Proposed Revision of *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* - Main Text -

There are no changes suggested for chapters 8 or 13.
Chapter 11 has been substantially revised and is provided under separate cover.
New text is underlined. Text to be removed is ~~struck through~~.
Comments will be accepted until January 31, 2017.

CHAPTER 1
Section B, Justice, 2nd paragraph

Treating people fairly and equitably does not always mean treating people in the same way. Differences in treatment or distribution are justified when failures to take differences into account may result in the creation or reinforcement of inequities. One important difference that must be considered for fairness and equity is vulnerability. Vulnerability is often caused by limited decision-making capacity, or limited access to social goods, such as rights, opportunities and power. Individuals or groups whose ~~in vulnerable~~ circumstances may make them vulnerable in the context of research have historically included children, the elderly, women, prisoners, those with mental health issues and those with diminished capacity for self-determination. Ethnocultural 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. People or groups whose circumstances cause them to be vulnerable or marginalized may need to be afforded special attention in order to be treated justly in research.

CHAPTER 2
Article 2.1

The following requires ethics review and approval by an REB before the research commences:
(a) research involving living human participants;
(b) research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.
(c) pilot studies involving (a) and/or (b) conducted for the purpose of assessing the feasibility and/or informing the design of a larger, main study.

CHAPTER 2
Article 2.1 Application, last paragraph

The scope of this Policy includes pilot studies. For the purposes of this Policy pilot studies do not include the pre-testing of a particular research instrument such as a questionnaire. Pilot studies are normally smaller versions of the primary study (e.g., fewer participants, shorter duration). As with the primary study, REBs shall adopt a proportionate approach to research ethics review such that the level of review of pilot studies is determined by the level of risk presented by the research. The purpose of a pilot study is

to assess the feasibility and/or inform the design of a subsequent study intended to address a research question. They are not intended to produce definitive results with regard to the research question but they can facilitate the successful conduct of the primary study. For example, pilot studies can help identify recruitment issues, safety issues, the need to calibrate measures, adjust equipment, or improve procedures. The information provided may assist the researcher to decide whether and how to conduct the primary study. The design of pilot studies and the criteria used to determine feasibility may vary by discipline. Researchers should clearly identify the purpose of pilot studies in their application for research ethics review (see Article 6.11).

CHAPTER 2
Article 2.2 Application, 6th paragraph

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

CHAPTER 2
Article 2.3 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.~~ For the purposes of this article, observational research is used to mean a study involving humans that does not involve an intervention by the researcher. Naturalistic or non-participant observational research is the study of human acts or behaviours in a natural environment in which people involved in their normal activities are observed with or without their knowledge by researchers who do not participate in the activity. Participant observational research is the study of human acts or behaviours in a natural environment in which people involved in their normal activities are observed with or without their knowledge by researchers who engage in the activity. Participant observational research generally does not meet condition (a) of Article 2.3 as there is interaction with the individuals or group being studied. Epidemiological observational research is an epidemiological study that does not involve any intervention by the researcher. Epidemiological observational research that involves personal health information (e.g., review of medical charts) generally does not meet condition (b) of Article 2.3 as health information is considered to be private.

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

CHAPTER 2
Section A, Activities Not Requiring REB Review

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

When in doubt about the applicability of the articles to their studies, researchers should consult their REBs.

CHAPTER 2
Article 2.5A

Course-based research activities intended solely for pedagogical purposes do not constitute research for the purposes of this Policy, and are not subject to REB review.

Application

Course-based research activities may be required of students (at all levels) with the objective of providing them with exposure to research methods in their field of study. Such activities are assigned to students for the purpose of teaching them how to conduct research in a structured educational context. This includes, for example, asking students to interview fellow students, family members, or members of the general public for the purpose of collecting data to be used in a course assignment. To the extent that the sole purpose of the activity is pedagogical with no expectation to disseminate outside the requirements of the course or for any subsequent use of data, REB review is not required. Such pedagogical research activities may raise ethical issues. Institutions may decide to review such activities through mechanisms other than the REB, for example, at the department or faculty level.

If these activities are used for the purposes of research (e.g., as part of a researcher's own research program), they should be reviewed following the regular institutional REB procedures. Theses or equivalent research projects involving human participants typically meet this Policy's definition of research (Application of Article 2.1), and should be reviewed by the REB following a proportionate approach (Article 6.12).

If data collected for the purpose of course-based research activities are later proposed to be used for research purposes, it would be considered secondary use of information. At that time it may require REB review in accordance with this Policy (Chapter 5, Section D).

CHAPTER 2
Section B, Concepts of Risks and Potential Benefits

Assessing risks and potential benefits of research involving communities

In research involving communities, risks and benefits must be considered from the perspective of the participant, the community and the individual members of the community (who may or may not be research participants). For example, research about the prevalence of sexually transmitted infection (STI) in a specific neighbourhood may present risks to these three groups. Risks may differ among them. Research participants may experience the emotional distress of discovering they have a sexually transmitted infection. The neighbourhood may be stigmatized should the findings show a high prevalence of STI in that neighbourhood's community. And finally, the residents of that neighbourhood may be stigmatized as individuals because of their association with the stigmatized neighbourhood. The same study may present similar or different benefits to all three groups. Research participants identified as having a sexually transmitted disease can seek treatment. The community may benefit from the identification of the local determinants associated with STI, allowing it to take steps to minimize the risks of infection. Individual members of the community may have access to additional health resources during the study and/or as a result of the study.

