

## FOREWORD

In 1994, the Presidents of the Medical Research Council of Canada (MRC), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC), collectively appointed a multi-disciplinary working group (the Tri-Council Working Group) and gave it the mandate to develop new policies and regulations to replace the Councils' existing guidelines for research involving humans. The Code of Ethical Conduct for Research Involving Humans (the Code) is the result of that process and supersedes both the MRC Guidelines on Research Involving Human Subjects 1977 and the 1987 SSHRC Ethics Guidelines for Research with Human Subjects. This Code complements the 1990 MRC Guidelines for Research on Somatic Cell Gene Therapy in Humans.

In constructing the Code, numerous guidelines and codes of ethics for research involving humans were taken into account. Disciplinary and professional codes for ethical research involving humans were also considered. Finally, close attention was paid to the extensive work of scholars on the ethics of research involving humans from diverse fields such as law, philosophy, religious studies, social sciences, engineering, and health sciences.

In 1996, a draft Code was completed by the Tri-Council Working Group and was distributed throughout the academic and lay communities for comment; over 2,000 pages were received from over 250 respondents. In light of those comments and further discussions within and beyond the Working Group, a final version of this Code was produced and submitted to the Councils in May 1997.

The Code has two parts. Part 1 contains a general discussion of the context and scope of the Code and provides an Ethical Framework for understanding and resolving ethical issues. Part 2 is made up of ten Sections each including prescriptions, procedures, and practices. The Articles are the prescriptive elements of the Code. Articles appear in **bold print** and are identified by arabic numerals. Articles are closely connected to the procedures to be followed by researchers and Research Ethics Boards (REBs). At various points in the ten Sections, suggestions are made about good ethical practices for research involving humans. These practices are based on the cumulative experience of researchers in relevant fields, including those conducting research on the ethics of research involving humans, but are not to be regarded as mandatory. For ease of reference, the Code also includes a Glossary of Working Definition. The first major use of a defined term contained in a glossary is indicated by **bold print**.

## SCOPE OF THE CODE

This Code was written to help researchers, Research Ethics Boards, and administrators of institutions develop and maintain the highest standards of ethical conduct in research involving humans. Researchers, REBs, and administrators can regard this Code as a source of guidance on **ethical** conduct in research and not simply as a set of rules that must be followed without consideration of the principles on which those rules are based. This Code also can be regarded as an educational tool for anyone involved in the design and/or conduct of research involving humans.

### A. GOALS OF THE CODE

This Code covers the broad range of research involving humans. While researchers in diverse disciplines have specialized research perspectives, procedures, and standards, all researchers engaged in research involving humans face common ethical challenges. Part 1 of the Code, particularly the Ethical Framework for Research Involving Humans following this Introduction, will help researchers and REBs recognize and address central ethical challenges, including those in areas where there still remains considerable uncertainty and debate.

It is crucial for society and for the future of research in Canada that the highest ethical standards be maintained in research involving humans. Hence, the **Councils** trust that other research sponsors, be they in the public, private, or not-for-profit sectors, will join in adopting and adhering to this Code as the standard for all Canadian research involving humans.

### B. WHY A SINGLE CODE?

This Code articulates a common set of principles and procedures to govern research involving humans, with sufficient flexibility for dealing with the wide range of research conducted by Canadian researchers. The Councils' decision to develop a unified approach to the **ethics** of research involving humans relates to the importance of bringing together the perspectives of researchers from diverse disciplines. In contrast to the disciplinary "solitudes" of the past, today many scholars are convinced that no research topic involving humans is purely biomedical, humanistic, scientific or social. Many of the ethical questions raised in research involving humans are common across all disciplines.

For their part, research participants should be able to expect that, in a clear and unequivocal way, their rights — particularly to make voluntary and informed choices about participation in research projects and to be free from undue risk of harm — are respected, regardless of the researcher's discipline. In this context, harm includes a wide range of possibilities such as physical or psychological harm, loss of reputation, breach of confidentiality, loss of familial or social relationships, and betrayal of the participant's trust. Furthermore, there are legitimate societal expectations that the benefits of research will be fairly distributed and that adequate protection will be given to those who are unable to choose for themselves or who otherwise are vulnerable. These are common issues faced by researchers. Indeed, the ethical lessons learned in one discipline generally have relevance in others.

In many institutions, a single REB is responsible for evaluating projects funded by the different Councils. In other institutions, there are unified appeal mechanisms for multiple REBs

that deal with different types of research. In general, the ethical issues that REBs must address in evaluating research projects in diverse fields are more likely to be similar than dissimilar. Accordingly, REBs will benefit from having a uniform set of procedures and a common mandate. Similarly, for those projects involving researchers within different disciplines or institutions, and for partnerships between the Councils, other organizations, and private sponsors, a single Code will harmonize the ethics review process. A single Code also will harmonize continuing ethics education for researchers and for those in training to become researchers.

### **C. MAJOR CHALLENGES IN DEVELOPING A SINGLE CODE**

The first major challenge is to avoid imposing one disciplinary perspective on scholars in other fields while at the same time express the shared wisdom of researchers in diverse fields on the ethics of research involving humans. This Code is designed to leave enough flexibility for researchers and REBs to take into consideration and accommodate the needs of specialized research disciplines.

The second major challenge is in addressing multiple audiences. Previous guidelines largely have been viewed primarily as directed toward REBs and only directed secondarily to researchers. This Code emphasizes the educative and supportive role of REBs in addition to their regulatory role. This Code is also addressed to **research institutions** and research sponsors.

