ALBERTA CLINICAL RESEARCH CONSORTIUM
Managed by Alberta Innovates

APPENDIX 1: ACRC PROVINCIAL TRAINING RECOMMENDATIONS COURSE DESCRIPTIONS-UPDATED NOVEMBER 2019

- Health Information Act (HIA)

  The HIA sets out the rules for the collection, use, disclosure and protection of health information that is in the custody or under the control of a custodian. Examples of custodians include Alberta Health, Alberta Health Services, Covenant Health, physicians, pharmacists, registered nurses, and dentists.

- Freedom of Information Protection (FOIP) Act

  This course is available to public bodies (i.e. post- secondary institutions, health care bodies) and covers
  - What is personal information & the purpose of FOIP
  - Collection, use and disclosure of personal information under FOIP
  - Protecting personal information & how the public may access information
  - Offences and penalties under FOIP & Formal and informal complaint and oversight mechanisms.

- AHS Information Privacy & IT Security Awareness

  IT Access to IT systems for Research can be considered for those who are listed as study staff or research personnel on a REB-approved study. For those who are approved access by AHS to one of these systems, these individuals must complete this mandatory privacy training before access is granted.

- A pRoject Ethics Community Consensus Initiative (ARECCI Level 1)

  ARECCI recommends that all projects be screened for ethical risk and offers two decision-support tools to help identify risks, determine the category of risk and determine the appropriate ethics review.

- Panel on Research Ethics – TCPS2 Tutorial Course on Research Ethics (CORE)

  This self-paced course is a media-rich learning experience that features interactive exercises and multi-disciplinary examples. CORE consists of eight modules ranging from Core Principles to REB Review. It is designed primarily for the use of researchers and REB members – though anyone may take this course and print their own certificate of completion.

- Ethics and Human Subject Protection Course-ACRP
  Complementing *Good Clinical Practice* this course takes a deep dive into the ethical considerations facing clinical research professionals and enables them to put the rules into practice to ensure human subject safety and well-being at all times.

- CIHR Research Data Management learning module
  CIHR has developed a learning module focusing on key themes, challenges, and considerations in research data management (RDM). This module includes information, tools and resources to support effective RDM practices. The module has been developed as a compliment to the *Tri-Agency Statement of Principles on Digital Data Management*, which articulates Canadian RDM priorities and funder expectations.

- Understanding How Medical Devices are Regulated in Canada
  An e-Learning tool that is intended to educate stakeholders on the premarket regulatory requirements for medical devices in Canada. Designed as an interactive learning platform, it covers a range of topics, including risk classification, licensing and labelling requirements, required submission documents, licence application types, licence amendments, and management of applications.

  This tool is recommended for various medical device stakeholders, including manufacturers, importers, distributors, consultants, healthcare groups and academia.

- CIHR-Sex and Gender Training Modules
  These interactive modules are designed to help researchers and peer reviewers account for and appropriately assess the integration of sex and gender across multiple areas of health research.

  Course 1: Sex and Gender in Biomedical Research

  Course 2: Sex and Gender in Primary Data Collection with Human Participants

  Course 3: Sex and Gender in the Analysis of Secondary Data from Human Participants

CITI-Canada

In recognition of the importance of quality training for research staff the organizations have provided access to the following courses offered by CITI-Canada. The current available topics are:

- Good Clinical Practice (GCP): Full Course

  In Canada, the International Conference on Harmonisation (ICH) guidance E6 R2: 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. The 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) - and it also offers information on U.S. Food & Drug Administration (FDA) regulatory requirements.

- Good Clinical Practice (GCP): Refresher Course

  The GCP Refresher course is a summarized version (7 modules) of the Full GCP course, complete with new quiz questions. It is ideal for clinical research investigators who have already taken CITI-Canada GCP training and need to demonstrate that they are up-to date in their knowledge of GCP.

  These courses are suitable for persons conducting clinical trials of drugs and devices primarily in Canada. Many pharmaceutical companies have accepted CITI course in lieu of their own in-house training (e.g. Pfizer, Abbott, Novartis, BMS, Astra-Zeneca, Bayer, Lilly, J&J, Roche, Sanofi-Aventis, Pharmanet and Amgen). Furthermore, the U.S. non-profit organization "TransCelerate BioPharma" which represents a large number of biopharmaceutical companies has recognized that both the Full and Refresher courses meet their criteria for ICH GCP training for investigator site personnel. This means that completion of the CITI-Canada course eliminates the need for completion of another GCP course often requested by a particular company and thus reduces duplication.

- 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 the 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 subject to Division 5 Regulations and provides practical solutions and methods for complying with the Health Canada Regulations.

- Transportation of Dangerous Goods (TDG/IATA) Course
  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 consists of 6 modules: Introduction to TDG, Identification and Classification of Dangerous Goods; Packaging and Containment; Marking and Labelling; Documentation; ERAP and Accidental Release Reporting.

- Social and Behavioral Research Course
  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. It covers the current version of the Tri-Council Policy Statement (TCPS) in greater detail than the tutorial offered by the Panel on Research Ethics, with more information that is specifically aimed at a social and behavioural research audience. Modules include: History and Ethical Principles, Assessing Risk in Social and Behavioural Sciences; Informed Consent; Privacy and Confidentiality; Research with Children; Research in Vulnerable Circumstances; Internet Research and Conflicts of Internet.

- Biomedical Research Ethics Course
  This course is an introduction to a variety of ethics issues that are important to consider when conducting biomedical research with human participants. It will assist in the understanding and application of principles of ethics, ethics guidelines, regulations and legislation when conducting biomedical research. The course covers the current version of the Tri-Council Policy Statement (TCPS) in even greater detail than the tutorial offered by the Panel on Research Ethics with more information aimed at a biomedical research audience.

- Clinical Research Coordinator*
  The purpose of this course is to provide CRCs, or those performing research coordination activities, with a foundational training specifically focusing on operational and regulatory elements necessary for the ethical conduct of clinical trials. **Course is available containing US content only (Canadian course content is not yet available).*

- Responsible Conduct of Research (RCR)
  How should you conduct your research? What practices should you follow? Researchers are expected by the public and by their colleagues to follow many rules and commonly accepted practices. The Responsible Conduct of Research (RCR) course provides the learner with a solid foundation of knowledge relating to the norms, principles and rules governing responsible research practice in Canada.