As with individual participant risk, community risk may be social, behavioural, psychological, physical or economic. Consideration must be given to the magnitude or seriousness of the harm and the probability that it will occur. Risks should be assessed from the perspective of the community in consideration of the social, economic and cultural context. Research involving communities may introduce special risks associated with the relationships between individuals and their communities. For example, the implementation of a research project may reveal to a community that its leaders do not speak for its members and this may introduce conflict within the community. The onus is on the researcher to engage the community and to minimize the risks of research to participants, the community and to individual members of the community. Research involving communities should be designed to benefit the community as well as the individuals within the community (Article 9.13).

CHAPTER 2
Article 2.10

Research-Attributable Risk

Article 2.10

When describing the foreseeable risks and potential benefits of research involving participants who are also exposed to other risks, researchers should clearly distinguish between the risks that are attributable to the research (including cumulative risks), and the risks to which participants would normally be exposed.

In their evaluation of risk, REBs should ensure that they are evaluating only those risks that are attributable to the research (including cumulative risks) and not compounding them with the other risks to which the participants are exposed (e.g., serious illness, volatile environment, impoverished conditions).

Application

The evaluation of foreseeable risks to participants can be complicated if the prospective participants are already exposed to risks in the course of their daily lives. The REB must take into consideration the ethical implications of recruiting people in high risk circumstances (e.g., receiving high-risk clinical care, living in war torn regions) into studies that may offer additional risk. In accordance with Articles 4.1 and 4.7 on vulnerability and inclusion/exclusion criteria, prospective participants who are in high risk circumstances should not be inappropriately included in, or excluded from, participating in research.

The REB may approve research involving participants who are exposed to risk in their daily lives, where the REB finds a favourable balance between the foreseeable risks attributable to the research and the potential benefits.

In addition to describing any other alternatives to the study (where relevant), researchers must ensure that prospective participants are informed of the foreseeable risks and potential benefits attributable to the research, as distinct from those arising from their circumstances. REBs should ensure that all consent materials reflect this distinction.

CHAPTER 2
Article 2.11

Research Benefit Misconception

Although involvement in a study may provide benefits to some participants, the purpose of research is to address a research question. Research benefit misconception occurs when participants do not understand that research is aimed primarily at producing knowledge and may not provide any direct benefit to them. It also occurs when participants enter studies without understanding the ways in which elements of a study design may not meet their own objectives. These misconceptions are more likely when the researcher is also viewed by participants as a person of authority (e.g., a teacher, a doctor, a counselor) (Article 3.1).

In clinical trials, research benefit attribution is better known as therapeutic misconception. With the exception of some phase I trials, clinical trials usually involve individuals in need of treatment, for whom the experimental therapy is hoped to be effective. Even when foreseeable risks, potential benefits and treatment alternatives are explained to them, it is common for clinical trial participants to not fully appreciate the differences between clinical care and research participation. As a result, some 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 clinician believes it would contribute to their health.

Article 2.11

REBs and researchers should be conscious of the phenomenon of research benefit misconception (known in clinical trials as therapeutic misconception), and how it can be exacerbated by researchers who have dual roles. Researchers should ensure that procedures for recruitment and consent clearly address possible misconceptions of the extent of research benefits. In studies involving people receiving some form of intervention, it is important to emphasize the differences between experimental interventions and the standard of care or services individuals might otherwise receive.

Application

To help participants make an informed consent decision, it is important to ensure that participants clearly understand whether the research may provide direct benefits to them, indirect benefits to the group they belong to and/or to society (e.g., the advancement of knowledge). When researchers who have dual roles conduct research with their students, patients or employees, special efforts may be required, as part of the consent process, to distinguish between their dual roles. In some cases researchers may have multiple roles.

Researchers in dual roles must take care not to overplay the benefits of research participation or understate foreseeable risks to prospective participants as they may then enter studies with unrealistic expectations. Research has shown that researchers in dual roles, particularly those in a position of authority, can affect how well their participants appreciate the uncertainty of research, the seriousness and magnitude of risks, and the possibility that participation may not result in any direct benefits (see Article 3.1). Providing a clear description of those elements of participation that are experimental in nature and those not primarily intended to benefit the participant directly can help participants avoid unrealistic expectations (see Article 3.2).

To preserve the trust on which their professional relationships with participants reside, researchers should take all necessary measures to separate their role as researcher from other roles. It is important that REBs appreciate the potential conflicts between these roles and the possible impact on the welfare of prospective participants.

In general, research benefit misconception can be minimized by ensuring that researchers who interact with participants in other roles (e.g., clinicians who provide the patient's regular care, student supervisors and instructors) are involved as little as possible in the recruitment and the consent process. Ideally, the functions of each role should be performed by different people. However, there may be instances in which participants' best interests are served by having the researcher with a dual role involved in recruitment and consent. In these cases, the research proposal shall indicate what other measures will be taken to minimize research benefit misconception.

CHAPTER 2
End of Chapter

Research Involving Communities

Article 2.12

Where researchers intend to conduct research involving humans based on their membership in specific communities, researchers shall consider relevant guidance in Chapter 9 on research involving First Nations, Inuit and Métis peoples of Canada, when appropriate.