The third major challenge is to reflect and encourage among diverse groups a thoughtful consensus around ethical issues. The approach to informed choice in most research involving humans is an important instance of such consensus (Section I). In other areas, concepts that have evolved over the last 10 years require the elucidation and application of new standards, for example, issues around inclusiveness in research (Section VI) and research involving collectivities (Section VII). Still, in other research areas, there are major issues that need to be resolved and ethical standards that need to be formed. In human genetics (Section VIII), for example, and in research involving embryos and fetuses and new reproductive technologies (Section IX), the rapidly developing ethical questions and issues of research involving humans are so numerous and profound that there is no consensus on how these issues should be resolved. The Councils would be derelict in their duties if they provided no moral direction in these areas.

The fourth major challenge is in developing a common language for the ethics of research involving humans. Not only are there diverse disciplinary perspectives and methodologies, each often with its own vocabulary, but the choice of vocabulary often implies taking a substantive moral position. For example, the term research participant has been used in place of the term research subject because the latter term suggests passivity, submission, and an absence of moral agency. Similarly, the broader reaching idea of scholarly standards has been used instead of scientific validity. This was done to recognize diverse standards of research and scholarship across the many disciplines that conduct research involving humans.

### **D. RESEARCH REQUIRING ETHICS REVIEW**

All research involving humans as research participants requires ethics review. **Research** involves the systematic investigation to establish facts, principles or generalizable knowledge.<sup>1</sup> In general, **research participants** are living individuals or groups of living individuals about whom a

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<sup>1</sup> South African Medical Research Council, Guidelines on Ethics for Medical Research, Revised edition, 1993.

scholar conducting research obtains (1) data through intervention or interaction with the individual or group, or (2) identifiable private information.<sup>1</sup> There are also some special provisions when research involves collectivities (see Section VII). In addition, research involving humans includes the use of human remains or cadavers, embryos, fetuses, tissues or biological fluids.<sup>2</sup>

While research involving humans requires ethics review, it is essential to recognize that some research about humans does not involve them as research participants. It does not follow that because individuals or collectivities are the subjects of research they are also research subjects. Thus, research involving information in the public domain or archival data are not subject to REB review (Article 3.1). This can be contrasted with a situation in which the researcher interviews individuals or seeks access to their personal records. In certain situations, there may be ambiguity as to whether a particular project counts as research involving humans. For instance, it may be unclear if a particular case of innovative therapy or **quality assurance** is research even though it involves humans as participants. In such cases, the opinion of the REB should be sought concerning the need for formal review.

An REB may be asked to do ethics review of various innovative therapies, procedures, devices, and biological agents being submitted to a government agency for regulatory review. Similarly, there may be a request for an REB to review the ethics of a project that is purely a matter of quality assessment. While research institutions may well ask REBs to perform such additional, albeit important, tasks, it is important that REBs use appropriate standards and expertise for assessing such proposals and not treat them as if they were research proposals subject to the same requirements of advancing knowledge.

## **E. RESEARCH AS A PROCESS**

The responsibilities of various players in research fall into six stages.

The first stage occurs in the planning of the research project. The onus in this stage falls primarily on researchers who are responsible for the consequences of their research (whether positive or negative) for all people who will be affected by it (see Ethical Framework). Because research is a complex social phenomenon, researchers, research funders, and institutions have major responsibilities in the planning stage.

The second stage involves assessment of the quality of research. It is important that institutions involved in research (e.g., universities, hospitals, and private enterprise) ensure the scholarly standards of the work. Such assessment requires specialized expertise. In various ways, responsibility for this stage is shared among the researchers, the institution, and the research sponsors.

The third stage is the ethical scrutiny of research procedures to protect the research participants who are taking the concrete risks. This scrutiny is undertaken by REBs. It is essential that the parent institution guarantee the independence of REBs and provide sufficient resources for their regulative and educational activities.

The fourth stage has to do with the informed choice process. The researcher and other members of the team have an essential role to play in the process by which the consent of prospective participants or their representatives is ascertained. The quality of the information given,

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<sup>1</sup> United States Department of Health and Human Services, Office for Protection of Research Risks (OPRR): Protecting Human Research Subjects : Institutional Review Board Guidebook, Washington, 1993.

<sup>2</sup> National Research Council Canada (NRC), Research Involving Human Subjects: Guidelines for Institutes, Ottawa, March 1995.

the absence of coercion, and the provision of time for reflection and consultation with relatives, where appropriate, all enable individuals to make informed and voluntary choices regarding participation.

The fifth stage has to do with carrying out the research. The informed choice process continues and the REB may require monitoring of the entire research process.

The sixth stage occurs when the active involvement of the research participants has been completed. It involves publication and dissemination of results and, in some cases, dealing with the effects of the research on the participants (e.g., counselling, continued treatment, and debriefing).

All research must meet ethical standards, regardless of where it is conducted and who is funding it. Hence, researchers, research institutions, and sponsors have responsibilities to society for the performance of research. These collective responsibilities can be partitioned in at least two ways: into stages of the research process and among the various players in research.

## **F. ACCOUNTABILITY TO THE COUNCILS**

The Councils have adopted this Code as the standard of research ethics for the conduct of research involving humans. The Councils require that funded researchers and their institutions comply with the spirit of the ethical principles expressed in this Code and comply strictly with the Articles of this Code. The Councils have the right to review or audit research which they fund and to withdraw financial support.

