

High quality research stems from training and a knowledgeable research team. *“Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).”* [ICH GCP E6 (R1) (2.8)]

It is with this principle in mind that on March 20, 2015 the ACRC, speaking as representatives of the partner organizations endorsed the inaugural series of *training recommendations*.

The inaugural provincial training recommendation document has recently undergone review and subsequent revisions to reflect the changing regulatory landscape and was approved and endorsed by the ACRC Executive Committee on October 3, 2018.

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- Alexander Clark, Professor & Associate Vice President (Research) Nursing, University of Alberta
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- Derek Exner, Associate Dean (Clinical Trials), Professor, Libin Cardiovascular Institute of Alberta, University of Calgary
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**Recommended Training by Project Type\***

The ACRC has developed the following tables to guide individuals on the training courses that are recommended and applicable to their work (refer to Appendix 1 for training/course descriptions). Frequency of training is adequately flexible to accommodate different experience levels, and gaps in training of research study staff. Each course may be re-taken at any time if an individual warrants additional training.

***Refer to your organizational and institutional guidelines for additional training requirements.***

\*The Provincial Training Recommendations are subject to change in the event of significant course material content changes or updates; or with changes to either provincial and/or Health Canada regulations and guidelines.

Course/Training Name	Clinical (Health) Research		Knowledge-Generating Projects <sup>1</sup>
		Does <u>not</u> involve drug, medical device or natural health product	
<a href="#">Health Information Act</a>	√	√	√ Study involves health information
<a href="#">Freedom of Information Protection (FOIP) Act</a>	√ Study involves personal information		
<a href="#">AHS Information Privacy &amp; IT Security Awareness</a> <i>For affiliates of AHS</i>	√ Study involves access to either health or personal information held by AHS and Covenant Health		
<a href="#">ARECCI Level 1</a>			√
<a href="#">Panel on Research Ethics – TCPS2 Tutorial Course on Research Ethics (CORE)</a>	√	√	
<a href="#">CIHR Research Data Management learning module</a>	√	√	√
<a href="#">Understanding How Medical Devices are Regulated in Canada</a>	√		
<a href="#">CIHR-Sex and Gender Training Modules</a> (Course 1: Biomedical Research; Course 2: Primary Data Collection with Human Participants; Course 3: Analysis of Secondary Data from Human Participants)	Optional for all persons involved in clinical (health) research & knowledge-generating projects		

<sup>1</sup> Projects that have the primary purpose to improve practice or service delivery within your organization or setting, is site or program-specific, targets a service (Quality Improvement or Process Improvement); Evaluation; Projects that involve an innovation and/or new methodologies. Examples include: Artificial Intelligence (AI), Real World Evidence (RWE), Machine Learning (ML)



Course/Training Name (CITI Canada)	Clinical (Health) Research		Knowledge-Generating Projects <sup>1</sup>
		Does <u>not</u> involve drug, medical device or natural health product	
<b>Good Clinical Practice (CITI Canada)</b> GCP Full Course-is to be taken only once with no need to repeat GCP Refresher Course-must be taken 3 years after the completion of the basic course and repeated every 3 years thereafter to maintain certification	√	√	
<b>Health Canada Division 5 – Drugs for Clinical Trials Involving Human Subjects (CITI Canada)</b> No expiry on training	√	Optional	
<b>TDG/IATA (Transportation of Dangerous Goods/International Air Transport Association) (CITI Canada)</b>	√ Study staff involved in the packaging, transportation and/or receiving of dangerous goods		
<b>Social and Behavioral Research Course (CITI Canada)</b>	√ For all persons involved in social and behavioral research		
<b>Biomedical Research Ethics Course (CITI Canada)</b>	√ For all persons involved in biomedical research		
<b>Clinical Research Coordinator (CITI Canada)*</b> *Currently contains only US content	Optional for all persons performing research coordination activities		
<b>Responsible Conduct for Research (CITI Canada)</b>	√	√	

<sup>1</sup> Projects that have the primary purpose to improve practice or service delivery within your organization or setting, is site or program-specific, targets a service (Quality Improvement or Process Improvement); Evaluation; Projects that involve an innovation and/or new methodologies. Examples include: Artificial Intelligence (AI), Real World Evidence (RWE), Machine Learning (ML)