

Policies and Statements for Conducting Research with Humans

There are a number of policy statements that have been developed over the years to promote the commitment of researchers in conducting responsible and ethical research involving human subjects:

1. Declaration of Helsinki

<http://www.wma.net/en/30publications/10policies/b3/index.html>

The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. For more information, please consult the link above.

2. Tri-council Policy Statement for Ethical Conduct of Research Involving Humans

http://www.pre.ethics.gc.ca/policy-politique/tcps-eptc/docs/TCPS%20October%202005_E.pdf

<http://www.pre.ethics.gc.ca/policy-politique/docs/TCPS-Draft2-eng.pdf>

The Tri-council policy describes the policies of the Canadian Institute of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC). The joint policy expresses the three agencies continual commitment to the people of Canada to promote the ethical conduct of research involving human subjects. For more information, please consult the link above.

3. International Conference on Harmonization (ICH) Guidance for Industry: Good Clinical Practice: Consolidated Guidelines (ICH Topic E6)

<http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6-eng.php>

This is an international document was adopted by Health Canada and applies to drug and device studies undertaken by industry or with industry support. This guidance document is meant to provide assistance to industry and health care professionals on how to comply with the policies and governing statutes and regulations when conducting clinical research trials. For more information, please consult the link above.

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4. Drugs for Clinical Trials Involving Human Subjects (Division 5, Food and Drug Regulations (1024 – Clinical Trials))

(<http://www.hc-sc.gc.ca/dhp-mps/compli-conform/clin-pract-prat/reg/1024-eng.php>)

Within the Food and Drug Regulations, under Section Part C (*Drugs*), Division 5 (*Drugs for Clinical Trials Involving Human Subjects*) there lays information pertaining to how research involving human subjects should be conducted. For more information, please consult the link above.

5. Privacy Legislation in Canada

Canada has two federal privacy laws: the *Privacy Act* and the *Personal Information Protection and Electronic Documents Act*.

The *Privacy Act* imposes obligations on federal government departments and agencies to respect privacy rights by limiting the collection, use and disclosure of personal information. The *Personal Information Protection and Electronic Documents Act (PIPEDA)* imposes ground rules for how private sector organizations may collect, use or disclose personal information in the course of commercial activities. Both acts allow individuals the right to access and request correction of personal information that may have been collected about them. For more information, please consult the links below:

- Office of the Privacy Commissioner of Canada
(http://www.privcom.gc.ca/index_e.cfm)
- Privacy Act
(http://www.privcom.gc.ca/leg_c/leg_c_a_e.cfm#contenttop)
- Personal Information Protection and Electronic Documents Act (PIPEDA)
(http://www.privcom.gc.ca/leg_c/leg_c_p_e.cfm#contenttop)

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6. Privacy Laws in Ontario

Ontario has three privacy laws to help protect the personal information held by the government and health care practitioners and organizations: the *Freedom of Information and Protection of Privacy Act*, the *Municipal Freedom of Information and Protection of Privacy Act* and the *Personal Health Information Protection Act*. These acts contain specific rules on how they may collect, use, retain, disclose and dispose of your personal information. For more information, please consult the links below:

- Office of the Information and Privacy Commissioner of Ontario
(<http://www.ipc.on.ca/index.asp?navid=1>)
- Freedom of Information and Protection of Privacy Act (FIPPA)
(http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_90f31_e.htm)
- Municipal Freedom of Information and Protection of Privacy Act
(http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_90m56_e.htm)
- Personal Health Information Protection Act (PHIPA)
(http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm)

7. International Committee of Medical Journal Editors' (ICMJE) Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication

(<http://www.icmje.org/index.html>)

In September 2004, the members of the International Committee of Medical Journal Editors (ICMJE) published a joint editorial (http://www.icmje.org/clin_trial.pdf) aimed at promoting registration of all clinical trials. The most recent update to the joint editorial occurred in 2008 (http://www.icmje.org/urm_full.pdf). The ICMJE member journals now require, as a condition of consideration for publication, registration of all clinical trials in a public trials registry. The registration of trials must occur at or before the onset of subject enrollment into any clinical

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trial. In June 2007, the ICMJE adopted the World Health Organization's (WHO) definition of a clinical trial, and now defines a clinical trial as *"any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes."* Health-related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes). Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) will not require registration. For more information, please consult the links above.