## **G. FUTURE REVISIONS OF THE CODE**

The Councils recognize that this Code will require continuing review and modification in light of the ongoing experience of researchers, REBs, and institutions. As new knowledge emerges, it too will have an impact on the ethics of research conducted by Canadians which will require timely amendments and additions to the Code.

# CONTEXT

In research involving humans, researchers, their sponsors, research participants, and society pursue various goals which may include the production of goods and techniques to meet concretely defined needs (e.g., life-saving pharmaceuticals or more ergonomically designed technologies) or a better understanding of the human condition or the history of various communities. The research disciplines involved in producing these results are extremely wide, ranging from anatomy to anthropology, engineering to sociology, history to philosophy, and commerce to literature. Canadian researchers can take pride in having produced benefits for research participants and society, and in having advanced our knowledge of humans.

## **A. THE CURRENT CONTEXT OF RESEARCH**

Significant and rapid changes have occurred across the broad range of research disciplines. New insights, methods, and paradigms have emerged, sometimes bringing with them controversy, uncertainty, and challenges to predominant perspectives. More than ever, Canadian research is affected by many internal and external forces including the development of new research tools, a changing work environment, and economic pressures.

New research tools, from the computer to the analysis of DNA, carry with them their own imperatives. For example, data banks that contain identifying genetic, psychological, social or financial information can help researchers gain major insights into human behaviour, but can also threaten privacy. These new tools create an impetus towards greater specialization as well as a contrary thrust towards a more integrated understanding of the connections among diverse domains of knowledge.

In many areas, research has shifted from individuals working alone in libraries or laboratories to multidisciplinary team endeavours, often with members of the team located in multiple centres across the country or around the world. Moreover, research is increasingly taking place outside institutions of higher learning in industry, public sector, and community-based agencies. This raises major ethical questions about the appropriate beneficiaries of research, in particular, around questions of ownership and commercialization.

Economic factors exert a significant impact on Canadian research. Researchers work under the pressure of rising costs and shrinking research budgets. Further complications are added when the research project involves human participation, for, in addition to their role-defined perspectives, researchers must also pay close attention to the participants' perspectives and to social concerns about the justification of research.

## **B. THE RESEARCHER'S RESPONSIBILITIES**

Researchers have certain responsibilities, of which the paramount one is the advancement of knowledge imposes the duties of honest and thoughtful enquiry, rigorous critical and responsible analysis of established ideas, and the need for respect to their discipline and for accountability to their colleagues, students, and research institutions, as well as to the society that supports them. To secure the maximal benefits from research, society needs to allow researchers certain freedoms which they must not abuse. These freedoms include the freedom to challenge mainstream thought in the areas in which they are competent. These duties and freedoms are, and must be, open

continually to critical assessment and debate; these freedoms can never be taken for granted. Central to these debates are questions about what counts as "good" research in two senses, high quality research and ethical research. These two questions are at the centre of this Code.

Researchers, research institutions, and sponsors have established accountability relationships for the conduct of research. All research, whether funded or not, is submitted for peer review. Some research proposals are submitted to sponsors, including the Councils, for peer review. Thus, in a variety of formal and informal ways, colleagues and the general public are encouraged to discuss and evaluate a researcher's findings and results.

In order to have a balanced perspective, it is essential for researchers to move beyond their own perspectives to see how their work affects research participants, that is, to see things from the point of view of research participants.

### **C. THE RESEARCH PARTICIPANT'S PERSPECTIVE**

Not all individuals will experience research interventions in the same way; therefore, it is important to appreciate the range of research endeavours in which individuals are involved and the diversity of participants. For example, politicians being interviewed by historians about their roles in constitutional talks are not in the same position as survivors of abuse in a residential school being interviewed by counselling psychologists. Nor are participants in high risk Phase I drug trials in the same position as commerce students involved in research on co-operative versus non-co-operative behaviour in answering questionnaires.

Individuals may be involved as research participants simply because private information is sought about them in a variety of ways, such as observation, interviews, surveys, and tests. Information may be sought about attitudes, habits, life stories or values. Such research is a matter for ethical consideration because it touches on the private lives of individuals, their standing in social groups or on the functioning of entire communities; indeed, it can even affect the sense of identity of an individual or group.

Individuals may also be involved both physically and behaviourally as research participants. Once again, different methods are used, such as clinical trials, laboratory tests, behavioural interventions or samples taken, each of them entailing, to varying degrees, observation and physical, chemical, sociological or psychological interventions. In such research, the whole person is often implicated, mind and body, that is, their integrity or wholeness as a person. As well, their involvement may have significant implications for families, friends, associates, groups, and communities. Special cases arise when participants are ill, distraught, confused, or under pressure, and are thus vulnerable. Because of potential harms, not only to health and life but also to psychological and social stability, there must be a careful ethical evaluation of benefits and harms for prospective research participants that run parallel to their hopes and fears.

In an ethically sensitive approach to research involving humans, a central question to ask is, "What are the hopes and fears of prospective research participants?"

Prospective participants have a variety of hopes. To some, the benefit of research is a longer, more productive life or an improved environment. A terminally ill cancer patient, for example, may hope for a cure when given an experimental drug; a lonely person in a long-term care facility may seek friendship when participating in a research project on psychological welfare; a community may desire special help in dealing with difficult law enforcement problems; or

individuals participating in a genetic study may hope to benefit other members of their family or their descendants. There may just be the altruistic hope that through one's participation in research one will have contributed to the good of others.