Application

While Chapter 9 is designed to guide research involving First Nations, Inuit and Métis peoples of Canada, its discussion of respectful relationships, collaboration and engagement between researchers and participants may also be an important source of guidance for research involving other distinct communities. For example, research involving the Deaf community, which is a distinct and unique visually-based culture within the larger mainstream hearing culture, may benefit from engaging with this community by including a Deaf community member on the research team and connecting with members of this community directly in order to understand how best to reach and support prospective participants. Consideration should also be given to presenting research materials and findings in a culturally relevant format (e.g., in a signed language).

CHAPTER 3
End of Article 3.1 Application

Recruitment

Consent is a process that typically starts with recruitment. Recruitment is the seeking out of individuals, groups or communities that meet the inclusion criteria of a study.

A fair and equitable recruitment process is based on inclusion and exclusion criteria that are justified by the research question (Article 4.1). It allows individuals, groups and communities to indicate their interest in participating without risk to their privacy (Article 5.1). For example, handing out the researcher's contact information at a gathering of prospective participants is more respectful of privacy than asking those interested to provide their contact information on a publicly visible sign-up sheet. Consideration should be given to ensuring recruitment is voluntary (Article 3.1), informed (Article 3.2) and respects cultural protocols, customs and circumstances of the participant community (Article 9.8).

Recruitment may involve several stages of contact and screening that precede the seeking of consent to participate in research. Researchers may need the collaboration of third parties to access specific populations or information. It is up to the third party to decide whether or not to collaborate with the researcher or to grant access to information relevant to recruitment (subject to privacy legislation). For example, if a study requires the participation of people undergoing medical treatment, the researcher may need the cooperation of clinicians delivering that treatment to make their patients aware of the study. Or, a researcher may request access to a database for the purpose of identifying people who meet the inclusion criteria of the study.

CHAPTER 3
Article 3.7A Application, 8th paragraph

Participants' Vulnerability ~~in Vulnerable Circumstances~~

In considering the need for an alteration to consent requirements, researchers and REBs should also consider whether the prospective participants (as individuals, groups, or populations) are in ~~vulnerable~~ circumstances that may make them vulnerable in the context of research (see Article 4.7). The existence of such ~~vulnerable~~ circumstances may require greater effort to minimize risks to participants and/or maximize potential benefits (see Chapter 2, Section B).

CHAPTER 3
Article 3.7A Application, last paragraph

Community-level interventions controlled by researchers that have been approved to proceed without consent or a community engagement process may inadvertently expose people who do not meet the study's inclusion criteria to the intervention. Researchers and REBs should assess whether there are any risks to individuals posed by this exposure, and if so, consider ways to narrow the focus of the intervention. For example, the use of observational methods, census data, or a source informed about the community could help researchers identify community members who should be excluded (e.g., don't knock on their doors; don't send flyers to that address). In the case of interventions that cannot help but be

visible to, or affect, the entire community (e.g., billboard ads, radio broadcasts, sky-writing), there would be no way to exclude non-target population community members or visitors to the community. Accordingly, the REB should be satisfied that any risks of inadvertent exposure to the intervention are minimal.

CHAPTER 3
Article 3.7B Application, 2nd paragraph

Researchers must explain 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. In cases where participants were not asked for their consent prior to collection of data and/or human biological materials, researchers must explain why this exception to consent requirements was necessary. Researchers must give details about the importance of the research, the necessity of having to use alterations to consent requirements, and address any concerns raised by participants. In order to address any misconceptions that may have arisen, researchers must explain why these research procedures were necessary to obtain scientifically valid findings. When debriefing, researchers should be alert and sensitive to participants' needs, feelings, reactions and concerns. REBs should assess the risks and benefits of the debriefing itself and whether the proposed plan is appropriate for participants – particularly those whose ~~are in vulnerable~~ circumstances may make them vulnerable in the context of research and/or who lack the capacity to make a consent decision.

CHAPTER 3
Article 3.8 Application, 5th paragraph

Because their incapacity to make decisions puts them in ~~vulnerable~~ circumstances that may make them vulnerable in the context of research, 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 prospective participants in advance so that consent may be sought prior to the occurrence of the emergency situation; consultation with former and prospective participants; and special monitoring procedures to be followed by data safety and monitoring boards.

CHAPTER 3
Section C., 4th paragraph

As indicated in Chapter 1, Respect for Persons and Concern for Welfare entails particular ethical obligations to individuals whose ~~in vulnerable~~ circumstances may make them vulnerable in the context of research. Such obligations often translate into special procedures to promote and protect their interests. This may include the development of consent materials that are appropriate to the cognitive and communication abilities of prospective participants. Articles 3.9, 3.10 and 3.11 describe special procedures for research involving individuals who lack decision-making capacity.

CHAPTER 4
Article 4.1 Application, 1st and 2nd paragraphs

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. This duty is explicitly stated because groups have been inappropriately excluded from participation in research on the basis of attributes such as gender, race, ethnicity, age and disability. Similarly, some groups have been unfairly included in research because they are convenient populations for research (e.g., prisoners, people with limited financial resources or those in other circumstances of vulnerability).

