations Regional Longitudinal Health Survey (RHS), www.rhs-ers.ca/english/
- NAHO Ajunnginiq Centre. Research and Research Ethics Fact Sheets, www.naho.ca/inuit/e/ethics/
Chapter 10

QUALITATIVE RESEARCH

Researchers in social sciences and humanities – such as anthropology, 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 quantitative research approaches. Many of the research practices and methodological requirements that characterize qualitative research approaches parallel those that characterize quantitative approaches – concerns regarding research quality, for example – but, as is the case with all research involving human participants, the criteria are adapted to the particular subject matter, context and epistemological assumptions about the nature of knowledge in the specific area of research of the specific project.

This chapter seeks to provide specific guidance on some issues that are particularly germane to qualitative research although such guidance may also be applicable to research using quantitative or mixed methods. In particular, it addresses issues of consent, privacy and confidentiality that may have unique manifestations in 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 guidance on principles, norms and practices applicable to qualitative research.

A. The Nature of Qualitative Research

Qualitative research reflects an 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 phenomena based on discourse, actions and documents and how and why 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 a 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 perspective of the researcher as an observer and analyst. As a result, qualitative researchers devote a great deal of attention to demonstrating the trustworthiness of their findings using a range of methodological strategies.

The section below provides a summary of the general approach as well as methodological requirements and practices of qualitative research.

**General Approach 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 theoretical approaches, questions that guide the research, methodologies, epistemological approaches 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 during the course of the research itself of questions, concepts, strategies, theories and ways to gather and engage with the data (e.g. in emergent design research, see Article 10.6) requires a constant reflective approach and questioning from the researcher. Such flexibility, reflexivity and responsiveness contribute to the overall strength and rigour of data collection and analysis.

(d) **Diverse, Multiple and Often Evolving Contexts:** Qualitative research takes place in a variety of contexts, each of which presents 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.

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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 particularly useful or rich sources of information for furthering one’s understanding of phenomena of interest, not because the results may prove statistically significant.

A researcher may rely on multiple sources of information and data gathering strategies to enhance data quality. Researchers use a variety of methods for data gathering, including interviews, participant observation, focus groups and other techniques. In some cases, gathering of trustworthy data comes best from closeness and extended contact with research participants. In other cases, researchers and participants may continue research exchanges through electronic or other means after collection of data in the field. Qualitative studies of textual and image-based materials, such as published books, websites, interview transcripts, photographic images, or video, use a variety of content analysis techniques.

Appropriate treatments of data after they are gathered may vary greatly (see Article 10.5 and also Article 5.3). At the time of the initial consent discussion, researchers inform potential research participants about the confidentiality of the data and discuss the expectations of research participants (See Chapters 2, 5 and 9).

(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 Consent Process:** Entry into a particular setting for research purposes sometimes requires negotiation with the population of interest; sometimes the researcher cannot ascertain the process 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, such as 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 (e.g. 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 sometimes
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,
advance 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 certain 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 often
viewed as more of a theoretical issue than a procedural or sampling issue.

### B. Research Ethics Review of Qualitative Research

This section provides guidance on implications particularly germane to 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 potential benefit arising from the research, and the welfare of the participants
individually or collectively.

### Timing of the REB Review

**Article 10.1** Researchers shall submit their research project for REB review and approval of
its ethical acceptability prior to the start of recruitment of research participants
or access to data. Subject to the exception in Article 10.6, REB review is not
required for the initial exploratory phases involving contact with individuals or
communities intended to establish research partnerships or the design of a
research study. (See Article 6.11).
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, diary writing, and observation made long before the researcher formalizes a research project. These types of preliminary activities are not subject to REB review. (See Article 6.11).

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 involving Aboriginal populations (see Chapter 9) 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.

Modalities of Expression of Consent

Article 10.2 Researchers shall explain in their research design the consent procedures and strategies they plan to use for documenting consent.

Application REBs should consider the range of strategies for documenting the consent process that may be used by researchers using qualitative research approaches. Under a variety of circumstances, written consent is not required in qualitative research. However, where there are valid reasons for not recording consent in writing, the procedures used to seek consent must be documented.

The consent process should reflect trust between the research participants and the researcher. Often this is based on mutual understanding of the project’s goals and objectives. The research participant may sense attempts to legalize or formalize the process as a violation of that trust. 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 documented via completed 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 and whether a waiver of the requirement for signed written consent may affect the welfare of the 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 (e.g. a communications officer or spokesperson for an organization), consent can be inferred by the participant’s agreeing to interact with the researcher for the purpose of the research. For example, some political science research focuses on power structures and persons in positions of power (e.g. a senior partner in a law firm, a cabinet minister or a senior corporate officer). In this type of research, where a potential participant agrees to be interviewed on the basis of sufficient information provided by the researcher, it may be sufficient to signify consent to participate in the research. Researchers should demonstrate to the REB that the participant will be informed about the option not to participate or to withdraw from the study at any time. Nothing in this article should be interpreted to mean that potential participants need not to be informed about the study prior to their participation in the study.

Researchers and REBs should consult Chapter 3 and Article 3.12 in particular for additional details and considerations on consent.

**Proportionate Approach to Review of Observational Studies**

**Article 10.3** Research ethics review is required for research involving observation in places where personal information is being collected. When considering research involving observation in such environments or settings where the researcher collects personal information and where individuals or groups have a reasonable presumption of privacy, REBs 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 that does not allow for the identification of the participants in the dissemination of results, that is not staged by the researcher and is non-intrusive should normally be regarded as being of minimal risk. REBs
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should focus on projects above the threshold of minimal risk, or they should modulate requirements for protection proportionate to the magnitude and probability of harms, including the likelihood that published reports may identify individuals or groups.

Observational research is of two kinds: “non-participant” where the researcher observes, but is not a participant in, the action (also known as “naturalistic observation”); and “participant” where the researcher engages in, and observes, the action.

Participant observation is often 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 consent from individuals in that setting; in others, researchers will engage in covert participant observation. Researchers should demonstrate to the REB how they will address ethics issues derived from the specific methodological approaches in these types of research.

Observational studies raise concerns for the privacy of those being observed. In this regard, the nature of the research, its aims and its potential to invade sensitive interests may help researchers better design and conduct research. A matter that is public in the researcher’s culture may be private in a prospective participant’s culture. For example, observing sacred ceremonies without approval from the appropriate individuals or groups (e.g. Elders or traditional knowledge holders in Aboriginal research) and without engaging them about the subsequent use or interpretation of the data may have unintended negative implications. (See Articles 9.6 and 9.8). REBs and researchers need to consider methodological requirements of the proposed research project and the ethical implications associated with observational approaches, such as the possible infringement of consent or privacy. 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.

Waiver of Consent

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 consent. Covert observation of queuing behaviours in shopping malls, which does not involve any audio or video...
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recording that may allow identification of particular individuals is one example of a study where the research could not be completed if shoppers knew that they were being observed. Some forms of qualitative research seek to observe and study criminal behaviours, violent groups, or groups with restricted membership or access, using covert participant observation. 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. Other observational studies may be anonymous but involve intervention by the researcher (e.g. studying the propensity of bystanders to help in an emergency normally requires a staged emergency). Researchers should justify whether the need for such covert research justifies an exception to the general requirement for consent, and REBs should exercise their judgment taking into consideration the methodological requirements (See Article 3.7). Researchers and REBs may also consider whether debriefing is possible or necessary.

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.