Two points should be mentioned about these hopes. The first is that there be at least the implicit promise that the research will be beneficial either for the research participants themselves or others, or for the advancement of knowledge. It is important that researchers be aware of and honour whatever explicit or implicit commitments have been made to prospective participants and only promise what they can realistically deliver. Researchers have a responsibility to encourage only realistic expectations on the part of prospective or actual participants. In part, this is a matter of the researcher candidly providing participants with accurate and understandable information.

The second is the recognition that in many cases prospective participants are more strongly motivated by their trust in the researchers than by the cool and careful assessment of the pros and cons of research participation.<sup>1</sup> This is especially likely when the researcher has a beneficial or professional relationship with prospective participants, for example, as their caregiver or educator, or is operating within an institutional context where benefits are commonly provided to clients, for example, a hospital, school or legal aid office.

Research participants may have fears of physical and psychological pain and perhaps of irreversible injury. They may be afraid of losing their freedom or self-control. They also may fear humiliation as individuals or as members of a group or collectivity. In brief, research participants may fear dehumanization.

There are a variety of reasons for these fears. There have been well-known instances in which researchers have abused participants — particularly vulnerable populations including children, restricted or dependent populations, patients, and adults lacking competence. In some cases, this abuse was deliberate, in others, it was much more a matter of negligence. At times, researchers have been so involved with their methodologies and the desire to produce significant research results that they have paid insufficient attention to the legitimate concerns of participants.

Just as some of the hopes of prospective participants may be unrealistic and exaggerated, so too may some of their fears. Even with unrealistic or exaggerated fears, it is important for researchers to try to anticipate and, insofar as is realistically possible, sincerely attempt to allay these concerns, especially with vulnerable populations.

#### **D. THE BENEFITS OF RESEARCH**

Research can be justified in terms of three general categories of benefits: for the participant, the group, and the acquisition of new knowledge.

First, benefits for research participants can include improved treatments for illnesses, a better understanding of oneself as an individual or as a member of a group, insight into motivations, behaviour or cognitive abilities, the discovery of information vital to one's welfare, altruistic satisfaction, and knowledge of the process of research.

Second, benefits for the group be it society as a whole (the common good), a particular group within society, or other individuals, include epidemiological information about the incidence of a contagious disease that may lead to improved public health efforts or sociological or

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<sup>1</sup> Kass, Nancy E. et al., "Trust: the fragile foundation of contemporary biomedical research", *Hastings Center Report* 26, 5 (Sept.-Oct. 1996) pp. 25-29.

psychological information about lifestyles that may result in social reform. As well, insights into political and economic behaviour can produce new legislation and greater efficiencies in the production of goods and services.

Third, research involving humans may be justified in terms of the acquisition of knowledge for its own sake. In other words, satisfaction of the basic human desire to understand the world and the place of human beings in it is a good reason for research.

Parallel to these three categories of research benefits are possible research harms to individuals, society, and to the advancement of knowledge. The achievement of these three types of benefits and the avoidance of the three types of harm can be used to justify and describe the role of researchers conducting research involving humans. Central to this role is the researcher's responsibility for the advancement of knowledge about humans. For it is only through such advancement that there will be benefits for society as a whole and, at least in some instances, direct benefits for research participants.

## **E. THE MORAL IMPERATIVE**

So far three general categories of benefits have been identified which can be brought together by addressing two questions:

- How is research involving humans ethically justified?
- What are the ethical limits for research involving humans?

These questions must be viewed in light of the changing context of research described above and ethical principles must be useful in actual, not rare or idealized, research environments.

An ethic of research involving humans as individuals or as members of groups must include two essential components: one is concerned with the selection and achievement of morally acceptable ends, and the other, with the means to those ends. The first component is directed at securing the benefits of research outlined earlier, namely, benefits for the participants themselves, benefits for the group, and the benefit of advancing knowledge. Therefore, one set of ethical criteria for research involving humans is described in terms of achieving these worthy benefits. But this in itself is not enough, for it might involve treating participants as a mere means to these ends, (e.g., when the participant's choice is ignored or distorted by misinformation, manipulation, fraud or force). Hence, there also needs to be a comparable focus on the second component, namely, an ethically appropriate means of conducting research.

It is ethically indispensable for researchers to bring together their legitimate and laudable concerns for producing the benefits of research with a concern and commitment to the autonomy and other rights of research participants. Put another way, how can Kant's moral imperative — "act in such a way that you always treat humanity, whether in your own person or in the person of any other, never simply as a means but always at the same time as an end" — be translated into concrete measures? It is morally unacceptable to treat other persons as a means (mere objects or things), and by so doing, not respect their human dignity.

It must be emphasized that **respect for persons** is respect for real life individuals, socially and historically situated, and not the idealized, abstracted, and decontextualized rational beings posited in various theories (e.g., the ideally rational agent, the egoistic consumer or the compliant patient). This means that respect must be shown for people as they identify themselves both as

individuals and as members of groups. Factors such as race and gender, membership in a collectivity, and personal and social relationships can all have implications for the ethics of research involving humans.

In this context, the notion of "respect" should not be confused with that of "admiration" or "endorsement." The moral imperative of respect for persons is quite consistent with the researcher maintaining an independent and even critical perspective on the activities and motivations of research participants. What is not morally permissible is ignoring or disregarding the research participant as a person, for example, by taking private data without permission or tricking a person into participating on the basis of a false promise of benefits. Respect for persons involves treating people in accord with basic ethical principles. It is essential to develop an ethical framework for research involving humans which provides the benefits of research, is aligned with the significant responsibilities that researchers have assumed in this regard, and pays heed to the legitimate expectations of research participants.