The determination of inclusion and exclusion criteria affects the fair and equitable distribution of the burdens and benefits of research. 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. Some research may be focused on a certain individual (such as in a biography), or a group of individuals who share a specific characteristic (e.g., an identifiable group of painters who happen to be all of one sex; a religious order that is restricted to one sex). Other examples include research that is focused on specific cultural traditions or languages, or on one age group (e.g., a biomechanical modeling study of posture corrections in adolescents). 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.

CHAPTER 4
End of Chapter

Dissemination of Research Results

Any prohibition or undue limitation on the publication or dissemination of findings from research is ethically unacceptable. Providing a summary of research results to participants is as important as dissemination to the research community (Equitable Distribution of Research Benefits, Chapter 4).

Article 4.8

Researchers shall disseminate, through publication or otherwise, the analysis of data and interpretation of research results including those that do not support the research hypotheses. The dissemination shall take place in a timely manner without undue restriction.

Application

To justify the involvement of 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 (e.g., published in a peer-reviewed journal, added to a publicly available database, posted on a website, a public presentation) 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, REBs and institutions have an ethical responsibility to make reasonable efforts to publicly disseminate research findings in a timely manner and without undue restriction.[1]

Researchers should also endeavour to publish the results of pilot studies that provide useful information about the feasibility of research designs. Disseminating this knowledge can help other researchers and participants avoid wasting their time and efforts on study designs that have been determined to be unsuccessful. Researchers can instead focus on developing more useful studies.

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 findings of research. Sources of funding, any restrictions regarding public disclosure of study data, institutional affiliations, and conflicts of interest should be declared in publications. All findings should be published. The following risks may result from failing to publish all research findings, including those that do not support the research hypotheses:

- making misinformed decisions based on incomplete or skewed data;
- developing inappropriate and potentially harmful policy, educational or clinical practices;
- negatively affecting participant welfare;
- needlessly duplicating research with associated risks to participants and waste of resources;
- introducing fraud or deception in the research process;
- eroding participant and/or public trust and accountability in research.

Data Availability

Researchers are encouraged to make their data available for further analysis or verification by their peers. When sharing participant data with peers, researchers must be mindful of their responsibility to safeguard participant privacy (see Articles 3.2, 5.1 and 5.5A) and may have to code or anonymize the data to do so.

CHAPTER 4
References

United Nations Declaration of the Rights of the Child, 1959

CHAPTER 5
Article 5.1 Application, 3rd and 4th paragraphs

The ethical duty of confidentiality must, at times, be balanced against competing ethical considerations or legal or professional requirements 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 participant, ~~or~~ a third party, a community or the general population. Researchers are expected to be aware of ethical codes (such as professional codes of conduct) or laws (e.g., those requiring the reporting of children in need of protection or the presence of reportable communicable diseases) 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. 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 the relationship between research ethics and law.

Certain areas of research (such as research involving children at risk of abuse, studies of criminal behaviour or research about reportable communicable diseases) are more likely to put researchers in positions where they may experience tension between the ethical duty of confidentiality and disclosure to third parties (Article 5.2~~1~~, Application). Where possible, practicable and appropriate, researchers should design their research to avoid or mitigate foreseeable conflicts, e.g., by collecting the minimal identifiable information that is necessary to answer the research question. Researchers shall maintain their promise of confidentiality to participants within the extent permitted by ethical principles and/or law. 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. Public health researchers should consult with someone knowledgeable about public health laws and regulations in the relevant jurisdictions.

CHAPTER 5
Article 5.1 Application, last paragraphs

Researchers, REBs and institutions share the responsibility for protecting participant confidentiality. In granting its approval for a study, the REB engages the responsibility of the institution to support researchers in their commitment to protect participant confidentiality (see Articles 6.1 and 6.2). Institutions are responsible for creating and maintaining a supportive research environment, establishing appropriate institutional security safeguards, training researchers and REBs regarding best privacy practices and implementing processes and policies that guide and support researchers and REBs in protecting participant confidentiality (see Articles 5.4, 6.2, 6.7 and the Agreement on the Administration of Agency Grants and Awards by Research Institutions).

In situations where there is an attempt by legal means (e.g., warrant, subpoena) to compel disclosure of confidential participant information, institutions are required to provide researchers with financial and other support to obtain independent legal advice or to ensure that such support is provided. For the purposes of this Policy, "legal advice" includes all legal services that a researcher in this situation may require, including representation. The purpose of independent legal advice is to permit the researcher to make an informed decision as to whether to disclose or to resist disclosure of confidential participant information. Researchers who are considering resisting disclosure must be aware of the personal consequences of choosing to respect ethical principles rather than legal obligations where the two cannot be reconciled. Such advice should be independent of any advice to the institution.

Institutions should consider whether research being conducted under its auspices or within its jurisdiction is likely to put researchers in positions where they may experience tension between the ethical duty of participant confidentiality and the legal obligation of disclosure of confidential participant information or attempts to compel disclosure of confidential participant information to third parties. Where that likelihood exists, the institution should establish a policy that explains how it will fulfill its responsibilities to support its researchers. The policy should include an explanation of the nature and the scope of the support, a mechanism to determine the level of support in individual cases, the source of funding (e.g., dedicated fund, insurance, agreement with professional association) and any other relevant criteria. The institution should establish such a policy in collaboration with its researchers.

