Building Quality into Research through Training & Certification

Hamilton Health Sciences has compiled a platform of key training resources for investigators and research personnel working under the auspices of HHS research enterprise that offers access to training and certification courses, as well as reference tools to help fulfill the standards governed by federal and provincial regulatory and legislative bodies.

Key training and certification courses are highlighted in subsequent slides. To view the comprehensive web-based platform, visit Training & Certification.

Included here are selected key documents on Conducting Clinical Research in Canada:

- Health Canada
- Tri-Council Policy Statement 2 (2014)
- ICH Guidelines
- Declaration of Helsinki
- The Belmont Report

Building Quality into Research through Training

Through HHS' membership affiliation with N2 Canada, the HHS research community has access to free online education training and certification courses offered through The Collaborative Institutional Training Initiative (CITI Canada Program). To obtain access and log-in instructions contact Daniela Bianco, Manager – Research Development and Relations.

Good Clinical Practice – Full (Basic) and Refresher Courses

The International Conference on Harmonization (ICH) guidance E6: Good Clinical Practice (GCP) has been adopted to aid compliance with regulatory requirements for clinical Research. The full course is composed of 13 modules that present ICH-E6-GCP Standards as they relate to clinical trials of drugs, biologics and devices. Content is designed to meet the specific regulatory framework in Canada focusing on the Health Canada Food and Drugs Act, Food and Drug Regulations and the current version of the Tri-Council Policy Statement (TCPS). The GCP Refresher course is a summarized version consisting of 7 modules from the full GCP course.

CITI Canada Privacy Course

This course provides an introduction to privacy and security requirements for health research with human subjects. It offers important information based on accepted privacy and security standards and regulatory requirements for the appropriate collection, use, dissemination and retention and destruction of Personal Health Information (PHI) within the health research environment. The materials address requirements set out in guidance documents such as the Tri-Council Policy Statement (TCPS) as well as federal, provincial and territorial legislation including PIPEDA: Personal Information Protection and Electronic Documents Act

Building Quality into Research through Training & Certification

Health Canada Division 5 – Drugs for Clinical Trials Involving Human Subjects

Part C, Division 5 of the Food and Drugs Act and Regulations defines specific requirements for the sale and importation of drugs used in human clinical trials in Canada. According to Health Canada, the Qualified Investigator must ensure compliance with regulations from every person conducting clinical trials on their site. The successful completion of this course can be used as evidence of training in Division 5 Regulations. This course covers all research that is subject to Division 5 Regulations and provides practical solutions and methods for complying with Health Canada Regulations.

Responsible Conduct of Research (RCR) – Life Science Canada

Researchers are expected by the public and by their colleagues to follow many rules and commonly accepted practices. The two RCR courses provides a solid foundation of knowledge relating to the norms, principles and rules governing responsible research practice in Canada.

Biomedical Research Ethics Tutorial – Canada

This course is an introduction to a variety of ethics issues that are important to consider when conducting biomedical research with human participants. The course content covers the current version of the Tri-Council Policy Statement in detail that will assist in understanding and the application of principles of ethics, ethics guidelines, regulations and legislation when conducting biomedical research.

Building Quality into Research through Training & Certification

TCPS 2 Tutorial Course on Research Ethics (CORE)

CORE provides an applied approach to the guidance provided in TCPS 2 and covers topics from Core Principles to REB Review. To access the TCPS 2 Tutorial, click here.

Chart/Health Records Retrospective Review Tutorial

This training is available for investigators to complete as it is a requirement before an Application for Retrospective Review can be processed or reviewed by HiREB. The tutorial ensures that researchers are aware of the privacy issues that arise in research involving retrospective review and how to complete the HiREB Application for Retrospective Review. To access the tutorial, click here.

Social and Behavioural Research Ethics

This course is an introduction to a variety of ethics issues that are important to consider when conducting social and behavioural research with human participants. The course content covers the current version of the Tri-Council Policy Statement in detail with more information that is specifically aimed at social and behavioural research audience.

Transportation of Dangerous good (TDG)

Specific training is required to ensure that all people conducting research with dangerous materials, agents, or devices are in compliance with all applicable laws. The course content covers: Introduction to TDG, Identification and Classification of Dangerous Goods, Packaging and Containment, Marking and Labelling, Documentation, ERAP and Accidental Release Reporting.

Resources and Tools Available to Support Clinical Trials

In addition to the platform of free online learning and certification courses offered through The Collaborative Institutional Training Initiative (CITI-Canada Program), Hamilton Health Sciences also has reference tools and resources to help fulfill the standards governed by federal and provincial regulatory and legislative bodies, as well as assist with increasing clinical research and clinical trials activities involving human participants.

Set of Standard Operating Procedures for Research

HHS Clinical Trials Website – what researchers need to know

N2 ItStartsWithMe – Website, Video and Brochure

N2 Participant Bill of Rights