

Guidance for Research Training Requirements

All types of research require some form of training on conduct and compliance.

The Research Department supports the required training and provides training materials to ensure that research is efficient, high-quality and regulatory-compliant. This guidance provides clarifications on training requirements for all research that involves human participants at Island Health.

This training is designed to enable both an understanding of the regulations and guidelines for the ethical conduct of clinical research, as well as the *practical application* of that knowledge in practice settings. In addition, it is important to know that studies will often have their own training requirements on the protocol, this is standard and key to understanding how to implement the study.

Tracy Wong, Research Quality Assurance Specialist at Tracy.Wong@islandhealth.ca will support your training pathway. Table 1: Key Training Pieces for Clinical Research at Island Health, below, outlines requirements specific to Island Health; however, they are adapted to meet specific needs of each individual and study.

Once the requirements in Table 1 are met, practical "hands on" training will be provided by members of the Clinical Research Team.

Clinical research, which is different from clinical medicine, requires specific knowledge about regulations and required guidelines.

SUMMARY FOR THOSE NEW TO CLINICAL RESEARCH:

- Step 1: Contact <u>ClinicalResearch@islandhealth.ca</u> discussion of planned research
- Step 2: Introduced to Tracy.Wong@islandhealth.ca training on Table 1 elements
- Step 3: Study Protocol Requirements (conducted by study Sponsor, may be concurrent during Step 2)
- Step 4: Hands on, Practical Application training by Clinical Research Unit

For more information please contact:

Tracy Wong, Research Quality Assurance Specialist: <u>Tracy.Wong@islandhealth.ca</u>

E. Sarah Bennett, Manager, Research Ethics & Compliance: Elizabeth.Bennett@islandhealth.ca

For questions around clinical research support and "hands on" training contact: ClinicalResearch@islandhealth.ca

Table 1: KEY TRAINING PIECES FOR RESEARCH AT ISLAND HEALTH *Requirements may change*

MANDATORY FOR ALL RESEARCH					
TYPE OF TRAINING	TIME TO COMPLETE	HOW TO ACCESS	OTHER		
TCPS 2: CORE-2022 Tutorial	2.5 - 4 hours	TCPS 2: CORE-2022	For more information click <u>here</u> .		
Confidentiality Information Management (CIM) Code of Practice	Up to 1 hour	<u>Learning Hub</u>	Valid for 1 year (All Island Health staff, physicians and agents are required to take foundational privacy education.) Registries or trials requiring access to health records or use/viewing of personal health information		
Applicable Island Health Standard Operating Procedures (SOPs)	10 - 15 minutes per SOP	Will be provided as needed	*SOPs recommended depending on the type of research (e.g. registries, observational studies, Biobanks)		

FOR REGULATED CLINICAL TRIALS					
TYPE OF TRAINING	TIME TO COMPLETE	HOW TO ACCESS	OTHER		
Island Health Standard Operating Procedures (SOPs)	10 - 15 minutes per SOP	Will be provided as needed	E.g. informed consent, management of investigational products, source documentation.		
Health Canada Division 5	3-4 hours	See Training & Compliance	Valid for 10 years		
Research Compliance presentation: Investigator Training Session	1 hr	Contact Tracy.Wong@islandhealth.ca	*for New Investigators and Study Team Members*		
Association of Clinical Research Professionals (ACRP) Investigator Responsibilities	1-2 hrs	Contact Tracy.Wong@islandhealth.ca	*for New Investigators*		
Good Clinical Practice	3-4 hours	See <u>Training & Compliance</u>	Valid for 3 years		
Transportation of Dangerous Goods/IATA	1-2 hours	See <u>Training & Compliance</u>	Valid for 2 years: *for study team members processing biological samples		

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