CHAPTER 5
Article 5.2 Application, 1st, 2nd and 3rd paragraphs

This article recognizes that some research projects and some areas of research 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 intergenerational violence raises a reasonably foreseeable prospect that researchers may acquire information that a child is being abused. Another example is community health research where researchers may be required to notify public health authorities of participants who have contracted a reportable communicable disease. Researchers who reasonably foresee that their inquiries may give rise to an ethical or legal obligation ~~reason~~ to disclose information obtained in the research context shall advise the REB and prospective participants about the possibility of compelled disclosure. Advising participants of reasonably foreseeable disclosure requirements is an important aspect of the consent process.

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 validity of 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 colleagues, any relevant professional body, the REB, ~~colleagues, relevant professional body~~ and/or legal counsel. Public health researchers should consult with someone knowledgeable about public health laws and regulations in the relevant jurisdiction(s).

Researchers shall also inform participants and seek their consent if their personal information may be shared with mandated government departments or agencies (such as local public health authorities), 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.

CHAPTER 5
Article 5.6

When secondary use of identifiable information without the requirement to seek consent has been approved under Article 5.5A, researchers who propose to contact individuals for additional information or for reasons related to the welfare of the participant 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. In rare cases, during the course of analysis, a researcher may discover a finding that has a potential impact on an individual's welfare. If the researcher suspects that welfare implications to the participant may be significant, the researcher and REB should refer to the guidance in Article 3.4 which addresses material incidental findings. Under Article 5.5A, the REB may have approved secondary use without the requirement to seek consent, based, in part, on the impossibility or impracticability of seeking consent from all individuals whose information is proposed for use in research. 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 potential 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 to individuals. The proposed plan shall 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 shall also ensure that a plan for follow-up contact complies with applicable privacy legislation. For example, some privacy laws prohibit researchers from contacting individuals unless the custodian of the information has first obtained individuals' consent to be contacted. Whenever possible, it is preferable that re-contact with participants be carried out by the organization or the custodian holding the biological materials. Researchers will need to seek consent from individual participants for any new collection of data or biological materials. Article 3.1 provides further guidance on consent and approaches to recruitment.

CHAPTER 6
Article 6.4 Application, 4th paragraph

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, population and public health research, research ~~education or topics~~ involving ~~Aboriginal~~ First Nations, Inuit or Métis peoples, or research using qualitative methodologies, should have members that are knowledgeable and competent to address those fields of research, disciplines and methodologies.

CHAPTER 6
Article 6.11

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

CHAPTER 6
Article 6.11, Application 1st paragraph

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

CHAPTER 6
Article 6.11, Application 3rd paragraph

Some types of research using quantitative or qualitative research methods, or a combination of ~~these~~ methods as well as collaborative or community-based research (see Chapters 9 and 10), may entail prior contact and dialogue with individuals or communities ~~as a normal and integral component~~ to establish research collaborations or partnerships prior to the actual design of the research. Other research may not involve humans ~~at their~~ in the initial stages, ~~not involve humans~~, but may require ~~engaging the research team, setting up equipment and other~~ preparatory work ~~stages~~, e.g., observing a research setting, taking notes, setting up equipment. These exploratory activities may precede REB review. If, however, the researcher wishes to use any information gathered from individuals or communities during the exploratory phase, this intention must be made clear in the research proposal, along with any provisions for seeking the consent of those who contributed the information.

CHAPTER 6
Article 6.11, Application last paragraph

Pilot Studies

As an integral component of their research design, researchers may undertake pilot studies involving participants. The level of ethics review for pilot studies depends on the level of risk.

A pilot study is intended to assess the feasibility and/or inform the design of a larger, main study. Pilot studies do not typically yield definitive findings with respect to the research question(s). Typical outcomes for pilot studies include:

- do not continue – main study is not feasible;
- continue with modifications to the study design (e.g., a change to the study instrument); and
- continue without modifications – main study is feasible.

Some of the ethical issues to consider in the review of pilot studies concern recruitment and sample size. Although pilot studies may offer indirect benefits to groups and to society by informing the design of the main study (and other similar studies) they often provide no direct benefits to participants. Researchers have an ethical responsibility to fully disclose the nature and likelihood of benefits to participants during recruitment and when seeking consent. When reviewing pilot studies, REBs should ensure that recruitment and consent materials provide this information and describe how the findings of the pilot study will be used to determine the feasibility of conducting a larger study (see also Article 3.2). The design of pilot studies and the criteria used to determine feasibility may vary by discipline. REB Chairs should ensure that REB members with the relevant expertise are involved in primary review (see Articles 6.4 and 6.5).

When considering the ethical acceptability of pilot studies, REBs should keep in mind that the primary purpose of a pilot study is not to provide a definitive answer to the research question(s). Accordingly, the number of participants specified may not equal the sample size that would be required in the main study. The researcher should provide justification for the sample size based on the focus of the pilot study: to test feasibility and/or to inform study design.