## AN ETHICAL FRAMEWORK

In the context of research involving humans, the ethical principle of respect for persons has a very important implication, namely, that research participants should be regarded as partners in research. Since neither the researcher nor society at large has a right to require that individuals or groups participate in research projects, participants must be treated as volunteers, not conscripts in the cause of research, otherwise participants will not be shown the respect they deserve.

Informed choice is central in this Code (see Section I). Prospective research participants or their representatives (**authorized third parties**) must have the information they need to make an informed choice. They also must be in a situation in which their choices are voluntary and not affected by threat, coercion, manipulation, or undue inducement. The term informed choice has been used, in most instances rather than that of informed consent to signal that prospective participants have a choice as to whether or not to participate. Thus, consent on the part of the prospective participant is an acceptable choice, but so equally is refusal. Only on the basis of an informed choice to participate may research proceed. Even then the researcher and the REB must make an independent judgement of the harms, benefits, and general appropriateness of the criteria for participation.

Since some research participants are vulnerable, especially in terms of the inability to make informed or voluntary choices, it is important for researchers to reflect upon the relationships they have with participants. Thus, when **immature children** are research participants, researchers and REBs should appreciate that they have a trust or fiduciary relationship not only with the children but also with their parents and guardians. Researchers and REBs have a responsibility to make an independent assessment of the appropriateness of research participation for prospective participants who are incompetent or who are unable to act voluntarily. As noted above, researchers involved in a care relationship with participants must be careful to live up to the explicit or implicit commitments made to them as patients, clients, students, and the like.

### A. THE INTERFACE OF PRINCIPLES AND PROCEDURES

This Code has two essential elements: one contains substantive guidance on ethical issues in research involving humans, namely the articulation of fundamental principles — including values, rules, and ideals — to guide the conduct of researchers; and the other element provides procedures designed to implement the fundamental principles articulated in the first part of the framework and to establish accountability relationships. Having substantive guidance in terms of principles, values, rules, and ideals without adequate procedures would simply be empty rhetoric. Conversely, setting up procedures without enunciating basic principles and goals would leave both researchers and research participants without clear direction, rights or responsibilities.

The needed congruence between principles and procedures in the vast majority of countries that contribute significantly to research involving humans is achieved by processes of ethics review and approval of research projects before they are permitted to start. For many years, in Canada as in most leading research countries, this review has been carried out by committees working within research institutions. Section II of this Code sets out the rules governing REB, which are designed to bring about implementation of the ethical principles that are the concern of the remaining Sections. For example, an REB must have a membership that is knowledgeable in distinct areas, such as potential benefits and harms of research or the role of the researcher. It is important that

there be people of judgement on the REB, firmly committed to sound ethical principles, who have the moral courage to act on their collective convictions. If the REB is to have credibility in the many sectors that are concerned with research involving humans, it must act and be perceived to act in a fair, unbiased, and reasonable manner. Moreover, the REB and its members must avoid conflicts of interest (see Section IV). At the same time, the REB has an educational role to assist researchers in meeting the ethical challenges in their research. So in their regulatory and educational roles, REBs will put into practice the general principles provided in this Part and in the rest of this Code.

## **B. FOUR BASIC PRINCIPLES**

The approach taken in this ethical framework is to guide and evoke thoughtful actions based on principles rather than to lay down rules. **Rules** definitively determine what is to be done and can often be mechanically applied. By contrast, a **principle** is a consideration that should be taken into account when making a decision but may itself not be decisive in the circumstances. As well, more than one principle may apply to a specific case, and principles may point towards opposite actions; for example, the principle of beneficence may conflict with the principle of non-maleficence. In their best uses, principles serve as short-hand reminders to researchers and REBs of more complex and context-specific moral knowledge.

The four principles that follow are based on the Belmont Report<sup>1</sup> and Beauchamp and Childress' Principles of Biomedical Ethics<sup>2</sup>. They are cited here because they have been widely adopted in many research communities. However, many individuals knowledgeable in ethics are critical of approach. They have argued that principles can be used in formulaic ways as a mantra which discourage rather than encourage thoughtful reflection and action. Accordingly, a number of alternative approaches to ethics afterwards.

The first basic principle is **respect for persons**. This has two fundamental aspects: first, there must be respect for the **autonomy** of those individuals or groups who are capable of making informed choices and for their capacity for self-determination; second, there must be protection of persons with impaired or diminished autonomy, that is, those who are incompetent or whose voluntariness is seriously compromised. Those who are dependent or vulnerable must be protected against abuse.

The second basic principle is **non-maleficence**, or do no harm to others. Here, harm is understood in terms of wrongfully injuring, whether deliberately or negligently. Sometimes this principle is best understood as an absolute prohibition of certain types of inhumane treatment. For example, the notion of non-maleficence is expressed in various human rights provisions, such as those forbidding torture, genocide, and the exploitation of vulnerable groups in research (e.g., prisoners, children or the incompetent). As well, certain types of research (e.g., germline genetic alteration) may be prohibited provisionally (see Section VIII) because they currently lack in sufficient information to adequately assess future consequences. Usually, however, the principle of non-maleficence is interpreted in light of the principle of autonomy and in terms of the threshold for normally acceptable risk (see below).

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<sup>1</sup> The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, OPRR Reports", April 18, 1979.

<sup>2</sup> Tom L. Beauchamp and James F. Childress, "Principles of Biomedical Ethics", New York: Oxford University Press, 1979; Fourth Edition, 1994.