Researchers and REBs should consult Chapter 3 and Chapter 5 for additional details and considerations.

Observational Studies Exempt from REB Review

Article 10.4 REB review is not required for research involving the observation of people in public places where:

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

(b) it does not involve collecting personal information that will be disseminated through photographic, film or video footage in the research results; and

(c) where individuals or groups targeted for observation have no reasonable expectation of privacy.

Application For the purpose of this Policy, data collection through observation of acts or behaviours occurring in public places intended to attract public attention are exempt from review by the REB. Research involving observation of people in public spaces where there is no presumption of privacy and where no personal 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) – does not require REB review, since it
can be expected that participants are aware of the public nature of the event or gathering. Similarly, where individuals should reasonably expect that their identities will be evident – for instance, as a result of their celebrity or public persona – research that refers to their presence does not require REB review. To determine whether Article 10.4 applies, when designing their research researchers shall pay attention to whether dissemination of research results will allow the identification of individuals in published reports. When in doubt, researchers should consult the REB prior to the conduct of the research involving observation in public places.

Some activities carried on in public places may be intended to involve a particular community of interest and may be based on a limited presumption of privacy. For example, individuals involved in religious services or practices, or chat rooms on the internet, may assume that participants and observers will accord the proceedings some degree of respect. Data collection for research purposes through observation of such acts or behaviours occurring in public places are subject to research ethics review and Article 10.3 of this Policy.

Where no personal information is collected, consent is not required. (See also Articles 2.2, 2.3 and Chapter 5).

Privacy and Confidentiality in the Dissemination of Research Results

Article 10.5 Researchers shall discuss with prospective participants whether their identity will be disclosed in publications or other means of disseminating research results, as appropriate to the research context. Researchers shall record the waiver of confidentiality by the participant.

Application In some types of qualitative research – oral history, a biographical study or a study involving specific personalities, for example – 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. For instance, in an interview study with visual artists concerning some aspect of the way they work, it might be appropriate and respectful to identify the respondents. 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 practices of their discipline. For example, social historians seek to document and archive the lives of individuals or highlight the contributions that ordinary people make in social and political life. In oral history anonymity is the exception. Researchers make the option for anonymity known to participants as part of the discussion around the nature and conditions of their consent.

In some types of critical inquiry, anonymity would result in individuals in position of power not being held accountable for their actions and for how the exercise of power of some has implications for others. The safeguard for
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those in the public arena is through public debate and discourse, and in extremis, through action in the courts for libel.

In much other social science and some humanities research, it is primarily the harm that can result from violations of research confidentiality that pose risks which the REB and researchers need to address. 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 maintain confidentiality of the research data. Where confidentiality is preferred or where there is no compelling reason to the contrary, confidentiality would be maintained in a manner commensurate with the expectations of the research participants and the project. In some cases, the researcher may decide to maintain anonymity of the research participant in publications or dissemination of research results to ensure confidentiality of data of other research participants.

REBs need to be sensitive to whether anonymity, confidentiality or identification is operative in any given research context, and acknowledge that individuals may want to be credited for their contribution.

Researchers and REBs should consult Chapter 5 for additional details and considerations. (See also Chapter 9).

Emergent Design

In qualitative research involving emergent design – that involves data collection and analysis that can evolve over the course of a research project in response to what is learned in earlier parts of the study – specific questions or other elements of data collection may be difficult to articulate fully in the research plan in advance of the project’s implementation.

Article 10.6 In studies using emergent design in data collection, researchers shall provide the REB with all the available information to assist in the review and approval of the general procedure for data collection.

Researchers shall inform the REB in cases, where changes to the data collection procedures during the conduct of the research may present ethical implications and risks to the participants associated with the new proposed change.

Application 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 in data sources, or discovery 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.

Researchers should provide the REB with all the available information to allow for a proportionate review of the study using emergent design. 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 methodological requirements and acknowledge that
questionnaires or interview guide may change to adapt to emerging data or
circumstances in the field.

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. Where changes of data collection procedures would
represent a change in the level of the risk that may affect the welfare of the
research participants, researchers should reflect on these changes and notify the
REB. Additional REB review may be required. (See Chapter 2 and Articles
6.14 and 6.15).

References

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Chapter 11

CLINICAL TRIALS

A. Overview

A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials.

Interventions include but are not restricted to drugs, radiopharmaceuticals, cells and other biological products, surgical procedures, radiologic procedures, devices, genetic therapies, natural health products, process-of-care changes, preventive care, and manual, behavioural and psychological therapies, etc. Clinical trials may also include questions that are not directly related to therapeutic goals – for example, drug metabolism – in addition to those that directly evaluate the treatment of study participants.

Clinical trials are most frequently undertaken in biomedical or health research, although research that evaluates interventions, usually by comparing two or more approaches, is also conducted in related disciplines, such as psychology. Clinical trials commonly involve testing new drugs or testing established drugs for new indications. For this reason, and for convenience, references in this chapter are made primarily to drug testing. The guidance provided in this chapter also applies, as appropriate, to trials involving other therapies or interventions.

Clinical trials take many forms, ranging from “n of 1” studies to multi-centre randomized controlled trials. Although the various types and forms of clinical trials have methodological differences, the ethical principles and procedures articulated in this Policy apply to and can be adapted for each of them. The primary focus of the chapter is on randomized controlled trials.

In addition to this Policy, national regulations and international guidelines provide direction on ethical principles and regulatory requirements for conducting clinical trials. For example, researchers undertaking clinical trials intended for use in seeking regulatory marketing approval in Canada must comply with Health Canada regulations. Researchers, specifically undertaking clinical trials pertaining to investigation in respect of a drug, should also respect the International Conference on Harmonization Good Clinical Practice Guidelines (ICH-GCP), which have been adopted by Health Canada, and other applicable policy or guidance documents. At the international level, the Declaration of Helsinki provides guidance for physicians conducting research. The European Convention on Human Rights and Biomedicine and The Council for International Organizations of Medical Sciences’ International Ethical Guidelines for Biomedical Research Involving Human Subjects provide general guidance on medical research on humans. These international guidelines have similar substantive aims but may employ different mechanisms for achieving such aims.
Clinical trials may draw participants from a variety of geographically diverse places. Data collected from all of the trial sites are pooled for analysis. Issues relating to such multi-site clinical trials are discussed in Chapter 8.

This chapter provides guidance on the ethical issues that are relevant specifically to clinical trial research. Clinical trial research is also subject to the general guidelines that are applicable to research involving humans. These guidelines are set out and discussed in Chapters 3 through 7.

B. Assessing Safety and Minimizing Risk

Participants enrolled in clinical trials are commonly exposed to experimental therapies, interventions, drugs or devices, each of which carries specific risks.

Article 11.1 Research ethics boards (REBs) should ensure that the risk to participants from drugs and other interventions in clinical trials is: (a) justified by the potential benefits to be gained; and (b) appropriately minimized.

Application The approach of proportionate review (see Chapter 2) dictates that studies deemed to be of greater risk 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, and/or have an expert evaluation undertaken on its behalf, to ensure that the risk from its use is: (a) justified by the potential benefits to be gained; and (b) 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 below), or take other steps reasonably necessary to promote the safety of participants.

Monitoring Safety and Reporting Adverse Events

A key responsibility of researchers and REBs is to ensure that, as a clinical trial proceeds, the risks to participants remain in the acceptable range and the safety of participants is monitored. It is the basis of the requirement for the reporting of serious adverse events or serious adverse drug reactions.

