[Section 2]

FREE AND INFORMED CONSENT

A. Requirement for Free and Informed Consent

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

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

(c) **The REB may approve a consent procedure[1] that does not include, or that alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided that the REB finds and documents that:**

- **i. The research involves no more than minimal risk to the subjects;**
- **ii. The waiver or alteration is unlikely to adversely affect the rights and welfare of the subjects;**
- **iii. The research could not practicably be carried out without the waiver or alteration;**
- **iv. Whenever possible and appropriate, the subjects will be provided with additional pertinent information after participation; and**
- **v. The waived or altered consent does not involve a therapeutic intervention.**

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

Free and informed consent lies at the heart of ethical research involving human subjects. It encompasses a process that begins with the initial contact and carries through to the end of the involvement of research subjects in the project. As used in this Policy, the process of free and informed consent refers to the dialogue, information sharing and general process through which prospective subjects choose to participate in research involving themselves.

Article 2.1(a) states the requirement in both ethics and law: to protect and promote human dignity. Ethical research involving humans requires free and informed consent. As elaborated more fully below, free and informed consent is exercised by an authorized third party for those who lack legal competence.

Article 2.1(b) states the preference for written evidence of free and informed consent. The article acknowledges that written consent is not always appropriate. For most people in our society, a signed statement is the normal evidence of consent. However, for some groups or individuals, a verbal agreement, perhaps with a handshake, is evidence of trust, and a request for a signature may imply distrust. Nonetheless, in most cases a written statement of the information conveyed in the consent process, signed or not, should be left with the subject. In some types of research, oral consent may be preferable. In others, written consent is mandatory. Where oral consent is appropriate, the researcher may wish to make a contemporaneous journal entry of the event and circumstances. These and like elements may sometimes need to be refined in concert with the REB, which plays an essential educational and consultative role in the process of seeking free and informed consent. When in doubt about an issue involving free and informed consent, researchers should consult their REB.

The requirement for free and informed consent should not disqualify research subjects who are not proficient in the language used by the researchers from the opportunity to participate in potential research. Such individuals may give consent, provided that one or more of the following are observed to the extent deemed necessary by the REB, in the context of a proportionate approach to the harms envisaged in the research and the consent processes that are to be used:

- An intermediary not involved in the research study, who is competent in the language used by the researchers as well as that chosen by the research subject, is involved in the consent process.
- The intermediary has translated the consent document or approved an existing translation of the information relevant to the prospective subject.
- The intermediary has assisted the research subject in the discussion of the research study.
- The research subject has acknowledged, in his or her own language, that he or she understands the research study, the nature and extent of his or her participation, including the risks involved, and freely gives consent (see exception in Article 2.1(c)).

Consent is not required from organizations such as corporations or governments for research about their institutions. However, individuals who are approached to participate in a research project about their organization have the right to give free and informed consent. In particular, they should be fully informed about the views of the organization's authorities, if these are known, and of the possible consequences of participation. In this context, researchers should pay special attention to confidentiality. Private corporations and organizations have the right as institutions to refuse to cooperate with researchers or to deny them access to their private records if they so wish, and may have rules governing the conduct of their employees. However, such organizations need not be approached for consent, and REBs should not require such an approach. Nor should institutions be given the right to veto research projects.

Under Article 2.1(c), the REB should exercise judgement on whether the needs for research justify limited and/or temporary exception to the general requirements for full disclosure of information relevant for a research subject's meaningful exercise of free and informed consent. In such cases, subjects may be given only partial information or may be temporarily led to believe that the

research has some other purpose because full disclosure would be likely to colour the responses of the subjects and thus invalidate the research. For example, social science research that critically probes the inner workings of publicly accountable institutions might never be conducted without limited recourse to partial disclosure. Also, some research in psychology seeks to learn about human responses to situations that have been created experimentally. Such research can only be carried out if the subjects do not know in advance the true purpose of the research. In some research, therefore, subjects may be told in advance about the task that they will be asked to perform, yet given additional information, perhaps as part of the consent process or as part of the manipulated experimental conditions, that provides subjects with a different perspective on some aspect of the task or experiment and/or its purpose. Another scenario, in questionnaire research, embeds questions that are central to the researcher's hypothesis within distracter questions, decreasing the likelihood that subjects will adapt their responses to their perceptions of the true objective of the research. For such techniques to fall within the exception to the general requirement of full disclosure for free and informed consent, the research must meet the requirements of Article 2.1(c).