Autonomous individuals or groups are able to waive their rights not to be harmed, usually to increase the probability of benefits for themselves or for others. However, there is generally thought to be significant ethical limits as to how much harm individuals may freely assume. In some circumstances, not harming can be extended to an obligation to prevent, and even remove, harms caused by others. Still, this principle has a negative or prohibitive moral flavour, which is directed against actions that harm or injure people, or violate fundamental rights.

The third basic principle is **beneficence**, or doing good to others, which, in contrast to non-maleficence, moves into the positive category of providing benefits to others. This concept has particular relevance for researchers in service professions such as social work, education, health care, and clinical psychology. But as noted earlier, three types of benefits were advanced as legitimating goals of research involving humans: benefits for participants themselves, benefits for society, and the advancement of knowledge. In most research, the primary benefits produced are for society and for the advancement of knowledge rather than for the participants themselves.

The fourth basic principle is **justice**, one criterion of which is fairness in the distribution of benefits and burdens. This concept should alert researchers to questions of distributive justice and has particular relevance in cases where groups of individuals (in particular, women and minority group members) have been excluded from research studies, much to their detriment. Justice also is particularly relevant for dealing with individuals or groups that are vulnerable and are unable to sufficiently protect their own interests and, as a result, are open to exploitation or neglect (e.g., infants and immature children, marginalized groups, and prisoners - see Section VI).

It is important to understand that these ethical principles do not exist in isolation from each other. Furthermore, good judgement and sensitivity are required to decide the extent, degree, and context for the application of potentially conflicting principles. An awareness of such potential conflicts can lead to the development of useful strategies to minimize them. For example, in genetic research, there may be a conflict between the principles of beneficence and justice. Doing good for particular individuals by, say, providing a genetic diagnosis may well have adverse effects on the rights of other family members who do not wish to receive information about their own genetic predisposition. Genetic counselling is a strategy that might be used to reduce these tensions (see Section VIII).

### **C. OTHER APPROACHES**

Besides the four basic principles discussed, there are other ways of approaching the ethics of research involving humans. In common, each requires respect for persons, regardless of their social or economic status, physical or mental condition, ethnicity, race or culture, or even their individual moral merits.

One alternative ethical approach is through thoughtful reflection on the moral virtues that a good researcher would possess and exhibit, for example, an ethic of care which involves an empathetic understanding of the hopes and fears of prospective research participants. Other virtues would include candour, compassion, prudence, fairness, and courage. Ethical action requires balance and judiciousness. Candour can degenerate into insensitivity, compassion into unfairness, courage into folly, and so on. A keen understanding of the context of one's actions is indispensable in exercising moral virtues or using ethical principles to guide choices.

Another approach that researchers and REBs will find helpful is in terms of reflecting on relationships of power and socially structured allocations of privilege and status. Feminist

researchers and ethicists have been concerned with such relationships and the ways in which they perpetuate disadvantage and inequality. This type of approach to ethics can be extremely illuminating in examining the diverse research agendas of various parties and in dealing with prospective participants who have been systematically disadvantaged.

Alternatively, communitarian approaches to ethics have examined how individuals participate in and identify with their communities and groups. This approach has emphasized qualities implicit in social roles and relationships including, for example, the role of a researcher standing in relation to research participants.

Researchers also have a responsibility to research participants, their institutions, and sponsors to ensure the integrity of their research. This refers not only to scholarly integrity<sup>1</sup> but also to the integrity or, literally, the wholeness of the research itself. In presenting oneself as a researcher who seeks the involvement or participation of prospective participants to carry the research to a successful conclusion, one has made an implicit promise regarding the quality of the research and its general benefits. Researchers must endeavour to live up to this promise.

There is literature in Canada on the ethics of research involving humans which can be readily accessed. The National Council on Bioethics in Human Research in Canada, like similar organizations in other countries, has been working to bring REBs together to discuss experiences. The law provides an essential foundation for all activities in this area, and the relevant legal requirements must be incorporated into these ethical decisions.

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<sup>1</sup> Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, Integrity in Research and Scholarship: A Tri-Council Policy Statement, Ottawa, 1994.

# CENTRAL CONSIDERATIONS FOR RESEARCHERS AND REBS

With a partnership perspective in mind, it is useful to look at three important considerations which should be central for both researchers and REBs.

- harms and benefits for research participants;
- social harms and benefits; and
- advancement of knowledge.

These considerations are listed in the order given in the list of benefits presented earlier in this Part. Some REBs may well apply these considerations in a different order.

## A. HARMS AND BENEFITS FOR RESEARCH PARTICIPANTS

To accurately evaluate the ethics of a particular research proposal, it is essential to examine how the research will affect the lives of prospective participants; therefore, it is essential to take a **participant-centred perspective**. In some cases, the researcher and the participant may not see the harms and benefits of a particular research project in the same way. For example, in medical or psychological research, the researcher may be focussed on specific physical or behavioural outcomes and fail to take into account what these mean for research participants. In such cases, it is possible to overlook or minimize the participant's fear, anxiety, and concern (e.g., at questions probing areas central to the research participant's self-esteem).

The researcher also may overlook a variety of economic and other costs that may be imposed on the participant: time lost, transportation and child-care expenses, fear of loss of reputation (e.g., in research that probes areas that are socially stigmatized). By concentrating solely on tangible losses, researchers may miss matters that have symbolic, religious or cultural value for research participants. REBs can help researchers recognize the less obvious harms and benefits in their research work.