CHAPTER 6
Article 6.12 Application, 3rd and 4th paragraphs

2. Delegated REB review of minimal risk research

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

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

CHAPTER 6
Article 6.12 Application, 6th and 7th paragraphs

~~An institution may decide that ethics review of course-based research activities intended solely for pedagogical purposes can be delegated to non-REB members at the institution's department, faculty or equivalent level. Such pedagogical activities are normally required of students (at all levels) with the objective of providing them with exposure to research methods in their field of study (e.g., interviewing techniques). If these activities are used for the purposes of research (e.g., as part of a researcher's own research program), they should be reviewed by the regular institutional REB procedures. Theses or equivalent research projects involving human participants typically meet this Policy's definition of research (see Application of Article 2.1), and should be reviewed by the REB following a proportionate approach (see Article 6.12). The REB should establish written procedures and set out criteria for determining which categories of research proposal may be eligible for this type of review, and specify who is responsible for implementing and overseeing the approval mechanisms.~~

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

CHAPTER 6
End of Chapter

Section E. Review of Sponsor-Researcher Contracts

The rights of sponsors with respect to the analysis of data, interpretation of results and publication of findings, and ownership thereof, are typically described in sponsor-researcher contracts. In the context of

clinical trials they are often referred to as clinical trial agreements. These contracts may seek to place restrictions on access to data, the publication of findings, either directly or through provisions that seek to protect their intellectual property rights to research procedures, data, or other information.

Institutions and REBs should ensure that sponsors' legitimate interests are reasonably balanced against researchers' ethical and legal obligations to participants and their duty to disseminate data and research findings.

Article 6.24

Institutions shall develop policies regarding acceptable and unacceptable clauses in sponsor-researcher contracts relating to confidentiality, publication, and access to data. The policies should:

(a) require that sponsor-researcher contracts be submitted to a responsible authority for a determination of their consistency with institutional policies and this Policy;

(b) require that any ethical concerns arising in the review be referred to the REB as an integral part of the research ethics review process;

(c) provide that all confidentiality and publication clauses:

- are consistent with the researchers' duties to share new information from research with REBs and study participants and to report study findings in a timely manner without undue restriction;
- stipulate that the researchers, especially the principal investigator, will assume the primary role and responsibility for the analysis, interpretation, and preparation of the findings for publication;
- permit principal investigators to access all study data;
- permit researchers to access all study data collected at their respective sites; and
- permit all researchers to access all study data in cases where no principal investigator is named.

Application

Institutions are responsible for the ethical acceptability of any research conducted under their auspices (see Article 6.1). Normally, review of the ethical aspects of researcher-sponsor contract clauses related to confidentiality, publication and access to data is the responsibility of the REB. This review may be delegated to an individual or group with the appropriate expertise. In institutions where contracts are reviewed by an authority other than the REB, the review must conform to the mandate and purposes of REB review and involve consultation with the REB.

Institutions and REBs should require the satisfactory amendment or removal of any confidentiality clauses or publication restrictions in sponsor-researcher contracts that unduly limit either the content of the scientific information that may be disseminated or the timing of dissemination.

In its review of sponsor-researcher contracts, the REB must be satisfied that none of the clauses will prevent researchers from reporting new information relevant to participants' consent and/or welfare. Further, the REB must be assured that new information will be reported in time to allow them to address any risks to participants.

Contracts should ensure that principal investigators have the necessary access to original study data, and the opportunity to analyze them, to ensure that they can report study findings fairly and accurately, particularly with respect to efficacy and safety. Normally, it is the responsibility of the named PI to examine the entire data set and to ensure that data are not inappropriately excluded from analyses and disseminations of findings.

The onus to justify restrictions on dissemination or access to data should lie with the one seeking any such restriction, usually the researcher or sponsor. The reasonableness of restrictions on either the content or timing of dissemination should be measured against 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 study. 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 or that are required to give appropriate context to a manuscript or other publication, are seldom, if ever, justified (see Articles 11.7 and 11.8).

CHAPTER 7

Article 7.4 Application, Financial Conflicts of Interest, 2nd paragraph

Financial incentives have the potential to distort researchers' judgment in ensuring the design and conduct of research is ethical. When researchers partner with organizations whose primary motive is profit, they must be aware of the potential for conflicts of interest. Consideration for the profitability of the research may threaten the ethical integrity of research design and conduct. Not all research sponsored by for-profit organizations gives rise to financial conflicts of interest. However, REBs should ~~shall~~ consider the potential for this type of conflict because its ability to undermine the ethical conduct of research has been empirically established.

CHAPTER 7
Article 7.4 Application, Financial Conflicts of Interest, 4th paragraph

If there is no appropriate institutional body or advisor to identify potential conflicts of interest in study documents such as budgets and contracts and then inform the REB, then it is the responsibility of the REB to so do. REBs should ensure that relevant documents are reviewed in order to identify conflicts of interest and develop strategies for minimizing and managing them. ~~The REB should examine budgets to ensure that there are no~~ Reviewers should look for issues such as inappropriate payments ~~to be made~~ or other unexplained expenses that may raise questions about conflict of interest. ~~Further,~~ Payment provisions should be scrutinized to ensure they do not create ethically inappropriate incentives to recruit quickly, at the expense of a careful review of the suitability of prospective participants. 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 project on the other. Disclosure of the kinds and amounts of payments and other budgetary details encourages the researcher to identify and appropriately manage potential conflicts of interest and helps the REB to assess them. Management by institutions and/or REBs may include prohibiting certain forms of payment.