The debriefing referred to in Article 2.1(c)(iv) 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 subjects were temporarily led to believe that the research, or some aspect of it, had a different purpose, or 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, and their concern about the welfare of the subject. They should seek to remove any misconceptions that may have arisen, and to reestablish any trust that might have been lost, assuring the research subject during debriefing that these research procedures were neither arbitrary nor capricious, but necessary for scientifically valid findings. Debriefing is an important mechanism in maintaining the subject's trust in the research community.

Immediate, full debriefing of all persons 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 subjects 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 subject's needs and feelings.

In studies in which a waiver of informed consent has been allowed, it may still be practicable for subjects to exercise their consent at the conclusion of the study, following debriefing. In cases where a subject expresses concerns about a study, the researcher may give the subject the option of removing his or her data from the project. This approach should be used only when the elimination of the subject's data will not compromise the validity of the research design, and hence diminish the ethical value of participation by other subjects.

When subjects express significant concern about being temporarily misled or about the use of partial disclosure in the research, the researcher should report those concerns to the REB.

B. Voluntariness

Article 2.2 **Free and informed consent must be voluntarily given, without manipulation, undue influence or coercion.**

The element of voluntariness has important implications. Consent must be freely given and may be withdrawn at any time. Undue influence may take the form of inducement, deprivation, or the exercise of control, or authority over prospective subjects.

Voluntariness is especially relevant in research involving restricted or dependent subjects. It is absent if consent is secured by the order of authorities or as a result of coercion or manipulation. The influence of power relationships on voluntary choice should be judged according to the particular context of prospective subjects. For example, the voluntariness of prisoners, members of organizations with authoritarian structures (such as the military, police, some religious groups or street gangs), or of employees or students may be restricted because their institutional context implies undue pressure. Care should be exercised in developing relationships between researchers and authorities, so as not to compromise either the free and informed consent or the privacy and confidentiality of subjects.

Conversely, situations may arise in which an organization, such as a corporation, a government, a political party or a criminal organization that may have been approached about a research project, may wish to prevent the research; however, individuals over whom the organization has some authority may be willing to participate. Researchers and REBs should not prevent such research, but should ensure that potential subjects are fully informed of the views of the organization's authorities and the possible consequences of participation, and pay special attention to confidentiality.

REBs should also pay particular attention to the elements of trust and dependency—for example, within doctor/patient or professor/student relationships—because these can constitute undue influence on the patient to participate in research projects, especially those involving residents in long-term care facilities or psychiatric institutions.

Researchers should avoid being put in a position of becoming informants for authorities or leaders of organizations. The offer of benefits in some contexts may amount to undue inducement, and thus negate the voluntary aspect of the consent of subjects who may perceive such offers as a way to gain favour or improve their situation.

C. Naturalistic Observation

Article 2.3 **REB review is normally required for research involving naturalistic observation. However, research involving observation of participants in, for example, political rallies, demonstrations or public meetings should not require REB review since it can be expected that the participants are seeking public visibility.**

Naturalistic observation is used to study behaviour in a natural environment. Because knowledge of the research can be expected to influence behaviour, naturalistic observation generally implies that the subjects do not know that they are being observed, and hence cannot have given their free and informed consent. Due to the need for respect for privacy, even in public places, naturalistic observation raises concerns of the privacy and dignity of those being observed. These concerns are accentuated if, for example, the research records permit identification of the subjects, or if the research environment is staged.

In considering research involving naturalistic observation, researchers and REBs 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 (in particular, whether it is to be staged for the purposes of the research); and the means of recording the observations (in particular, if the records will allow subsequent identification of the subjects). Naturalistic observation that does not allow for the identification of the subjects, and that is not staged, should normally be regarded as of minimal risk.

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.