The following definitions are drawn from the ICH-GCP, which has been adopted by Health Canada:

- **Adverse event** – “... any unfavourable and unintended sign ... symptom, or disease temporally associated with the use of a medicinal ... product, whether or not related to the medicinal ... product ...”

- **Serious adverse event/serious adverse drug reaction** – “any untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect.”
Principal investigators must comply with Health Canada’s reporting requirements. These include the need to immediately report any safety problems and all serious adverse events to the sponsor and participants, as well as the need to report unexpected serious adverse events to the regulatory authorities and REBs. Sponsors also have responsibilities to expeditiously report all unexpected serious adverse events suffered by participants at any site to the regulatory body, the researchers and REBs at all institutions taking part in the research.

Assessing Research-Attributable Risk

Article 11.2 In clinical trials, an REB may approve a study that involves high-risk therapies if the research-attributable risk is no greater, or only minimally greater, than that to which patient-participants would routinely be exposed in their usual clinical care. Full REB review is the default level of review unless it is determined that delegated review may be appropriate.

Application 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 are sometimes invited to participate in clinical trials. Some kinds of standard or recognized treatments themselves pose significant risks (e.g., surgery, chemotherapy or radiation therapy). An REB may approve a study that involves 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 patient-participants would routinely be exposed. (See Chapter 2 Section B). 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 patients:

- 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.

Because these populations are often vulnerable as a result of being exposed to relatively high levels of risks, full REB review is often warranted. REBs should assess these trials to determine if they are appropriate for delegated review.

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 informed of the risks and potential benefits attributable to research, as distinct from those arising from indicated therapy. (See Chapter 2, Article 2.9 dealing with a proportionate approach to REB review).

Article 11.3 Researchers shall provide the REB with an acceptable plan for monitoring the safety of trial participants, including a plan for the tabulation, analysis and reporting of safety data in a form that permits REBs to interpret and act upon the data.  

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 researchers, sponsors and/or Data Safety and Monitoring Boards (DSMBs), provide REBs with clear and up-to-date information about the safety of participants taking part in clinical trials. Such reports should be provided promptly 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 serious adverse event reports, accompanied by an evaluation, by the sponsor, of their relevance and significance to the trial and its participants.

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 prompt 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.

Data Safety and Monitoring Boards

A DSMB or Data Safety Committee (DSC) is a multi-disciplinary, independent expert advisory group that is responsible for safeguarding the interests of participants in randomized controlled trials, assessing the safety and efficacy of study procedures and monitoring the overall conduct of a study. It is composed of scientists with expertise in the clinical area, statisticians, pharmacists and individuals with expertise in ethics. Where the size and complexity of the trial support the establishment of a DSMB, it plays an important role in ensuring the safety of study participants, although its responsibilities differ from those of an REB.

These responsibilities include:

- ensuring the overall safety of participants based on a review of the totality of evidence and the principle of the emergence of evidence that is likely to influence clinical practice;
advising the principal investigator and steering committees about the conduct of the trial and the integrity of the data, so as to protect the validity and scientific credibility of the trial;

- developing and operating under a DSMB Charter governing the activities of the DSMB.

Although the DSMB reports its findings and recommendations to the principal investigator, it should act independently of the sponsor and of the investigator. 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 will also be responsible for making appropriate recommendations about informing participants of safety concerns. The DSMB can also recommend that the principal investigator 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 11.4 REBs shall develop procedures to review safety reports and to take appropriate steps in response.

Application For more complex trials, an external DSMB may be appointed to provide a more comprehensive mechanism to monitor and address trial safety. Should the REB desire copies of DSMB reports and recommendations, they should liaise with the principal investigator or steering committee. A DSMB must be independent of the trial and its members free of conflicts of interests with the study therapy, the trial sponsor, and the outcome of the research. Even when there is a DSMB, the sponsor still has a responsibility to provide reports of serious adverse events directly to the REB, upon which the REB may be obliged to act urgently. The existence of a DSMB does not mitigate the responsibilities of the sponsor, investigator or REB to monitor and address trial safety.

Article 11.5 Investigators shall inform participants, immediately, of serious adverse events as they pertain to the participant’s health and/or willingness to continue to participate in the trial. They should also report these events to the REB.

Application For the purposes of this Policy, adverse event includes adverse drug reactions. Investigators in multi-site trials should be encouraged to inform other site investigators of serious adverse events. Where a sponsor has discontinued or unblinded a clinical trial or a part of a clinical trial, the investigator has regulatory responsibility to inform both clinical trial participants and the REB of the discontinuance or unblinding and the reasons for it, and also to advise them in writing of any risks to the health of participants.
Investigators should feel free to use their discretion in communicating other adverse events to participants as they think beneficial. Adverse events should be communicated to individual participants based on the extent to which the adverse event may be relevant to the participant’s health, safety and ongoing consent. REBs should encourage communication of adverse events among site investigators.

Reports on adverse events should provide the necessary detail for REBs to contextualize the report and understand the impact of the adverse event on the health and safety of participants.

C. Phases of Clinical Trials

This section discusses the ethical issues pertaining to the different phases of clinical trials, primarily those involving drugs. The guidance provided in this section may also apply, as appropriate, to trials involving other therapies or interventions. Clinical trials involving pharmaceutical products are commonly categorized into four phases, each of which gives rise to particular ethical issues. In all phases of such clinical trial research, REBs should be aware of ethical issues including but not limited to safety, selection and recruitment of participants, undue inducement, consent, and real, potential or perceived conflicts of interests.

Article 11.6 When reviewing a clinical trial protocol, the REB should be aware of its phase and the special ethical issues that different phases of research may raise.

Application Some ethical issues are most likely to arise in a specific phase or phases of a clinical trial. Other issues may arise at any phase of a clinical trial.

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. Participants in Phase I clinical trials are usually healthy volunteers or patients who have failed conventional therapy. Pharmacokinetic studies (the study of the absorption, distribution, metabolism, and elimination of a drug or ingested compound) are one example of Phase I clinical trials.

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 offered incentives 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 incentives offered to participants, raises ethical concerns about safety, the selection and recruitment of participants, and the consent process. 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 incentives being offered, risks they would otherwise refuse.

Although there are clear benefits to conducting Phase I trials on healthy volunteers, 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 safety (e.g. short-term side effects) and efficacy of new drugs. They are conducted in populations with the disease or condition sought to be treated by the drug.

Ethical Concerns: Phase II or 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 risks and potential benefits of the study and thus may affect their decision whether to participate. Additionally, because participants in Phase II trials include patients who are often unwell and frequently not working, the REB should ensure incentives for participation is not coercive, and patients do not accept risks they would otherwise refuse, because of the incentives being offered. Researchers should be encouraged to consult with the REB at an early stage about any recruiting, consent or safety issues that arise.

During the course of a Phase II clinical trial, patients will have access to a new drug that may be efficacious (provide clinical benefit). Investigators should: a) as part of the consent process, provide details on access to the new drug upon trial completion; and b) make reasonable efforts to secure continued access to the drug following the Phase II trial, for those patients for whom the drugs appear to be efficacious.

Phase III

The drug or treatment is given to a large group of patients, often at several sites. Phase III trials determine the drug or treatments’ efficacy by comparing it with commonly used treatments, monitoring for side effects and collecting additional information to evaluate the overall risk-benefit relationship of the drug. This information will help support the safe use of the drug or treatment. These studies may lead to a new drug being marketed in Canada or to the use of an approved drug for a new indication.