CHAPTER 7
End of Chapter

Section E. Community Conflicts of Interest

Conflicts of interest may exist within the community (e.g., between the community leadership and its members), between the community and the researcher or between the community and institutions. Researchers must inform the community of any individual conflicts of interest as well as any institutional conflicts of interest of which they are aware that might have an impact on the research. Any real, potential or perceived conflict of interest should be avoided if possible. If a conflict of interest is unavoidable it should be disclosed and, if necessary, managed (see Introduction).

No changes to Chapter 8

CHAPTER 9
Article 9.8 Application, 4th paragraph

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 the requirement for ethics review of research involving naturalistic and participant observational studies, and associated ethical implications, which may include infringement on consent and privacy.

CHAPTER 10
Section A, General Approach and Methodological Requirements and Practices, 5th paragraph

Researchers sometimes engage in research that questions social structures and activities that create, or result in, inequality and injustice. Studies may involve participants whose ~~are in highly vulnerable~~ circumstances make them highly vulnerable in the context of research 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 institutional authorities. Regardless of the methodological approach, researchers who question social structures, or deal with the disempowered, may face pressures from authority figures. Research may also involve participants, such as business executives or government officials, who may be more powerful than the researchers.

CHAPTER 10
Section B, Introduction to Article 10.3, 1st, 2nd and 3rd paragraphs

In qualitative research, observation is used to study acts or behaviours in a natural environment. It often takes place in living, natural and complex communities or settings, in physical environments, or in virtual

settings. Observational studies may be undertaken in publicly accessible spaces (e.g., a stadium, library, museum, planetarium, beach, park), in virtual settings (e.g., online support groups ~~Internet chat rooms~~), or in private or controlled spaces (e.g., private clubs or organizations).

The o~~O~~bservational research addressed in this article is of two kinds: "non-participant" where the researcher observes, but is not a participant in, the activity ~~action~~ (also known as "naturalistic observation"); and "participant" where the researcher engages in, and observes, the activity ~~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 ~~non-participant or participant~~ observation and not seek consent.

CHAPTER 10
Section B, Introduction to Article 10.3, 5th paragraph

Observational studies in public places where there is no expectation of privacy may be ~~are~~ exempt from REB review (see Article 2.3).

CHAPTER 10
Article 10.3

In research involving observation of human acts or behaviours in natural environments or virtual settings where people have a reasonable or limited expectation of privacy, the researcher shall explain the need for an exception to the general requirement for consent. The REB may approve research without requiring that the researcher obtain consent from individuals being observed on the basis of the justification provided by the researcher and appropriate privacy protection.

CHAPTER 10
Article 10.3 Application, 2nd paragraph

Naturalistic or participant ~~O~~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 nonintrusive should normally be regarded as being of minimal risk.

CHAPTER 10
Article 10.3 Application, 5th and 6th paragraphs

For naturalistic and participant observational research in which consent is not sought, researchers shall demonstrate to the REB that necessary precautions and measures have been taken to address privacy and confidentiality issues.

Because the 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 for research purposes. Typically the researcher has no direct interaction with the individuals being observed and therefore their consent is not sought. Covert observation of queuing behaviours in shopping malls 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). These methodological approaches may require the researcher to seek ~~seeking~~ an exception to the requirement of ~~to seek~~ prior consent.

CHAPTER 10
Article 10.3 Application, last paragraph

This article applies to naturalistic and participant observational research. It does not generally apply to epidemiological observational research. Certain types of epidemiological observational research may qualify for an alteration to the general consent requirements (see Article 3.7A).

Chapter 11 provided under separate cover

CHAPTER 12
Article 12.4

When secondary use of identifiable human biological materials without the requirement to seek consent has been approved under Article 12.3A, researchers who propose to contact individuals for additional biological materials or information or for reasons related to the welfare of the participant 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. In rare cases, during the course of analysis, a researcher may discover a finding that has a potential impact on an individual's welfare. If the researcher suspects that welfare implications to the participant may be significant, the researcher and REB should refer to the guidance in Article 3.4 which addresses material incidental findings. Under Article 12.3A, the REB may have approved secondary use without the requirement to seek consent based, in part, on the impossibility or impracticability of seeking consent from all individuals whose biological materials are proposed for use in research. 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 potential 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 to 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 must also ensure that a plan for follow-up contact complies with applicable privacy legislation; for example, some privacy laws prohibit researchers from contacting individuals unless the custodian of the information has first obtained individuals' consent to be contacted. Whenever possible, it is preferable that re-contact with participants be carried out by the organization or the custodian holding the biological materials. Researchers will need to seek consent from individual participants for any new collection of data or biological materials. Article 3.1 provides further guidance on consent and approaches to recruitment.

No changes to Chapter 13

GLOSSARY ENTRIES

Clinical trial – any interventional study in which both the intervention(s) and the outcome(s) are health-related. ~~any investigation involving participants that evaluates the effects of one or more health-related interventions on health outcomes.~~

Delegated research ethics board (REB) review – The level of REB review assigned to minimal risk research projects. Delegated reviewers are selected from among the REB membership~~. with the exception of the ethics review of student course-based research which can be reviewed by delegates from the student's department, faculty, or an equivalent level.~~ Delegated reviewers who are ~~non-members or~~ non-voting members of the REB must have experience, expertise and knowledge comparable to what is expected of an REB member.