D. Informing Potential Subjects

D1. General Conditions

Article 2.4 **Researchers shall provide, to prospective subjects or authorized third parties, full and frank disclosure of all information relevant to free and informed consent. Throughout the process of free and informed consent, the researcher must ensure that prospective subjects are given adequate opportunities to discuss and contemplate their participation. Subject to the exception in Article 2.1(c), at the commencement of the process of free and informed consent, researchers or their qualified designated representatives shall provide prospective subjects with the following:**

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

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

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

(d) An assurance that prospective subjects are free not to participate, have the right to withdraw at any time without prejudice to pre-existing entitlements, and will be given continuing and meaningful opportunities for deciding whether or not to continue to participate; and

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

Under the normal process of obtaining written consent, the prospective subject should be given a copy of the consent form and any relevant written information. The consent of the participants shall not be conditional upon, or include any statement to the effect that, by consenting, subjects waive any legal rights.

In light of (b) and (c), REBs may require researchers to provide prospective subjects with additional information, such as that detailed in Table 1, below.

Article 2.4 indicates the requirement to give prospective subjects the information they need to give free and informed consent on whether to be involved in the research project. In a research team, the principal researcher is ultimately responsible for the actions of those acting with delegated authority.

Research subjects, whether inside or outside Canada, may have cultural values different from those of the researcher. Thus, as Articles 2.4(a-c) indicate, researchers must clearly explain the nature and goals of the research and other essential information, in a manner appropriate for the prospective subjects' cultural settings. With some cross-cultural research projects, it may not be possible to offer an adequate translation of the researcher's understanding to prospective subjects. REBs should proceed cautiously in such cases and require stringent protection for the interests of subjects, such as appointing an individual to act in an independent advocacy role. On the other hand, REBs should not assume an unnecessarily protective role that suggests that those who do not share the culture of the researchers, particularly those in foreign countries, are incapable of making rational decisions in their own interest.

Articles 2.2 and 2.4(d) help to ensure that a prospective subject's choice to participate is voluntary. Pre-existing entitlements to care, education and other services shall not be prejudiced by the decision on whether to participate. Accordingly, a physician should ensure that continued clinical care is not linked to research participation, and teachers should not recruit prospective subjects from their classes, or students under their supervision, without REB approval. Nothing in this section should be interpreted as meaning that normal classroom assessments of course work require REB approval. Article 2.4(d) also requires that researchers specifically ascertain continuing consent from subjects on the basis of new information.

TABLE 1

Additional information that may be required for some projects

1. An assurance that new information will be provided to the subjects in a timely manner whenever such information is relevant to a subject's decision to continue or withdraw from participation;

2. The identity of the qualified designated representative who can explain scientific or scholarly aspects of the research;

3. Information on the appropriate resources outside the research team to contact regarding possible ethical issues in the research;

4. An indication of who will have access to information collected on the identity of subjects, descriptions of how confidentiality will be protected, and anticipated uses of data;

5. An explanation of the responsibilities of the subject;

6. Information on the circumstances under which the researcher may terminate the subject's participation in the research;

7. Information on any costs, payments, reimbursement for expenses or compensation for injury;

8. In the case of randomized trials, the probability of assignment to each option;

9. For research on biomedical procedures, including health care interventions: information about (a) foregoing alternative procedures that might be advantageous to the subject, (b) which aspects of the research involve the use of procedures that are not generally recognized or accepted; and, (c) particularly in trials of therapeutic interventions, the care provided if the potential subject decides not to consent to participation in the study;

10. The ways in which the research results will be published, and how the subjects will be informed of the results of the research.

Article 2.4(e) reminds researchers of relevant ethical duties that govern potential or actual conflicts of interest, as they relate to the free and informed consent of subjects. To preserve and not abuse the trust on which many professional relations reside, researchers should separate their role as researcher from their roles as therapists, caregivers, teachers, advisors, consultants, supervisors, students, employers and the like. If a researcher is acting in dual roles, this fact must always be disclosed to the subject. Researchers should disassociate their role as researcher from other roles, in the recruitment process and throughout the project. Conflict of interest matters are further elaborated below in Section 4.