Ethical Concerns: The REB should 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). The REB should also address the issue of continuing access to the experimental therapy after the trial. If the treatment benefits participants and
is safe, will it continue to be provided? If so, for how long and at what cost? 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 (e.g. 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 determine the effectiveness 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 drug’s sponsor. However, the financial terms associated with these trials may create problems such as inappropriate prescription practices, billing practices or utilization of public resources (e.g. diagnostic services and medical imaging). 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, which includes a design and objective(s) that are scientifically, rather than commercially, driven. Phase IV trials designed with the primary goal of increasing sales, do not constitute legitimate research.

D. Sharing New Information

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

Article 11.7 Researchers shall promptly share information that may be relevant to participants’ ongoing consent to participate in the research with the REB, the participants, and other appropriate regulatory or advisory bodies.

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

Application Article 11.7 outlines a researcher’s continuing duty to share new and
relevant information from the clinical trial.

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 consent. (See Articles 2.8, 3.3, 3.4, and 6.15). To understand its particular relevance, the information should be considered from the perspective of the participant. New information that arises outside the trial (e.g. new findings in other related research), should also be disclosed when that information is relevant to the participant’s ongoing consent to participation. 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.

Researchers must promptly share new information with the REB and trial participants. What constitutes prompt disclosure may be set out in regulatory documents, such as Health Canada’s Food and Drug Act and Regulations, or in the absence of regulatory requirements, the REB may provide guidance. If sponsors fail 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 more promptly it should be disclosed. Researchers should also promptly share new information with other physicians administering the treatment and the scientific community to the extent that it may be relevant to the general public’s welfare.

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, as well as to the ongoing research elsewhere and the general public. If so, reasonable steps should be taken to inform such participants, and publicly disclose the information, in a meaningful and timely manner.

E. Therapeutic Misconception

Although clinical trials may provide benefits to some participants, the purpose of a clinical trial is to evaluate an experimental therapy or intervention, not to provide therapy. 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. 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. Even when research risks, potential benefits and alternatives are explained to them, it is common that trial patient-participants do not fully appreciate the differences between clinical care and research participation. 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 health. This may be particularly true when the researcher is the patient-participant’s own physician or care provider. 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.

Article 11.8 REBs 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 Article 3.2 describes the requirements for informed consent to research participation. It indicates that participants shall 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. 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 – clinician and researcher – and to ensure that patient-participants understand the research elements of the study. While the physician is ultimately responsible for patient care and safeguarding the patient’s health, patient-participants should understand that a physician who conducts research is acting in a capacity that is outside the traditional physician-patient relationship.

One way to minimize therapeutic misconception is to ensure that the health care professionals who provide the patient’s regular care are involved as little as possible in recruitment and the consent process, to ensure that clearly different people perform treatment and research functions.
Clinician-Researchers and Therapeutic Misconception

“Clinician” is defined as any health care provider. Research has shown that clinician-researchers may conflate research and clinical practice. Some clinicians may be unrealistically optimistic about an experimental intervention’s prospects. Clinicians may overstate the potential benefits and understate the risks of participation in a clinical trial when speaking with potential participants. Clinicians who conflate research and individual therapy may foster therapeutic misconception among patient-participants that may influence recruiting and the consent process. (See Chapter 3). They should take care not to create unrealistic expectations among participants with respect to the potential benefits of the research.

F. Financial Conflicts of Interests

Real, potential or perceived financial conflicts of interests are a feature of some clinical trials. Clinical trials may also be subject to other forms of conflict of interests. (See Chapter 7).

Industry-Sponsored Research

**Article 11.9** REBs should be aware of and consider the possibility of financial conflicts of interests. They 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** Researchers should not benefit financially from pharmaceutical or biotechnology companies. Financial incentives have the potential to distort researchers’ judgment in ensuring the design and conduct of the trial is ethical. Clinical trials are commonly undertaken under contract with pharmaceutical or biotechnology companies in order to secure marketing approval for the drug, device or product being tested. These companies operate on a profit-based model. 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). Financial conflicts of interests are not a feature of all industry-sponsored research. However, REBs shall consider the potential for conflicts of interests in clinical trials because it has been empirically established as a feature of some industry sponsored research and can undermine the ethical conduct of research.

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 11.10** REBs shall ensure that clinical trial budgets are reviewed to ensure that conflicts of interests are identified and appropriately managed.
Application  REBs may delegate the review of clinical trial budgets to an appropriate institutional body. The body should ensure financial conflicts of interests are reported to the REB. When no such institutional body exists, the REBs should review clinical trial budgets for financial conflicts of interests. 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. Researchers should disclose all kinds and amounts of payment to the REB. Budgets should also be examined to ensure that no inappropriate payments are to be made, such as incentives for identifying and recruiting participants or other unexplained expenses that may raise questions about conflict of interests. 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 incentives 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 and should be prohibited. 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 interests and encourages the researcher to identify and manage them appropriately. Management by institutions and/or REBs may include prohibiting certain forms of payment.

G. Placebo-Controlled Studies

With respect to establishing the efficacy of a new drug, the most compelling trial design is considered to be a Randomized Controlled Trial (RCT). There are many possible variations and choices of control groups for RCTs, including but not limited to active control, placebo control, dose-response, multiple arms and combination therapies. It is the responsibility of the trial sponsor to provide justification for the choice of control group. The International Conference on Harmonization: E-10 Choice of Control Group and Related Issues in Clinical Trials (ICH E10)\textsuperscript{12} guidance outlines the issues that must be considered when designing an RCT, as well as the implications of various design choices. 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 and welfare of participants.

Clinical Equipoise

Clinical equipoise means a genuine uncertainty on the part of the relevant expert community about the comparative therapeutic merits of each arm of a clinical trial. The tenet of clinical equipoise provides a clear moral foundation to the requirement that the health care of individuals not be disadvantaged by their participation in research.

Article 11.11  (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 only if:

- its use is scientifically and methodologically sound to establish the efficacy or safety of the test therapy or intervention; and
- it does not compromise the safety or health of participants; and
- the researcher articulates to the 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 shall ensure the general principles of informed consent are respected (see Article 3.2) and that participants or their authorized third parties are specifically 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

All clinical trials involve risk to participants. For all approved trials: a) the welfare of the participants need to be upheld under the specific conditions of the trial; and b) the trial needs to be scientifically sound. Risks to the safety of participants can come from lack of efficacy or from undesirable side effects. These risks must be assessed for each treatment arm, including the experimental and control arm(s). The choice of control arm, which may range from currently approved treatments to placebo, placebo add-on or no treatment, should, like all research, meet an acceptable risk-benefit ratio. As with other aspects of the trial design, the choice of control arm should be justified based on scientific, medical and methodological reasons.

According to Article 11.11, one should consider a proven effective therapy as control if one is available. A superiority trial with an active control is a straight forward and uncomplicated design. However, superiority against an active control may not always be a realistic expectation in a test therapy. A non-inferiority trial on the other hand is not as straight forward. There are many methodological requirements that need to be considered in the design of a non-inferiority trial. As a result, a non-inferiority trial may not be feasible or interpretable in some therapeutic areas for the management of certain conditions. Sponsors, researchers, and REBs should refer to ICH E-10 and be familiar with concepts such as assay sensitivity, historical evidence of sensitivity to drug effects, and choosing the non-inferiority margin. The implications of various choices of trial design directly affect the interpretability of trial results, and a trial that cannot return useful information is by definition not ethical. Good science is a necessary albeit insufficient condition for good ethics. To properly assess the ethics of placebo vs. active controlled non-inferiority trials, an appreciation of the
interplay of ethics and science is required. Conditions that work against carrying out a non-inferiority trial successfully include low and/or variable response to treatment, and high placebo response.