Efficacy/Effectiveness: One of the goals of interventional research is to find out if an intervention works. Two measures that describe how well an intervention works are efficacy and effectiveness. A study focused on **efficacy** tests the ability of an intervention to produce its specific beneficial effect under ideal circumstances. This includes the measurement of focused outcomes after application of the intervention by experts to study participants who meet strict inclusion and exclusion criteria and who fully receive the intervention as it was designed. For example, a study of drug efficacy might involve measurement of a specific outcome (e.g., blood pressure). The drug is prescribed by skilled specialists to carefully screened participants who (a) are truly representative of the target population, and (b) fully comply with the prescription instructions. Then the efficacy of the drug as a treatment for blood pressure is assessed. Similarly, an educational study of the efficacy of an experimental curriculum might involve measurement of a specific outcome (e.g., a test score). Expert teachers apply the curriculum to selected classes of highly motivated students who will comply with the requirements. Then the efficacy of the curriculum as a learning enhancement is assessed.

A study focused on **effectiveness** tests the ability of an intervention to provide overall benefit under real-world circumstances. This includes application of the intervention by those who will ultimately apply it and recruitment of all the types of people who will ultimately receive it. The study may also try to ensure that participants receive the intervention the same way they would if it were adopted. In the example of the drug study, effectiveness might involve measurement of overall quality of life. A broad selection of physicians would be asked to prescribe the medication to appropriate patients in their practices. The patients may or may not fully comply with the prescription instructions. Then the effectiveness of the

drug on quality of life would be assessed. In the example of the experimental curriculum study, effectiveness might involve measurement of overall educational achievement. A broadly representative sample of teachers who teach students with a wide range of abilities and motivation would be asked to apply the experimental curriculum. Then the effectiveness of the curriculum on educational achievement would be assessed.

It should be noted that efficacy and effectiveness lie at opposite ends of a continuum. The outcome measures of many studies may fall anywhere along the continuum – employing a mix of efficacy and effectiveness criteria.

Epidemiological observational research – An epidemiological study that does not involve any intervention by the researcher. Such a study may be one in which nature is allowed to take its course, with changes in one characteristic being studied in relation to changes in other characteristics. Analytic epidemiological methods, such as case-control and cohort study designs, are considered to be epidemiological observation because the investigator is observing without intervention other than to record, classify, count, and statistically analyze results. For example, a cohort study that follows smokers and non-smokers forward in time to determine if smokers have an elevated incidence of lung cancer is an epidemiological observational study because the researchers do not assign the exposure, e.g. smoking vs. not smoking, but rather it is a choice made by the participants.

Epidemiology – The study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to the control of health problems. Epidemiological studies generally fall into two categories – observational and experimental. In observational studies the researcher studies but does not alter what occurs. In experimental studies the researcher intervenes and then observes what happens.

Health-Related intervention – the planned imposition of an intervention intended to affect participants' health.

Health-Related outcome – any outcome that concerns the health status of an individual, group or population.

Intervention – the planned imposition of a set of conditions (e.g., a task, an activity, a treatment, exposure to stimuli, change to environment, etc.) on participants for the purposes of research (e.g., to describe, measure, evaluate, explain, or observe participants' reactions or responses to one or more of the imposed conditions). Interventions may, or may not be, health-related and may, or may not, have a health-related outcome.

Interventional research / Interventional studies – any study that prospectively assigns individuals or groups, to receive, or not receive, one or more interventions and that may involve more than minimal risk to participants. This definition includes pilot studies/trials, all phases of clinical trials and studies that may affect health or other aspects of participant welfare (e.g., educational opportunities, socio-economic status, access to services). Research that is focused on observing the effects of different conditions experienced by people due to circumstances other than researcher-directed prospective assignment (e.g., clinician prescription, provincial legislation, employer direction, natural occurrence), does not meet this definition of interventional research.

Naturalistic observational research – The study of human acts or behaviours in a natural environment in which people involved in their normal activities are observed with or without their knowledge by

researchers who do not participate in the activity. Also known as non-participant observational research.

Non-participant observational research – The study of human acts or behaviours in a natural environment in which people involved in their normal activities are observed with or without their knowledge by researchers who do not participate in the activity. Also known as naturalistic observational research.

Observational research – research involving humans that does not involve an intervention by the researcher. The term is used differently in different research communities. For example, naturalistic observational research is the study of human behaviour in a natural environment ~~in which~~ where people ~~involved in their normal activities~~ are observed ~~whether~~ with or without their knowledge. ~~This term does not include observational methods used in epidemiological research.~~ and where there is no intervention by the researcher. Epidemiological observational research is the study of health events in a population; it does not involve any intervention by the researcher.

Outcome – a change (or absence of change) in the variable or attribute of interest and/or related variables or attributes affected by an intervention in the context of research.

Participant observational research – The study of human acts or behaviours in a natural environment in which people involved in their normal activities are observed with or without their knowledge by researchers who participate in the activity.

Pilot study – a smaller version of the main study intended to assess the feasibility and/or inform the design of the main study. For the purposes of this Policy "pilot study" does not include the pre-testing of a particular research instrument such as a questionnaire.

Principal investigator – The leader of a research team who is responsible for the ethical conduct of the research, and for the actions of any member of the research team.

Prospective assignment of participants – the assignment of an intervention to participants in studies involving one or more interventions. Prospective assignment may be randomized or based on specific criteria relevant to the study conditions.

Research findings – the results of an investigation.