Table 1 also indicates other information that researchers may be required to provide in some areas of research for the purpose of obtaining free and informed consent. Item 2 refers to the qualified designated representative who is usually someone on the research team. When the research poses more than minimal risk, it may be advisable to have a person who is independent of the research team in this role. Item 3 acknowledges that some institutions may decide either to name an ombudsman for research subjects, or designate, with the agreement of the researcher, a resource person to handle queries, receive complaints, and transmit them to the REB. Item 7 is intended to prevent the development of a payment structure for research participation that might place undue pressure on research subjects either to join or remain within a research project. It does not imply that subjects should be paid for their participation in research. In research projects where subjects will be compensated, REBs should be sensitive to the possibility of undue inducement for participation, such as payments that would lead subjects to undertake actions that they would not ordinarily accept. REBs should pay attention to issues such as the economic circumstances of those in the pool of prospective subjects, and to the magnitude and probability of harms.

Item 10 in Table 1 indicates that subjects have the right to know whether they will be identified directly or indirectly in publications resulting from the research.

Rushing the process of free and informed consent, or treating it as a perfunctory routine, violates the principle of respect for persons, and may cause difficulty for potential subjects. The time required for the process of free and informed consent can be expected to depend on such factors as the magnitude and probability of harms, the setting where the information is given (e.g., hospital or home) and the subject's situation (e.g., level of anxiety, maturity or seriousness of disease).

In some circumstances, witnessing the signatures on the consent form may be felt to be appropriate. In law, the role of a witness is only to attest that the person actually signed the form; a witness is not responsible for certifying such factors as the signature being obtained under defined conditions or that the signers were competent. However, a court might subsequently seek the opinions of the witness on such issues.

E. Competence

Competence refers to the ability of prospective subjects to give informed consent in accord with their own fundamental values. It involves the ability to understand the information presented, to appreciate the potential consequences of a decision, and to provide free and informed consent. This ability may vary according to the choice being made, the circumstances surrounding the decision, or the time in question. Competence to participate in research, then, is not an all-or-nothing condition. It does not require prospective subjects to have the capacity to make every kind of decision. It requires that they be competent to make an informed decision about participation in particular research. Competence is neither a global condition nor a static one; it may be temporary or permanent.

The law on competence varies between jurisdictions. Researchers must comply with all applicable legislative requirements.

Ethical considerations around research involving those who are not competent to give a free and informed consent on their own behalf must seek to balance (1) the vulnerability that arises from their incompetence with (2) the injustice that would arise from their exclusion from the benefits of research.

As indicated in the Ethics Framework of this Policy, the principle of respect for human dignity entails high ethical obligations to the vulnerable populations. Such obligations often translate into special procedures to promote and protect their interests and dignity. The articles that follow detail the special procedures for research involving individuals with diminished decision making capacity.

Article 2.5 **Subject to applicable legal requirements, individuals who are not legally competent shall only be asked to become research subjects when:**

(a) **The research question can only be addressed using individuals within the identified group(s); and**

(b) **Free and informed consent will be sought from their authorized representative(s); and**

(c) **The research does not expose them to more than minimal risk without the potential for direct benefits for them.**

Article 2.5(a) expresses the general requirement to restrict research involving incompetent subjects to questions that cannot be addressed with competent subjects. It also expresses the general moral preference for involving competent rather than incompetent research subjects, and the need to avoid selecting prospective subjects merely because of convenience. Article 2.5(b) provides a means of protecting their interests and dignity through the free and informed consent of authorized representatives (see also Articles 2.6 and 2.7), who are acting in the interests of the potential subjects and are not influenced by conflict of interest. Article 2.5(c) restricts the extent to which their authorized representatives can consent on their behalf.

Sound ethical reasoning and the subject-centred perspective require attention to context. In this instance, the notion of harm applied to children should be understood differently from harm in adults. Harm induced in children may have longer-term consequences to their growth and development. Furthermore, harms and benefits for children with chronic disabilities and terminal illnesses require special consideration. Every researcher working with child subjects must consider the possibility of the children suffering pain, anxiety or injury, and must develop and implement suitable precautions and ameliorating measures. Cumulative physical, moral, psychological and social consequences (relevant to pain, anxiety and injury) should be reviewed by REBs when assessing the probability, magnitude and character of any harmful impact the research may have on the child.