Participants in the test arm of a trial of a new therapy are not receiving proven effective therapy. Risks to the safety of participants can come from lack of efficacy or from undesirable side effects. These risks should be assessed for each treatment arm, including the experimental and control arm(s).

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.

Great care should be taken to avoid abuse of placebo comparators. However, they are acceptable in any of the following situations:

1. there are no established effective therapies for the population or for the indication under study;
2. existing evidence raises substantial doubt within the community of treating physicians regarding the net therapeutic benefit of available therapies;
3. patients are resistant to the available therapies by virtue of their past treatment history or known medical history;
4. the study involves adding a new investigational therapy to established effective therapies: established effective therapy plus new therapy vs. established effective therapy plus placebo;
5. patients have provided an informed refusal of established effective therapy, and withholding such therapy will not cause serious or irreversible harm.

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 both must be documented.13

The use of a placebo comparator in situation (5) is permitted because potential trial participants are not using established therapies and therefore are not benefiting from therapy. For that reason such participants would not be further disadvantaged if enrolled in a placebo controlled trial than participants in a trial for whom there is no established effective therapies for the indication under study. Research protocols submitted to REBs should include sufficient support and justification of the study design and use of placebo comparator.

The following scenarios, while not exhaustive, may be used as guide for assessing the ethics and choice of trial designs:
Scenario 1
- no proven effective therapy available;
- efficacy can be established with a placebo controlled superiority trial.

Scenario 2
- available treatment highly and consistently effective;
- efficacy can be established with an active controlled non-inferiority trial;
- consider adding a placebo arm if acceptable ethical conditions are met.

Scenario 3
- available treatment modest and inconsistent;
- new treatment expected to be more effective than available treatment;
- efficacy can be established with an active controlled superiority trial;
- consider adding a placebo arm if acceptable ethical conditions are met.

Scenario 4
- available treatment modest and inconsistent;
- new treatment expected to be more effective than available treatment;
- relatively high placebo response;
- a case for placebo controlled superiority trial to establish efficacy;
- acceptable ethical conditions must be met or perform an active controlled superiority trial.

Scenario 5
- available treatment is modest and inconsistent;
- new treatment is not expected to be more effective than available treatment;
- strong case for placebo controlled superiority trial to establish efficacy;
- acceptable ethical conditions must be met or perform an active controlled superiority trial.

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 11.12 With respect to research findings:

(a) Institutions and REBs should take reasonable measures to ensure that sponsors, researchers and institutions share clinical trial research results and publish or otherwise disseminate the analysis and interpretation of clinical trial 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 clinical trial research contracts relating to confidentiality, publication and access to data.

Application

To justify the involvement 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 could lead to publication bias and thus contribute to a series of risks, 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.

Although it is beyond the scope of the Policy to provide guidance for journal editors and publishers, both have ethical obligations with regard to the publication of the results of research. Both negative and positive results should be published. Sources of funding, institutional affiliations and conflicts of interests should be declared in publications.

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, as far as reasonably possible, that principal investigators have the necessary access to original 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. When access to original trial data is not possible, the sponsor should provide the REB with the reason for restricting access to trial data.

Institutional and REB 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.
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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 (e.g. 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, above);
   (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 all 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 11.7), 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 11.13 All clinical trials within the scope of this Policy shall be registered with a recognized and easily web-accessible public registry.14

Application Clinical trial registration is the international standard. Registration of all clinical trials is strongly encouraged, including trials that are not subject to this Policy. Clinical trial registries are one way to help ensure that negative trial results are widely available. These, in addition to editorial policies,15 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.

Clinical trials (as defined in Chapter 11 “Overview”) should be registered before recruitment of the first trial participant in a registry acknowledged by the World Health Organization (WHO) or International Committee of Medical Journal Editors (ICMJE). Researchers should provide the REB with the number assigned to the trial upon registration.

Endnotes

1 This definition is drawn in part from World Health Organization, International Clinical Trials Registry Platform (ICTRP), www.who.int/ictrp/en


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7 See note 3 above, Section 1.2.

8 See note 3 above, Section 1.50.


11 The description of the clinical trial phases above has been adapted from the U.S. National Library of Medicine of the National Institutes of Health, “FAQ: What are clinical trial phases?” www.nlm.nih.gov/services/faqctgov.html


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

14 CIHR requires that randomized clinical trials be registered with an International Standard Randomized Controlled Trial Number (ISRCTN) at www.controlled-trials.com and World Health Organization, International Clinical Trials Registry Platform (ICTRP) at www.who.int/ictrp/en


References


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Chapter 12

HUMAN BIOLOGICAL MATERIALS AND MATERIALS RELATED TO HUMAN REPRODUCTION

The use of materials originating from human bodies for research contributes greatly to the advancement of biomedical science. The sources of these materials could be from patients following diagnostic or therapeutic procedures, autopsy specimens, donations of organs or tissue from living or dead humans, body wastes or abandoned tissue. Biological materials may also be sought from individuals for use in a specific research project. Once collected, biological materials may be held in biobanks to serve as a research resource for many years.

Ethical considerations raised by such research centre on acceptable access to and use of biological materials, potential privacy concerns arising from the handling of information derived from such materials, and the special status some individuals and groups accord to the human body and its parts. Because the significance of biological materials varies among individuals and groups, it is important to assess the ethics of research involving such materials with an awareness of, and sensitivity to, known values, beliefs and attitudes of those from whom materials originated.

Sections A to D of this chapter provide guidance on research involving human biological materials. Human biological materials include tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva, and other body fluids. Section E addresses research involving materials related to human reproduction.

As noted in Chapter 2, an individual whose data and/or biological materials are used in research becomes a research participant. In regard to human biological materials, individuals may become research participants by agreeing to provide a blood sample for use in a particular study. Individuals may also choose to donate organs, tissue or their entire body for research that occurs after their death. In this way, they become research participants through their donation. Researchers may seek access to human biological materials for secondary use in research and, in accordance with Section C of this chapter, a research ethics board (REB) may waive a requirement for individual consent.

A. Types of Human Biological Materials

As described in Chapter 5, information may be categorized along a spectrum of identifiability. Similarly, human biological materials vary in the extent to which they are identifiable. Researchers and REBs must consider if human biological materials proposed for use in research are identifiable or non-identifiable.

Human biological materials are identifiable if they, alone or when combined with other information available to the person who receives the materials and/or information, can reasonably be expected to identify an individual.
The following categories, similar to those found in Chapter 5 in regard to information, help explain the spectrum of identifiability for the purposes of this Policy.

- Identified human biological materials – identified human biological materials are labelled with a direct identifier (e.g. name, personal health number). Materials and any associated information are directly traceable back to a specific individual.

- De-identified/coded human biological materials – direct identifiers are removed from human biological materials and replaced with a code. Depending on access to the code, it may be possible to re-identify specific individuals (e.g. a principal investigator who has the key that links the code with a specific individual can re-link the biological material to the individual).

- Anonymized human biological materials – human biological materials are irrevocably stripped of identifiers and a code is not kept to allow future re-linkage.

