

CONTEXT OF AN ETHICS FRAMEWORK

Norms for the ethics of research involving human subjects are developed and refined within an ever-evolving societal context, elements of which include the need for research and the research community, moral imperatives and ethical principles, and the law.

A. The Need for Research

Research involving human subjects is premised on a fundamental moral commitment to advancing human welfare, knowledge and understanding, and to examining cultural dynamics. Researchers, universities, governments and private institutions undertake or fund research involving human subjects for many reasons; for example, to alleviate human suffering, to validate social or scientific theories, to dispel ignorance, to analyze policy, and to understand human behaviour and the evolving human condition. Research involving human subjects imparts at least three general categories of benefits:

- The basic desire for new knowledge and understanding is the driving force for research.
- The quest to advance knowledge sometimes benefits research subjects. Subjects may benefit from improved treatments for illnesses; the discovery of information concerning one's welfare; the identification of historical, written, oral or cultural traditions; or the satisfaction of contributing to society through research.
- As well, research benefits particular groups and society as a whole. Thus, insights into political behaviour may produce better policy; information about the incidence of disease may improve public health; sociological data about lifestyles may yield social reform; and disciplines based on, for example, texts, dance, theatre or oral history, continue to illuminate past and present realities.

B. A Moral Imperative: Respect for Human Dignity

An ethic of research involving human subjects should include two essential components: (1) the selection and achievement of morally acceptable ends and (2) the morally acceptable means to those ends.

The first component is directed at defining acceptable ends in terms of the benefits of research for subjects, for associated groups, and for the advancement of knowledge. The second component is directed at ethically appropriate means of conducting research. For example, even in the most promising of research initiatives, the Agencies object to a person being tricked into participating through a promise of false benefits. Part of the core moral objection would concern the use of another human solely as a means toward even legitimate ends.

The objection provides moral insight that proves pertinent to human research in several ways: First, it translates into the familiar moral imperative of respect for human dignity. It is unacceptable to treat persons solely as means (mere objects or things), because doing so fails to respect their intrinsic human dignity and thus impoverishes all of humanity. Second, it translates into the requirement that the welfare and integrity of the individual remain paramount in human research.¹ Thus, the moral imperative of respect for human dignity translates into a number of important correlative ethical principles in research ethics. These are elaborated in Section C, below.

C. Guiding Ethical Principles

The approach taken in this framework is to guide and evoke thoughtful actions based on principles. The principles that follow are based on the guidelines of the Agencies over the last decades,² on more recent statements by other Canadian agencies,³ and on statements from the international community.⁴ The principles have been widely adopted by diverse research disciplines. As such, they express common standards, values and aspirations of the research community.

Respect for Human Dignity: The cardinal principle of modern research ethics, as discussed above, is respect for human dignity. This principle aspires to protect the multiple and interdependent interests of the person—from bodily to psychological to cultural integrity. This principle forms the basis of the ethical obligations in research that are listed below.

In certain situations, conflicts may arise from application of these principles in isolation from one other. Researchers and REBs must carefully weigh all the principles and circumstances involved to reach a reasoned and defensible conclusion.

Respect for Free and Informed Consent:⁵ Individuals are generally presumed to have the capacity and right to make free and informed decisions. Respect for persons thus means respecting the exercise of individual consent. In practical terms within the ethics review process, the principle of respect for persons translates into the dialogue, process, rights, duties and requirements for free and informed consent by the research subject.

Respect for Vulnerable Persons: Respect for human dignity entails high ethical obligations toward vulnerable persons—to those whose diminished competence and/or decision making capacity make them vulnerable. Children, institutionalized persons or others who are vulnerable are entitled, on grounds of human dignity, caring, solidarity and fairness, to special protection against abuse, exploitation or discrimination. Ethical obligations to vulnerable individuals in the research enterprise will often translate into special procedures to protect their interests.

Respect for Privacy and Confidentiality: Respect for human dignity also implies the principles of respect for privacy and confidentiality. In many cultures, privacy and confidentiality are considered fundamental to human dignity. Thus, standards of privacy and confidentiality protect the access, control and dissemination of personal information. In doing so, such standards help to protect mental or psychological integrity. They are thus consonant with values underlying respect for privacy, confidentiality and anonymity.

Respect for Justice and Inclusiveness: Justice connotes fairness and equity. Procedural justice requires that the ethics review process have fair methods, standards and procedures for reviewing research protocols, and that the process be effectively independent. Justice also concerns the distribution of benefits and burdens of research. On the one hand, distributive justice means that no segment of the population should be unfairly burdened with the harms of research. It thus imposes particular obligations toward individuals who are vulnerable and unable to protect their own interests, to ensure that they are not exploited for the advancement of knowledge. History has many chapters of such exploitation. On the other hand, distributive justice also imposes duties to neither neglect nor discriminate against individuals and groups who may benefit from advances in research.