Article 2.6 **For research involving incompetent individuals, the REB shall ensure that, as a minimum, the following conditions are met:**

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

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

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

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

Article 2.6 outlines other safeguards to protect the dignity, interests and integrity of those who lack competence to give their free and informed consent to participation in research. The article details various considerations relevant to the use of third-party authorization. Beyond the legal requirements for obtaining free and informed consent from authorized third parties, family members and friends may provide information about the interests and previous wishes of prospective subjects. In some cases, the REB will have to determine from whom the free and informed consent should be sought.

Article 2.7 **Where free and informed consent has been obtained from an authorized third party, and in those circumstances where the legally incompetent individual understands the nature and consequences of the research, the researcher shall seek to ascertain the wishes of the individual concerning participation. The potential subject's dissent will preclude his or her participation.**

Many individuals who are not legally competent are still able to express their wishes in a meaningful way, even if such expression may not fulfil the requirements for free and informed consent. Prospective subjects 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 competence is in the process of development, such as children whose capacity for judgement and self-direction is maturing; (b) those who once were capable of making an informed decision about

informed consent, but whose competence is now considerably, but not completely, diminished, such as individuals with early Alzheimer's disease; and (c) those whose competence remains only partially developed, such as those suffering from permanent cognitive impairment.

F. Research in Emergency Health Situations

Article 2.8 **Subject to all applicable legislative and regulatory requirements, research involving emergency health situations shall be conducted only if it addresses the emergency needs of individuals involved, and then only in accordance with criteria established in advance of such research by the REB. The REB may allow research that involves health emergencies to be carried out without the free and informed consent of the subject or of his or her authorized third party if ALL of the following apply:**

(a) **A serious threat to the prospective subject requires immediate intervention; and**

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

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

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

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

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

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

For purposes of studying potential improvement in the treatment of life-threatening conditions, Article 2.8 outlines an exception, in addition to that in Article 2.1(c), to the general obligation of obtaining the free and informed consent from those participating in research.

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

Researchers must justify to the REB recourse to the provisions of this exception. The underlying assumption of Article 2.8 is that direct research benefits to the subject could not be secured without forgoing the free and informed consent of the subject or of his or her authorized third party. Article 2.8 indicates that research in emergency medicine must be reviewed by the REB, be restricted to the emergency needs of the subjects, and be conducted under criteria designated by the REB. Article 2.8 outlines the minimal conditions necessary for the REB to authorize research without free and informed consent.

It is unethical to expose subjects to any additional risk of harm without their free and informed consent if standard efficacious care exists, unless it can clearly be shown that there is a realistic possibility of significantly improving the subject's condition. Accordingly, Articles 2.8 (b) and (c) indicate that researchers and REBs must assess the potential risk of harms and benefits of proposed research against existing standard efficacious care. Together, Articles 2.8(b) and (c) require that the therapeutic aspects of the trial satisfy the requirements of clinical equipoise. To respect the autonomy of the research subject, Article 2.8(e) requires researchers to undertake diligent efforts to contact family members or authorized third parties, if reasonably feasible, and to document such efforts for the benefit of both the subject and for the monitoring or continuing review functions of the REB. The article also requires that research subjects who become competent be promptly afforded the opportunity to give free and informed consent concerning continued participation. Concern for the patient's well-being is paramount and should be informed by ethical and professional judgement.

Because their incapacity to exercise free and informed consent makes them vulnerable, prospective subjects for emergency research are owed special ethical obligations and protection commensurate with the harms involved. Their interests, rights, and welfare should be protected by additional safeguards which should include, where feasible and appropriate, one or more of the following:

- Additional scientific, medical or REB consultation;
- Procedures to identify potential subjects in advance to obtain free and informed consent prior to the occurrence of the emergency situation;
- Consultation with former and potential subjects;
- Special monitoring procedures to be followed by safety and monitoring boards; and
- Careful review by the REB of the relative harms and benefits of participation.

Endnotes

[1] Article 2.1(c) was adapted from U.S. Department of Health and Human Services, *Protection of Human Subjects*, Title 45: "Code of Federal Regulations" Part 46.116(d).