- Anonymous human biological materials – human biological materials that did not have identifiers attached to them at the time of collection.

Due to continuing technological development in genetics, individuals with access to stored human biological materials are increasingly able to use genetic markers to link a non-identifiable sample with an identified sample. For this reason, genetic testing has made it more difficult to categorize human biological materials as anonymous or anonymized. The definitions above relate to identification of individuals; however, some research involving human biological materials, especially genetic research, may involve identification of groups, even though the human biological materials are non-identifiable at an individual level. Researchers and REBs should be aware of, and guard against, threats to individual privacy and autonomy that arise from re-identification risks and risks to groups, particularly where sensitive research findings will be linked to specific groups.

To maintain confidentiality, it may seem desirable to use anonymized or anonymous human biological materials. However, the scientific requirements of many studies may require use of identifiable human biological materials, especially to link materials with information about participants, and to avoid using different samples from the same individual. Use of anonymized or anonymous human biological materials has the disadvantage of making it impossible to offer the benefits of research findings to participants 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. Use of non-identifiable human biological materials also precludes withdrawal of a participant’s material from research use, even at the participant’s request.

### B. Collection of Human Biological Materials

Human biological materials 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 human biological materials for research, which is described in this section. The latter two categories are relevant to subsequent, secondary uses of human biological materials for research that may not have been conceived at the time the tissue was taken. These are described in Section C below.

Article 12.1  Research involving collection and use of human biological materials requires ethics review by an REB, and:

(a) consent of the participant who will donate biological materials; or

(b) in the case of a participant who lacks capacity, consent shall be given by an authorized third party who should take into account any research directive that applies to the participant; or

(c) in the case of a deceased participant, consent may be given through a donation decision made prior to death or by an authorized third party.

Application Article 12.1 applies prospectively — that is, prior to the collection of human biological materials for research purposes. It applies the general elements of consent in Chapter 3 to collection and use of human biological materials. During the consent process, a clear distinction should be made between consent to research and consent for any clinical procedure or test. In practice, this may mean separate consent information and forms, but in any event, the different uses must be clearly explained. Individuals who do not wish to contribute human biological materials for research are free to withhold consent without penalty and without prejudicing access to any treatment they would otherwise receive. For individuals who lack capacity to consent, the guidance developed in Chapter 3 regarding authorized third parties should be observed.

Where a participant expressed preferences for future research participation in a research directive before losing capacity, researchers and authorized third parties should take such directives into account during the consent process. Chapter 3 provides guidance on research directives. REBs and researchers should be aware that provincial human tissue gift laws provide a legal framework for donation of tissue upon death.

Article 12.2 To seek consent for use of human biological materials in research, researchers shall provide to prospective participants or authorized third parties applicable information set out in Article 3.2 as well as the following details:

(a) the type and amount of biological materials to be taken;

(b) the manner in which biological materials will be taken, and the safety and invasiveness of the procedures for acquisition;
(c) intended uses of the biological materials, including any commercial use;

(d) measures to protect the privacy of and minimize risks to participants;

(e) the length of time the biological materials will be kept, how they will be preserved, location of storage (e.g. in Canada, outside Canada), and process for disposal, if applicable;

(f) anticipated linkage of biological materials with information about the participant; and

(g) the researchers’ plan for handling research results and findings, including clinically relevant information and incidental findings.

Application Chapter 3, especially Article 3.2, provides detailed guidance on the need for consent to participation in research. Article 12.2 provides additional guidance on information that prospective participants generally require to make an informed decision to donate biological materials for use in research. While all the basic guidelines of Chapter 3 regarding consent apply to research involving human biological materials, some deserve special attention. For example, explaining the potential for commercialization or financial conflict of interest is important, as some research with human biological materials may involve the possibility of significant commercial gain. The process for requesting withdrawal of biological materials from research should also be clearly explained, along with an explanation of the conditions under which researchers would not be able to remove a participant’s data from the study. For instance, where a participant requests withdrawal of biological materials, information already derived from the materials and aggregated into research findings cannot be withdrawn. Anonymization of biological materials may also preclude subsequent withdrawal. Chapter 3 provides further guidance on handling incidental findings.

C. Consent and Secondary Use of Identifiable Human Biological Materials for Research Purposes

Chapter 5 provides detailed guidance on secondary use of 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 human biological materials. As researchers who seek to use human biological materials for research will often also seek access to information about individuals from whom the materials originate, this section and Chapter 5 should be read together.

Secondary use refers to the use in research of human biological materials originally collected for a purpose other than the current research purpose. A researcher may seek to use human biological materials left over from a diagnostic examination or surgical procedure or materials that were collected for an earlier study. Secondary use avoids duplication in primary collection and therefore reduces burdens and costs for participants and researchers. Privacy concerns and questions about the need to seek consent arise, however, when human biological materials provided for secondary use in research can be linked to individuals and...
when the possibility exists that individuals can be identified in published reports or through linkage of human biological materials with other data.

Article 12.3 Researchers who seek a waiver of consent for secondary use of identifiable human biological materials in research shall satisfy the REB that:

(a) identifiable biological materials are essential to the research;
(b) the waiver is unlikely to adversely affect the welfare of individuals from whom the materials were collected;
(c) the researchers will take appropriate measures to protect the privacy of individuals and to safeguard the biological materials;
(d) the researchers will comply with any known preferences previously expressed by individuals about uses of their biological materials;
(e) it is impossible or impracticable to seek consent from individuals from whom the materials were collected; and
(f) the researchers have obtained any other necessary (e.g. legal) permission for secondary use of biological materials for research purposes.

If a researcher satisfies the conditions in Article 12.3(a) to (f), the REB may approve the research without requiring consent from the individuals from whom the biological materials were collected.

Application This Policy does not require that researchers seek consent from individuals for the secondary use of non-identifiable human biological materials. However, consent must be sought where researchers propose to use identifiable human biological materials, unless the researcher satisfies all the requirements in Article 12.3.

The waiver of consent in this article is specific to secondary use of human biological materials. The terms of Article 3.7 addresses alteration and waiver of consent in other circumstances and does not apply here.

Secondary use of human biological materials identifiable as originating from a specific Aboriginal community, or a segment of the Aboriginal community at large, is addressed in Article 9.20.1

Impracticable refers to undue hardship or onerousness such that the conduct of the research is jeopardized; it does not mean mere inconvenience. Consent may be impossible or impracticable when the group is very 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. Financial, human and other resources required to contact individuals and seek consent may impose undue hardship. In some jurisdictions, privacy laws may preclude researchers from using personal information to contact individuals to seek their consent for secondary use of information.2

At the time of initial collection, individuals may have had an opportunity to
express preferences about future uses of biological materials, including research uses. For example, individuals may have made an express donation of biological materials for research in accordance with human tissue gift legislation, or may have expressed objection to future use. Researchers and REBs shall respect any known preferences.

An REB may require that researchers engage in discussion with representatives of individuals or groups from whom the biological materials were collected where the proposed research involves greater sensitivity (e.g. research involving stigmatizing conditions). Discussion is not intended as proxy consent. Rather, a goal of discussion is to seek input regarding the proposed research, such as the design of the research, measures for privacy protection, and potential uses of research findings. Discussion may also be useful to determine that the research will not adversely affect the welfare of individuals from whom the biological materials were collected. Researchers should advise the REB of outcomes of such discussion and the REB may require modifications to the research proposal based on the feedback.