It is important not to over-generalize about what is likely to be an acceptable risk of harms for prospective participants. For example, in the case of an experimental cancer treatment, the risk of a scar or hair loss may feel like a great violation to an adolescent whose self-image is developing; such hair loss may be perceived less seriously by an elderly male, since it is a usual and progressive phenomenon of ageing for males. Similarly, the inability to respond quickly in a memory task may threaten self-esteem in the elderly by producing feelings of humiliation and anxiety, in which case appropriate explanations may be helpful in mitigating these feelings. Still, some research barely touches the lives of research participants (e.g., the use of anonymous data - see Section III). In such cases, a more generic judgement may be substituted for one focussing on specific individualized concerns. This requires careful attention to reliable quantitative and qualitative information in similar research populations.

Accordingly, REBs should take a **proportionate approach to ethics assessment** in which the general principle is that the more significant the potential impact on the participants' lives, the greater the care in assessing the research.

Potential **harms** are usually understood in terms of **risks**, where risks are defined in terms of the magnitude of a harm and the probability of its occurrence. A similar reading is commonly given to benefits. However, these definitions miss a feature of harms and benefits that is often of crucial importance for research participants, namely, the character of the harms and benefits in question. Thus, whether a harm or benefit is voluntarily accepted, or voluntarily or involuntarily imposed, is a matter of considerable importance to most participants. Even though two harms may be evaluated by the researcher as having the same magnitude and probability when measured on a standard scale (e.g., morbidity or mortality), one type of harm may be seen by the participant as far more significant than the other (e.g., cancer versus accidental injury). The same applies to types of benefits. Behind this heightened concern about some harms and benefits may lie important individual and cultural differences. A proper assessment of harms and benefits requires consideration of three factors: the magnitude, the probability, and the character of the harms and benefits of the research for participants.

In considering these three factors, it is important for researchers and REBs to establish an appropriate **threshold for normally acceptable risk**. Such a threshold can be established by the following standard: when the possible harms (e.g., physical, psychological, social, and economic) implied by participation in the research are within the range encountered by the participant in everyday life, then the research should be taken to fall within the range of normally acceptable risk. Above that, the research warrants a higher degree of scrutiny by REBs and greater provision for the protection of prospective participants' interests.

There is a similar threshold regarding what counts as undue or excessive offers of benefit. As an offer of a benefit (e.g., offer of payment for research participation) exceeds the normal range of benefits open to the research participant, it is increasingly likely to amount to an undue incentive for participation.

Below the threshold level, the primary focus of REB concern is with the informed choice of prospective participants or authorized third parties. If this threshold is exceeded, greater attention must be paid to mitigating the harms and ensuring that there are no undue inducements for research participation and, that the research will be monitored more stringently. As this threshold is exceeded, more attention must be focussed on questions about whether the scholarly quality of the work and the overall value or benefits of the research outweigh potential harms to research participants.

Behind the idea of a threshold for normally acceptable risk lies the following insight. Prospective participants who are well-informed about the magnitude, probability, and character of the risks of research participation will likely be willing to accept risks if they are within the risks of normal life because they would be no worse off taking part in the research than in not taking part. Of course, the standard for judgement about the threshold has to be the view of prospective participants and not the view of third parties, including the researcher or members of the REB. For example, exposure to sexually explicit materials would not cause psychological distress to many Canadian adults, but might do so for individuals in particular cultural or religious groups.

In cases in which the everyday lives of prospective participants are already filled with risk, the test for a threshold for normally acceptable risk must be applied with caution. For example, while it may be true that prisoners in a maximum security institution may be no worse off participating in a research project than in remaining in their cells, there might be in this high risk environment undue inducements to participate. Similarly, parents of very sick children may grasp at any research alternative that offers even the remotest chance of life-saving treatment, even though

this may be a highly debatable option from the perspective of the children's best interests. Special care must be taken not to exploit the vulnerability of both parents and children in such situations.

Finally, appropriate care in research involves a process of communication with research participants about potentially harmful and beneficial aspects of the research. Part of this process is the timely disclosure of harms and benefits revealed during the course of research. Only with such open communication will it be possible for individuals to make informed choices with regard to initiating and continuing research participation and for researchers and REBs to maintain the confidence of the general public.

## **B. SOCIAL HARMS AND BENEFITS**

Research that has no realistic possibility of producing social benefits commensurate to the overall burdens of the research for all parties concerned should raise serious ethical concerns. However, in examining questions of the overall social value of research, the role of the REB is relatively limited. It is not the REB's role to decide whether the research is the best possible use of research funds. Peer reviewers and sponsors may well be in a better position than researchers to judge the likely contributions of the research to the social good. Nonetheless, the REB should assure itself that there is enough likelihood of sufficient overall value from the research to outweigh any harms to research participants. This becomes especially significant when research risks exceed the threshold for normally acceptable risk.

In recent years, one area of social benefit that has deservedly received increased attention has been the inequitable distribution of the benefits of research to various groups, whether defined by gender, age, illness or social status. If members of particular groups (e.g., women, the elderly or immature children) are excluded as research participants, or are seriously under-represented, then it is quite likely that these groups will not only fail to reap the benefits of such research, but they may also suffer from the misapplication of outcomes of such research to their unique situations.

