ALBERTA CLINICAL RESEARCH CONSORTIUM
Managed by Alberta Innovates

APPENDIX 1: PROVINCIAL TRAINING RECOMMENDATIONS COURSE DESCRIPTIONS

- 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

  To gain access to the AHS network, affiliates of AHS must complete mandatory privacy training.

- A pRoject Ethics Community Consensus Initiative (ARECCI)

  Ethics decision support tools and training to assist in integration of appropriate ethics considerations in projects to protect participants, whether the project is evaluation, quality improvement, quality assurance, or research.

- 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.

- CITI-Canada

  CITI provides several online courses with integrated Health Canada and TCPS2 guidelines to researchers and staff affiliated with one of the ACRC partner organizations ((AHS, Covenant Health, CPSA, University of Alberta, University of Calgary). 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.

Changes to recommended training course offerings

- **The NIH – Protection Human Research Participants Course** has been discontinued by the NIH as of September 26, 2018. The course was one option to fulfill the protection of human subject education requirement. Institutions using the Protecting Human Research Participants course to fulfill this requirement may choose to use another training program to meet the requirement. The NIH does not endorse any specific programs to fulfill the requirement for education on the protection of human subjects. The NIH believes that institutions are in the best position to determine the training programs appropriate for fulfilling the education requirement for research staff. Some rare cases may arise where more training could be required as outlined by the Funding Opportunity Announcement (FOA). If this is the case, further requirements would be outlined in the application process.

  Refer to the NIH Research Involving Human Subjects Education Requirement webpage for further details. https://humansubjects.nih.gov/requirement-education

- The Association of Clinical Research Professionals (ACRP) is offering the **ACRP's Ethics and Human Subject Protection online course** available-free of charge-for clinical research professionals and organizations as a training option to the protection of human subject education requirement. https://www.acrpnet.org/courses/ethics-human-subject-protection/