**Article 12.4** When secondary use of identifiable human biological materials without consent has been approved under Article 12.3, researchers who propose to contact individuals for additional biological materials or information shall, prior to contact, seek REB approval of the plan for making contact.

**Application** In certain cases, a research goal may be achieved only through follow-up contact with individuals to collect additional biological materials or information. Under Article 12.3, the REB may have approved secondary use without consent based, in part, on the impossibility or impracticability of seeking consent. Where contact with a sub-group is feasible, researchers may subsequently wish to attempt to make contact with some individuals to obtain additional information or biological materials. Contact with individuals whose previously collected biological materials have been approved for secondary use in research raises privacy concerns. Individuals might not want to be contacted by researchers or might be upset that identifiable biological materials were disclosed to researchers without their consent. The research benefits of follow-up contact must clearly outweigh the risks to individuals of follow-up contact, and the REB must be satisfied that the proposed manner of follow-up contact minimizes risks for individuals. The proposed plan should explain who will contact individuals to invite their participation in the research (e.g. a representative of the organization that holds the individual’s biological materials) and the nature of their relationship with those individuals. Researchers will need to seek consent from these individuals for any new collection of biological materials or information. Article 3.1 provides further guidance on consent and approaches to recruitment.

**D. Storage and Banking of Human Biological Materials**

Collection and retention of human biological materials in banks, or “biobanks,” creates an increasingly important resource for research. Biobanks vary widely in their characteristics.
Some are very small and others hold biological materials from thousands of individuals. They may be disease-specific or contain materials from a wide population base. Different types of human biological materials may be stored in biobanks, such as blood, tumour or tissue samples. Biobanks may include or be linked with databases of identifiable or non-identifiable information. Materials held in a biobank may be intended only for use in a specific study or a biobank may be established to provide access to biological materials for numerous studies over many years. Researchers engaged in multi-centre research may seek access to materials held in biobanks in different jurisdictions; Chapter 8 provides additional guidance for such research.

Biobanking offers potential benefits by establishing sources of human biological materials to facilitate research. Access to stored human biological materials – and associated information about individuals whose materials are banked – can be particularly useful in helping researchers understand diseases that result from complex interactions between our genetic makeup, environmental exposures and lifestyles. Banking of human biological materials may also present risks to individuals whose biological materials and other personal information are stored, accessed, used, retained and disclosed through a biobank. Research involving such materials may also implicate the interests of biological relatives and others with shared genetic characteristics.

Article 12.5 Institutions and researchers that maintain biobanks:

(a) shall ensure that they have or use appropriate facilities, equipment, policies and procedures to store human biological materials safely and in accordance with applicable standards; and

(b) shall establish appropriate physical, administrative and technical safeguards to protect human biological materials and any information about participants from unauthorized handling.

Application Safe storage of human biological materials is important to maintain their scientific value and to protect materials and associated information about participants. Procedures for storage and record keeping shall include effective measures to ensure that participants’ identities are protected. Such measures include the security of facilities and effective procedures for data handling, record keeping and regulating access to human biological materials and information. Appropriate governance of biobanks is also important for managing access to and use of stored biological materials. The appropriate governance structure and management of a biobank will vary depending on its size and uses.

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.
Identifiable data derived from human biological materials 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 of Chapter 5.

### E. Research Involving Materials Related to Human Reproduction

This section sets out ethics guidelines relating to research involving human embryos, fetuses, fetal tissue, reproductive materials and stem cells. For the purposes of this Policy the following definitions apply:³

- **Embryo** means a human organism during the first 56 days of its development following fertilization or creation, excluding any time during which its development has been suspended, and includes any cell derived from such an organism that is used for the purpose of creating a human being.
- **Fetus** means a human organism during the period of its development beginning on the 57th day following fertilization or creation, excluding any time during which its development has been suspended, and ending at birth.
- **Fetal tissue** includes membranes, placenta, umbilical cord, amniotic fluid and other tissue that contains genetic information about the fetus.
- **Human reproductive materials** means a sperm, ovum or other human cell or a human gene, and includes a part of any of them.

### Research Involving Human Reproductive Materials

While research involving human reproductive materials has great promise for assisting the development of healthy pregnancies, curing illness, and repairing or rebuilding tissue, it raises special ethical considerations. 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 materials, privacy concerns, the potential for harm to those who provide reproductive materials, an embryo or fetus, and potential commodification of human reproductive materials and reproductive labour. 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 12.6

In addition to requirements in this Chapter that apply to all research involving human biological materials, the following guidelines apply to research involving human reproductive materials.

(a) Research using reproductive materials in the context of an anticipated or ongoing pregnancy, shall not be undertaken if the knowledge sought can reasonably be obtained by alternative methods.
Reproductive materials shall not be obtained, for research use, through commercial transaction, including exchange for services.

Application Because of the potential for harm to the woman or the fetus, Article 12.6(a) requires that the use of such reproductive materials be avoided where pregnancy is anticipated or ongoing, if research goals may be accomplished in some other way.

Article 12.6(b) reflects concerns about the commercialization or commodification of human reproduction. The purchase or sale, directly or indirectly, of any gamete, in vitro embryo or other reproductive material for the purpose of creating a human being, is ethically unacceptable.

Research Involving Human Embryos

Article 12.7 Research on in vitro embryos already created and 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 woman, or the subsequent fetus; and

(b) researchers closely monitor the safety and comfort of the woman 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.

The Assisted Human Reproduction Act prohibits the creation of a human embryo specifically for research purposes, with the limited exception of creating an embryo for the purpose of improving assisted reproduction procedures.

Article 12.8 Research involving embryos that have been created for reproductive purposes, but are no longer required for this purpose, may be ethically acceptable if:

(a) the ova and sperm from which they are formed were obtained in accordance with Article 12.7;

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

(c) embryos exposed to manipulations not directed specifically to their ongoing normal development will not be transferred for continuing pregnancy; and

(d) research involving embryos takes place only during the first 14 days after their formation by combination of the gametes.
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Application

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.4

Research Involving Fetuses and Fetal Tissue

Article 12.9

Research involving a human fetus or fetal tissue:

(a) requires the consent of the woman; and
(b) should not compromise the woman’s ability to decide whether to continue her pregnancy.

Application

Research may be undertaken on methods to treat, in utero, a fetus with genetic or congenital disorders. Because the fetus and the woman cannot be treated separately, any intervention to one involves an intervention to the other. Research involving a fetus or fetal tissue should be guided by respect for the woman’s autonomy and physical integrity. Research methods on the treatment of fetuses in utero pose no issues that are not addressed elsewhere in this Policy. Researchers should ensure that a clear distinction is made between consent to research and consent for any clinical procedures or testing. In practice, this may mean separate consent information and documents, but in any event, the different uses must be clearly explained.

Pluripotent Stem Cell Research

Article 12.10

Researchers who intend to conduct research to derive or use pluripotent stem cells shall follow the Guidelines for Human Pluripotent Stem Cell Research,5 as amended from time to time.

Hybrids and Chimeras

Research involving the creation of animal-human hybrids and chimeras may 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 these prohibitions. This legislation provides the following definitions.

Hybrid means:

- a human ovum that has been fertilized by a sperm of a non-human life form;
- an ovum of a non-human life form that has been fertilized by a human sperm;
- a human ovum into which the nucleus of a cell of a non-human life form has been introduced;
- an ovum of a non-human life form into which the nucleus of a human cell has been introduced; or
- a human ovum or an ovum of a non-human life form that otherwise contains haploid sets of chromosomes from both a human being and a non-human life form.
Chimera means:

- an embryo into which a cell of any non-human life form has been introduced; or
- an embryo that consists of cells of more than one embryo, fetus or human being.