Balancing Harms and Benefits: The analysis, balance and distribution of harms and benefits are critical to the ethics of human research. Modern research ethics, for instance, require a favourable harms-benefits balance—that is, that the foreseeable harms should not outweigh anticipated benefits. Harms-benefits analysis thus affects the welfare and rights of research subjects, the informed assumption of harms and benefits, and the ethical justifications for competing research paths. Because research involves advancing the frontiers of knowledge, its undertaking often involves uncertainty about the precise magnitude and kind of benefits or harms that attend proposed research. These realities as well as the principle of respect for human dignity, impose ethical obligations on the prerequisites, scientific validity, design and conduct of research. These concerns are particularly evident in biomedical and health research; in research they need to be tempered in areas such as political science, economics or modern history (including biographies), areas in which research may ethically result in the harming of the reputations of organizations or individuals in public life.

Minimizing Harm: A principle directly related to harms-benefits analysis is non-maleficence, or the duty to avoid, prevent or minimize harms to others. Research subjects must not be subjected to unnecessary risks of harm, and their participation in research must be essential to achieving scientifically and societally important aims that cannot be realized without the participation of human subjects. In addition, it should be kept in mind that the principle of minimizing harm requires that the research involve the smallest number of human subjects and the smallest number of tests on these subjects that will ensure scientifically valid data.

Maximizing Benefit: Another principle related to the harms and benefits of research is beneficence. The principle of beneficence imposes a duty to benefit others and, in research ethics, a duty to maximize net benefits. The principle has particular relevance for researchers in professions such as social work, education, health care and applied psychology. As noted earlier, human research is intended to produce benefits for subjects themselves, for other individuals or society as a whole, or for the advancement of knowledge. In most research, the primary benefits produced are for society and for the advancement of knowledge.

D. A Subject-Centred Perspective

Research subjects contribute enormously to the progress and promise of research in advancing the human condition. In many areas of research, subjects are participants in the development of a research project, and collaboration between them and the researcher in such circumstances is vital and requires nurturing. Such collaboration entails an active involvement by research subjects, and ensures both that their interests are central to the project or study, and that they will not be treated simply as objects. Especially in certain areas of the humanities and social sciences this collaborative approach is essential, and the research could not be conducted in any other way. For example, a study on how a theatrical company developed its approach to a particular play would be difficult without the participation of the theatre company in question. Nevertheless, some research will require a more formal separation between subject and researcher because of the nature of the research design.

A subject-centred approach should, however, also recognize that researchers and research subjects may not always see the harms and benefits of a research project in the same way. Indeed, individual subjects within the same study may respond very differently to the information provided in the process of free and informed consent. Hence, researchers and REBs must strive to understand the views of the potential or actual research subjects.

In this context, researchers should take into account that potential subjects who are asked to participate in research by, for example, their caregiver, teacher or supervisor may be overly influenced by such factors as trust in the researcher or the hope for other goals—more than by assessment of the pros and cons of participation in the research. A patient may hope for a cure from an experimental drug, an employee for better working conditions, and a student for better marks. This places extra demands on the researcher for accuracy, candour, objectivity and sensitivity in informing potential subjects about proposed research.

However, researchers and REBs should also be aware that some research may be deliberately and legitimately opposed to the interests of the research subjects. This is particularly true of research in the social sciences and the humanities that may be critical of public personalities or organizations. Such research should, of course, be carried out according to professional standards, but it should not be blocked through the use of harms-benefits analysis or because it may not involve collaboration with the research subjects.

E. Academic Freedoms and Responsibilities

Researchers enjoy, and should continue to enjoy, important freedoms and privileges. To secure the maximum benefits from research, society needs to ensure that researchers have certain freedoms. It is for this reason that researchers and their academic institutions uphold the principles of academic freedom⁶ and the independence of the higher education research community. These freedoms include freedom of inquiry and the right to disseminate the results thereof, freedom to challenge conventional thought, freedom from institutional censorship, and the privilege of conducting research on human subjects with public monies, trust and support. However, researchers and institutions also recognize that with freedom comes responsibility, including the responsibility to ensure that research involving human subjects meets high scientific and ethical standards. The researcher's commitment to the advancement of knowledge also implies duties of honest and thoughtful inquiry, rigorous analysis, and accountability for the use of professional standards. Thus, peer review of research proposals, the findings and their interpretation contribute to accountability, both to colleagues and to society.

Review of the ethics of research helps ensure a more general accountability to society. Accountability, moreover, requires that the whole process should always be open to critical assessment and debate.⁷

F. Ethics and Law

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

This legal context for research involving human subjects is constantly evolving, and varies from jurisdiction to jurisdiction. For this reason, researchers, institutions and REBs should have recourse to expertise to identify legal issues in the ethics review process.

However, legal and ethical approaches to issues may lead to different conclusions. The law tends to compel obedience to behavioural norms. Ethics aim to promote high standards of behaviour through an awareness of values, which may develop with practice and which may have to accommodate choice and liability to err. Furthermore, though ethical approaches cannot preempt the application of the law, they may well affect its future development or deal with situations beyond the scope of the law.

