GOALS OF THE POLICY

This *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) describes standards and procedures for governing research involving human subjects.

A. Mandate of the Agencies

The people of Canada, through Acts of Parliament,¹ have created and funded CIHR, NSERC and SSHRC to promote, assist and undertake research in the domains indicated by their names. In discharging our mandates, the Agencies wish to promote research that is conducted according to the highest ethical standards. The Agencies have therefore adopted this Policy as our standard of ethical conduct for research involving human subjects. As a condition of funding, we require, as a minimum, that researchers and their institutions apply the ethical principles and the articles of this Policy.

B. Goals and Rationale of the Policy

The interests of the Agencies in promoting ethical research, combined with the evolving needs of the research community, have led us to define a common policy of ethical conduct for research involving human subjects. This Policy seeks to respond to, and address, several needs:

- 1. The Policy addresses the interdependent duties to research subjects, which are shared by researchers, institutions and Research Ethics Boards (REBs).
- 2. By addressing common issues and needs, the Policy seeks to articulate ethical norms that transcend disciplinary boundaries. The fundamental ethical issues and principles in research involving human subjects are common across the social sciences and humanities, the natural sciences and engineering, and the health sciences. They reflect shared fundamental values that are expressed in the duties, rights and norms of those involved in research. Research subjects reasonably expect that their rights shall be equally recognized and respected, regardless of the researcher's discipline. Similarly, Canadian society legitimately expects that the benefits and harms of research shall be fairly distributed.
- 3. The Policy seeks to harmonize the ethics review process. The Agencies expect that REBs will benefit from common procedures within a shared ethical framework. This will also benefit those projects involving researchers from different disciplines or institutions. The Agencies hope that the Policy will serve as an educational resource.
- 4. The effective working of ethics review—across the range of disciplines conducting research involving human subjects—requires reasonable flexibility in the implementation of common principles. The Policy therefore seeks to avoid imposing one disciplinary perspective on others, while expressing the shared principles and wisdom of researchers in diverse fields. It is designed to help both researchers and REBs, as a matter of sound ethical reasoning, to scrutinize the contexts and accommodate the needs of specialized research disciplines.

5. The Policy updates some norms, while seeking to encourage continued reflection and thoughtful consensus around more contentious ethical issues. The Policy does not offer definitive answers to such ethical questions. Rather, it seeks (a) to outline guiding principles and basic standards and (b) to identify major issues, and points of debate and consensus, which are essential to the development and implementation of coherent policies for research ethics.

Endnotes

See Canadian Institutes of Health Research Act, Statutes of Canada, 2000, Chapter 6; Natural Science and Engineering Research Council Act, Revised Statutes of Canada, 1985, Chapter N-21; Social Sciences and Humanities Research Council Act, Revised Statutes of Canada, 1985, Chapter S-12.

During preparation of this Policy Statement, there was extensive discussion of the optimal term to describe those on, or about whom, the research is carried out. This discussion focused on the terms "participant" and "subject." Though research subjects may participate actively in research, so also do many others, including the researchers and their staff, administrators in the institutions, and funding sponsors and members of research ethics boards. Research subjects are unique among the many participants because it is they who bear the risks of the research. The Agencies have therefore chosen to retain the word "subject" because of its relative unambiguity in this context, and because the prime focus of the Policy Statement is on those who bear the risks of research.