**Endnotes**

1. See also the Canadian Institutes of Health Research Guidelines for Health Research Involving Aboriginal People, [www.cihr-irsc.gc.ca/e/29134.html](http://www.cihr-irsc.gc.ca/e/29134.html)

2. For discussion of factors relevant to assessing impracticability of consent, see, for example, the Canadian Institutes of Health Research *Best Practices for Protecting Privacy in Health Research* (September 2005), Section 3.3 “Secondary Use,” pp. 39 and 40.


5. The Guidelines for Human Pluripotent Stem Cell Research, [www.cihr-irsc.gc.ca/e/34460.html](http://www.cihr-irsc.gc.ca/e/34460.html)

**References**


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; the characterization of normal and disease conditions in individuals, biological relatives, families and groups; and 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, especially whole-genome 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 stigmatize individuals or groups who may experience discrimination or other harms because of their genetic status, or to treat them unfairly or inequitably.

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 Guidance regarding proportionate review, consent, privacy and confidentiality, research with human biological materials, 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 consent in Chapter 3, privacy and confidentiality in Chapter 5 and human biological materials and materials related to human production in Chapter 12. Other chapters relevant to the specific research proposal should also be consulted, such as Chapter 9 about research involving Aboriginal peoples or Chapter 11 on clinical trials. This chapter does not reiterate guidance set out in earlier chapters. Rather, it focuses on issues that arise specifically in the context of human genetic research and provides guidance for 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 shall:

(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 REB; and

(c) advise potential participants of the plan for handling information revealed through the research.

Application

The types of information that may be revealed through genetic research – and implications of this information for participants and their biological relatives – require that researchers and REBs ensure that an appropriate plan is in place for handling 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 adoption and 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 Article 13.3(b). 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, risks and potential benefits for research participants and other people whose interests are implicated. Plans may include sharing individual findings with participants or notification of general, non-identifiable research results through newsletters, websites or other means. In regard to
Article 13.3 Where researchers plan to share findings with individuals, researchers shall provide participants an opportunity to:

(a) make informed choices about whether they wish to receive information about themselves; and

(b) express preferences about whether information will be shared with biological relatives or others with whom the participants have a family or group relationship.

Application An individual’s right to privacy includes an interest in not knowing information about himself or herself. Further, the core 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 to 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.

Where individual results will be shared with 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, sharing research results with individuals may give rise to a need for genetic counselling.

Participants in genetic research should have an opportunity to express their preferences about sharing of information with relatives or others. These preferences are subject to overriding considerations that may warrant disclosure of information to relatives in exceptional circumstances where genetic research reveals information about a serious or life-threatening condition that can be prevented or treated through intervention. Articles 5.1 and 5.2 provide guidance on researchers’ ethical duty of confidentiality and situations where researchers may have a requirement to disclose information to third parties.

Chapter 5 also requires researchers to provide details to the REB regarding their proposed measures for safeguarding information through its full life cycle, including dissemination, and to guard against risks of re-identification. Funders of human genomics research may have policies requiring researchers to make genome sequence data publicly accessible. Where such policies apply, researchers must advise the REB and participants of data-sharing requirements.
and measures for protection of personal information. See Articles 5.2 and 5.3 for further guidance. Publication of aggregated data from genome-wide association studies has raised concerns about individual re-identification\(^1\). This example underscores the need for researchers and REBs to ensure that measures for safeguarding information are responsive to risks that arise from continuing advances in genetic research and data linkage.

### C. Genetic Counselling

**Article 13.4** Where researchers plan to share results of genetic research with participants, the research protocol should make genetic counselling available at that time, where appropriate.

**Application** Where the plan for handling information revealed in genetic research involves sharing individual results with 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 share information with biological relatives or other family or group members, genetic counselling should be made available to them and the research participants. The service provider must have the appropriate experience or training to provide genetic counselling, but need not necessarily hold a diploma, degree or professional designation in genetic counselling.

### D. Genetic Research Involving Families

**Article 13.5** Researchers who seek to recruit members of a family to participate in genetic research shall:

(a) ensure recruitment processes respect privacy and other personal interests of family members; and

(b) seek consent from individual family members.

**Application** Recruitment of members of a family may take place in various ways: through (a) the researcher, (b) an individual participant, or (c) a third party on behalf of an individual participant. A family group, such as parents and a child or several adult siblings, may all receive an invitation at the same time from the researcher to participate in genetic research. Alternatively, researchers may seek permission from an individual participant to contact family members to invite participation. Where appropriate to respect privacy interests or known sensitivities, it may be preferable for the participant to make initial contact with the family member. The participant may prefer to identify a third party to provide the family member 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 for further guidance in regard to the voluntariness of consent.

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. Where researchers seek participation from children or other members of a family who may lack capacity to consent, applicable provisions in Chapter 3 shall be followed.

E. Genetic Research Involving Communities

Article 13.6 Where researchers intend to recruit participants for genetic research based on their membership in specific communities, it may be appropriate for researchers to discuss the research with community leaders or representatives, in addition to seeking consent from individual participants. In these cases, researchers shall provide details to the REB about their proposed methods for engaging in discussion.

Application Some genetic research seeks to explore genetic variations within specific groups or communities. Such research may raise ethical concerns regarding stigmatization, unfair or inequitable treatment of groups, as well as social disruption in communities, especially if individual members disagree about participation in research. Engaging in discussion with leaders or representatives of the community may be appropriate. This determination 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 risks and potential benefits 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 community discussion processes foster free and informed decisions by individual members of a community. Refer to Chapter 3 for further guidance in regard to voluntariness of consent.

Researchers who propose to conduct genetic research involving Aboriginal participants or communities, or to use human biological materials identifiable as originating from Aboriginal peoples, should refer to the detailed discussion in Chapter 9 for further guidance.

F. Genetic Material Banks

Article 13.7 (a) Researchers who propose research involving collection and banking of
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genetic material shall 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, possibility of commercialization of research findings, 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 shall, likewise, indicate in their research proposal how they plan to address associated ethical issues.

**Application** Collection of human biological materials, including genetic materials, and their retention in biobanks provides an increasingly important research resource. Guidance for research involving human biological materials (see Chapter 12) applies to banking of genetic material. In Chapter 12, Section D provides guidance for creation of biobanks of genetic material, and Section C addresses access to and use of previously collected genetic material. Researchers who intend to bank genetic material shall inform participants of the potential for secondary use. Guidance regarding secondary use set out in Chapter 5 is also relevant.

**G. Gene Transfer**

Guidance set out in Chapter 11 applies 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 ongoing consent, and to follow up with participants to identify adverse events.

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 germ line alteration implies changes that could be transmitted to future generations.

Gene transfer research that involves alteration of human germ line cells is governed by statute in Canada under the *Assisted Human Reproduction Act* and its regulations. Researchers should be aware of how these apply to their work.

The special circumstances of gene transfer must be explained to potential research participants (or authorized third parties) during the consent process. This includes providing information about uncertain and potentially latent risks of gene transfer and any processes for long-term follow up of participants. Guidance regarding inclusion in research (see Chapter 4) should be followed where gene transfer research involves children or others who lack capacity to consent for themselves.
Endnotes
