Training Recommendations for Researchers and Research Staff for Clinical Research and Clinical Trials

Course/ Training Name	Clinical (Health) Research		Quality Improvement/Evaluation
MANDATORY Training Requirements			
	Involves drug, medical device, or natural health product	Does not involve drug, medical device, or natural health product	
Health Information Act	✓ Study involves health information.		
Freedom of Information Protection (FOIP) Act	✓ Study involves personal information.		
AHS Information Privacy & IT Security Awareness (for affiliates of AHS; AHS employees typically already have this)	✓ Study involves access to either health or personal information held by AHS or Covenant Health.		
ARECCI Project Ethics Course			✓
Good Clinical Practice (CITI Canada) – AHS (N2) GCP Full Course – is to be taken only once with no need to repeat. CGP Refresher Course – must be taken 3 years after the completion of the basic course and repeated every 3 years thereafter to maintain certification.	✓	✓	
Health Canada Division 5 – Drugs for Clinical Trials Involving Human Subjects (CITI Canada) No expiry on training.	✓ (drug trials)	Optional	
Health Canada – ISO 14155 Clinical Investigation of Medical Devices (CITI Canada)	✓ (device trials)	Optional	
Responsible Conduct for Research (CITI Canada)	✓	✓	
OPTIONAL Training for Research-Specific Roles			
Panel on Research Ethics – TCPS2 Tutorial Course on Research Ethics (CORE-2022)	✓	✓	
CIHR Research Data Management Learning Module	✓	✓	✓
Understanding How Medical Devices are Regulated in Canada	✓		

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Biosafety for Research & Clinical Trials • Module 1 - Introduction to Biosafety • Module 2 - Risk Groups and Containment Levels • Module 3 - Exposures, Lab Acquired Infections (LAIs) and Incident Reporting • Module 4 - Biosecurity, SSBAs and Dual Use • Module 5 - Biohazardous Spill Response and Reporting • Biosafety and Biosecurity Annual Refresher - Part 1 • Biosafety and Biosecurity Annual Refresher - Part 2 • Biosafety Awareness for Non-Lab Personnel • Biosafety Lab Safety Training	✓	✓	
CIHR Sex and Gender Training Modules	Optional for all persons in clinical (health) research & knowledge-generating projects.		
TDG/IATA (Transportation of Dangerous Goods/International Air Transport Association) (CITI Canada)	✓ Study Staff involved in the packaging, transportation and/or receiving of dangerous goods.		
Social and Behavioral Research Course (CITI Canada)	✓ For all persons involved in social and behavioral research.		
Biomedical Research Ethics Course (CITI Canada)	✓ For all persons involved in biomedical research.		
Clinical Research Coordinator (CITI Canada)* *Currently contains only US content	Optional for all persons performing research coordination activities.		

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 (R2) (2.8)

- 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. (ACRC)
- AHS is a member of N2 and has made N2 Standard Operating Procedures (SOPs) available to AHS-affiliated researchers and staff.
- Adapted from Network of Networks (N2) CITI-Canada Course Descriptions.
- If you have any questions, please contact the U of A Clinical Trials Office.