## **C. SCHOLARLY STANDARDS IN THE PURSUIT OF KNOWLEDGE**

Research has been defined as systematic investigation to establish facts, principles or generalizable knowledge. As noted earlier, **peer review** plays an essential part in this process. Part of the role of the peer reviewers is to apply the **scholarly standards** appropriate to the discipline or research area in question. Peer reviewers also typically examine the research for originality, insight, and contribution to knowledge. Peer review can take place at various times during the research process. Thus, it may occur when a research proposal is submitted for funding to one of the Councils or to another research sponsor. It typically also occurs when research findings are submitted for publication. Researchers themselves are subject to peer review processes when they are appointed and periodically reviewed. Although all research disciplines supported by the Councils use rigorous peer review processes, they do this in different ways and often at different times using the scholarly standards of the particular disciplines. In particular, review of research proposals prior to research taking place is common in disciplines where research is submitted for external funding. In other areas, for example, unfunded research in the humanities and social sciences, the emphasis is more on peer review at the publication stage.

There is general agreement in the research community that, when the proposed research is likely to go beyond the threshold for normally acceptable risk, the REB should be especially

concerned about whether the research advances knowledge. In some disciplines, particularly those that appeal to standards of scientific validity, there is the strong belief that all research should be assessed for meeting scholarly standards even when it poses less than the threshold for normally acceptable risk to participants. In other disciplines, particularly those where there is more pluralism in regarding scholarly perspectives, there is an equally strong conviction that REBs should refrain from assessing the scholarship of research within the range of normally acceptable risk.

There are complex reasons for these differences — in part, resulting from different scholarly paradigms, and in part resulting from different experiences with REBs. For example, REBs in health sciences have tended to be more active and interventionist than REBs in other areas. Whatever the reasons, the position taken in this Code allows two different procedures regarding the assessment of research for scholarship. Some REBs will continue to scrutinize all research, including research posing less than the threshold for normally acceptable risk for scholarship; others will reserve this scrutiny for research above the threshold for normally acceptable risk. It will be important for REBs to clearly communicate to researchers the approach they are taking. This will be especially important in assessing interdisciplinary research initiatives such as health care ethics research or health promotion research. With time and experience, there may well develop a broad consensus among Canadian researchers on this issue. In the interim, there should be mutual tolerance and acceptance of disciplinary diversity.

It is essential for REBs to recognize that disciplines have different scholarly standards. While the notion of scientific validity is the standard in many health science disciplines, engineering, and parts of the social sciences, it would be erroneous to describe this as the paradigm for other types of research. Thus, it would be inappropriate to use a scientific validity standard for assessing many research proposals in the social sciences, history, or in applied ethics. It is also essential then for REBs that assess many different types of research to resist the temptation to impose a monolithic model of scholarly standards on researchers.

Beyond this, it is important to realize that, in many disciplines, challenges to paradigms are a legitimate aspect of research. Indeed, a plurality of research paradigms is essential to a dynamic research discipline. It also should be remembered that in all fields there has been ground breaking research that completely overturned previously prevailing orthodoxies.

Research that falls below minimum scholarly standards may waste valuable resources (whether public or private), damage the overall credibility of research in general, and place research participants at risk. Involving participants in research that is known to be substandard, even if it poses little or no risk to them, is inconsiderate and may even be misleading. This is not to say that researchers or those who evaluate the scholarly standards of the research or its ethics can anticipate all potential problems in the area of research scholarship. Insofar as REBs evaluate research projects for scholarship, they should generally rely on the judgement of others by ensuring that an adequate peer review has been conducted. Insofar as REBs undertake the assessment of the scholarly aspects of the proposed research, it is absolutely essential that there be appropriate experts on, or added to, the REB for the purposes of reviewing the particular proposal.

It is also essential for members of REBs to have an adequate understanding of the major elements of a research proposal since some of these elements may be indicative of potential ethical issues. Thus, an REB should understand the purpose of the research. For example, is the aim of a particular project to assess the educational value of new learning software, or is the assessment mainly a device for product promotion? An REB also has to be knowledgeable about the type of research in question. For example, in a clinical trial, it is essential to ask if the appropriate

comparison is no therapy at all (including the use of a placebo - see Section V) or a generally recognized and efficacious non-experimental treatment (that is, the REB must know what is standard efficacious care).

Knowledge of the principal methods used in the research can alert REB members to ethically sensitive issues like deception and partial disclosure. With some types of research, it is appropriate to ask if the use of human participants is premature. Could the research be done using computer models or cell systems rather than risking the safety or privacy of human participants? Alternatively, could less vulnerable persons be used in the research (e.g., adults rather than immature children)? Are there already existing populations in the condition being studied (e.g., with a virus) so that the recruitment of additional research participants (e.g., to give them the same virus) would needlessly place them at risk? Understanding the criteria of inclusion and exclusion can help an REB identify issues of injustice, discrimination or exploitation.

#### **D. CONCLUSION**

In this Part, the aim has been to provide a review of the context of research and establish a framework for the ethics of research involving humans. The considerations and principles set out underlie the specific procedural and substantive rules advanced in the following Sections and provide the framework within which those rules should be interpreted and applied.

In understanding this Code, the following should be kept in mind: good **ethical reasoning**, like good reasoning in research, must be more than a matter of the mechanical and dogmatic application of rigid rules to fact situations. Ethical reasoning requires thought, insight, and sensitivity. As in research, peer judgement is important. In the case of ethics, peers include more than fellow researchers. Ethics peers include the larger intellectual community and society at large, including research participants. Securing the approval of an REB should be the occasion for more than simply jumping through another bureaucratic hoop. It should be an opportunity for informed, ethical reflection, and discussion with ethics peers.

With the ethics of human research, there is more at stake than the approval of particular research projects — there is the well-being and self-esteem of research participants, the trustworthiness of the research community, and the moral integrity of the researchers themselves.