Trillium Health Partners
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Human Subjects Research: Legislation, Guidelines, Policies and Regulations

Compliance	Summary
TCPS 2 (Federal Guidelines)	A policy created by Canada's three federal research agencies (CIHR, NSERC and SSHRC) to promote the ethical conduct of research involving humans. To be eligible to receive and administer research funds from the Agencies, institutions must agree to comply with Agency policies, which includes the TCPS. Researchers funded by the Agencies are expected to adhere to the TCPS. *- Panel on Research Ethics-*
ICH GCP E6 3.2.1 (International Guidelines)	An international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve human subjects. Compliance with GCP assures that the rights, safety, and well-being of trial subjects are protected and that the clinical trial data are credible. This International Conference on Harmonization (ICH) guidance provides a unified standard. *- U.S. Food and Drug Administration-*
PHIPA, 2004, Section 44 (Provincial Legislation)	Governs the collection, use and disclosure of personal health information by health information custodians practising within Ontario and the requirements for all parties involved in the disclosure of PHI for research purposes. At its core, PHIPA balances the requirement that personal health information be maintained in a private and secure fashion with the need to make such information readily available for the delivery of effective health care. *-Information and privacy Commission of Ontario -*
The Office of Human Research Protections (OHRP) (International Regulation) OHRP 45CFR Part 46 (US/FDA Regulations) U.S Department of Health and Human Services Office for Human Research Protections Terms of Federal wide assurance (FWA) for International (non-U.S.) institutions	The OHRP provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS) *-Department of Health and Human Services -*

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Health Canada's Food and Drugs Act and Regulations	Help to protect the health and safety of Canadians with respect to the sale of food and drug products and set out requirements for the manufacture, packaging, labelling, storage, importation, distribution and sale of foods, and prescription and non-prescription drugs in Canada. Requirements for drug clinical trials are also set out in the regulations. -Government of Canada-
U.S. Food and Drug Administration	FDA regulates scientific studies that are designed to develop evidence to support the safety and effectiveness of investigational drugs (human and animal), biological products, and medical devices. Physicians and other qualified experts ("clinical investigators") who conduct these studies are required to comply with applicable statutes and regulations –FDA-
Trillium Health Partners' Research Policies & Procedures (can be accessed through Paradigm 3 on the THPHub)	Provides guidelines to support researchers and to ensure the responsible conduct of research at Trillium Health Partners.