

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 materials to facilitate research that 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.

If your study is supported by the Clinical Trials Unit (CTU), once the requirements in Table 1 are met, practical “hands on” training will be provided by members of the CTU.

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 ClinicalResearch@islandhealth.ca – 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 Trial Unit

For more information please contact:

Tracy Wong, Research Quality Assurance Specialist: Tracy.Wong@islandhealth.ca

Phil Pollock, Manager, Research Ethics, Compliance & Business Unit: Philip.Pollock@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

Training requirements are subject to 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 here .
Confidentiality Information Management (CIM) Code of Practice	Up to 1 hour	Learning Hub	Valid for 1 year <i>(All Island Health staff, physicians and agents are required to take foundational privacy education.)</i> 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 (i.e registries, observational studies, Biobanks)

See next page for Regulated Clinical Trials...

FOR REGULATED CLINICAL TRIALS			
TYPE OF TRAINING	TIME TO COMPLETE	HOW TO ACCESS	OTHER
Network of Network (N2) Standard Operating Procedures (SOPs)	10 - 15 minutes per SOP	To request a copy of the N2 SOPs, contact ResearchCompliance@islandhealth.ca	<i>i.e. informed consent, management of investigational products, source documentation.</i>
Good Clinical Practice (GCP)	3-4 hours	See Training	Valid for 3 years
Health Canada Division 5	3-4 hours	See Training	Valid for 3 years
Research Compliance presentation: <i>Investigator Training Session</i>	1 hr	Contact ResearchCompliance@islandhealth.ca	*for new Investigators and Study Team Members*
Association of Clinical Research Professionals (ACRP): <i>Investigator Responsibilities</i>	1-2 hrs	Contact ResearchCompliance@islandhealth.ca	*for new Investigators*
Transportation of Dangerous Goods/IATA	1-2 hours	See Training	Valid for 2 years: *for study team members processing biological samples

If you have questions, please contact: ResearchCompliance@islandhealth.ca