G. Putting Principles into Practice

For meaningful and effective application, the foregoing ethical principles must operate neither in the abstract, nor in isolation from one another. Ethical principles are sometimes criticized as being applied in formulaic ways. To avoid this, they should be applied in the context of the nature of the research and of the ethical norms and practices of the relevant research discipline. Good ethical reasoning requires thought, insight and sensitivity to context, which in turn help to refine the roles and application of norms that govern relationships. Thus, because principles are designed to guide ethical reflection and conduct, they admit flexibility and exceptions. To preserve the values, purpose and protection that they attempt to advance, the onus for demonstrating a reasonable exception to a principle should fall on those claiming the exception.

National norms in research ethics should not be developed in a vacuum. REBs should be aware that there are a variety of philosophical approaches to ethical problems, and that debate between various schools of thought both informs ethical decisions and ensures an evolving context for ethical approaches. Some approaches are traditional, but others, such as feminist analysis, are centred on context, relationships of power and allocations of privilege that perpetuate disadvantage and inequality. Hence, the approach may help to correct the systemic exclusion of some groups from research.

Often, more than one principle will apply to a specific case. This is due in part to the diversity of research and in part to the range of fundamental values upon which the research ethics enterprise is founded. If the application of principles yields conflicts, then such conflicts properly demand probing ethical reflection and difficult value choices. Such choices and conflicts are inherent in the ethics review process. In their best uses, principles serve as short-hand reminders of more complex and context-specific moral reflection.

REBs should recognize that certain types of research—particularly biographies, artistic criticism or public policy research—may legitimately have a negative effect on organizations or on public figures in, for example, politics, the arts or business. Such research does not require the consent of the subject, and the research should not be blocked merely on the grounds of harms-benefits analysis because of the potentially negative nature of the findings.

Beyond a keen appreciation for context, effective guiding principles also depend on procedures and policies for their implementation. Indeed, modern research ethics are premised on a dynamic relation between ethical principles and procedures. This relationship is implemented through a mechanism that has emerged in many countries over the last decades and which consists of the articulation of national norms that are applied through prospective ethics review of research projects. Typically, the review is undertaken in local research institutions by independent, multidisciplinary ethics committees that apply substantive and procedural norms. This Policy is consistent with this model.

Endnotes

- ¹ Social Sciences and Humanities Research Council of Canada, *Ethics Guidelines for Research Involving Human Subjects*. Ottawa, 1977, p. 1; UNESCO, *Universal Declaration on the Human Genome and Human Rights*. Paris, 1997, article 10.
- ² Medical Research Council of Canada, *Guidelines for Research Involving Human Subjects*. Ottawa, 1987; *Ethics in Human Experimentation*. Ottawa, 1978.
- ³ See, e.g., National Research Council of Canada, *Research Involving Human Subjects: Guidelines for Institutes*. Ottawa, 1995; Royal Commission on New Reproductive Technologies, *Proceed with Care: Final Report of the Royal Commission on New Reproductive Technologies*. Ottawa, 1993, vol. 1: 53–66.
- ⁴ See, e.g., The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. Washington, DC, 1979; Council for International Organizations of Medical Sciences, *International Ethical Guidelines for Biomedical Research Involving Human Subjects*. Geneva, 1993. UNESCO, *Ethical Guidelines for International Comparative Social Science Research in the Framework of M.O.S.T. (Management of Social Transformation)*. Paris, 1994; The Research Council of Norway, *Guidelines for Research Ethics in the Social Sciences, Law and the Humanities*. Oslo, 1994.
- ⁵ During preparation of this Policy Statement, there was extensive discussion of the optimal way to refer to the decision made by the potential research subject on whether to participate in the research. The frequently used phrase “obtain informed consent” was rejected early in the discussion because “obtain” implies that getting the consent is the goal, whereas ethically the goal must be to enable the potential subject to choose freely, and with full information, on whether to agree to participate in the research. Though earlier drafts used both “choice” and “consent,” it was often difficult to be certain which was the most appropriate in the various contexts. Hence, a brief means of expressing this concept was sought. “Free and informed consent” was decided upon for a number of reasons: it states the requirement for voluntariness and information; it was felt to include the idea that consent is the act of deciding, perhaps as a result of balancing a number of choices; it retains the traditional word “consent”; and the phrase has unambiguous meaning in the law.
- ⁶ For a definition of academic freedom, see UNESCO, *Recommendation concerning the Status of Higher-Education Teaching Personnel*, Paris, 1997, Chapter VI. For responsibilities, see Section VII—“Duties and Responsibilities of Higher Education Teaching Personnel” and Section V—“Institutional Rights, Duties and Responsibilities.” Canada spoke in favour of, and voted for, this statement when it was adopted by the General Conference of UNESCO in 1997. For further definitions of academic freedom, see Canadian Association of University Teachers (CAUT), *Policy Statement on Academic Freedom*, Ottawa, 1977; Association of Universities and Colleges of Canada (AUCC), *Statement on Academic Freedom and Institutional Autonomy*, Ottawa, 1988.
- ⁷ UNESCO, *Recommendation concerning the Status of Higher-Education Teaching Personnel*, Paris, 1997, which deals with the rights and responsibilities of faculty. See also CAUT, *Policy Statement on Academic Freedom* and AUCC, *Statement on Academic Freedom and Institutional Autonomy*.