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.

Research Compliance at ResearchCompliance@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 ResearchCompliance@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 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.
Research Policy	10 minutes	Research Policies and Procedures	Found under 'Policies and Strategies'
Confidentiality Information Management (CIM) Code of Practice *(Note - for Medical Staff, please complete: Confidential Information Management (CIM) Code of Practice – Medical Staff)*	Up to 1 hour	Learning Hub	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 (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.e. informed consent, management of investigational products, source documentation.*
Good Clinical Practice (GCP)	3-4 hours	See Training	Valid for 3 years
ICH E8(R1) – General Considerations for Clinical Studies: ICH's Introductory Overview Video, October 2024	12 minutes	International Council for Harmonisation (ICH): Training/Training Library/E8R1/Training Material	Documented self attestation required to confirm completion of training (see memo)
Health Canada Division 5	3-4 hours	See Training	Valid for 3 years
Research Compliance presentation: *Investigator Training Session*	1 hour	Contact ResearchCompliance@islandhealth.ca	*for new Investigators and Study Team Members*
Association of Clinical Research Professionals (ACRP): *Investigator Responsibilities*	1-2 hours	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

APPENDIX 1: REQUIRED RESEARCH TRAINING MATRIX

REGULATED TRIALS – REQUIRED RESEARCH TRAINING								
	QI	SC	LAB	RATER	IMAGING	PHARMACY	VOLUNTEER	STUDENT
TCPS2	X	X	X	X	X	X	X	X
CIM	X	X	X	X	X	X	X	X
GCP	X	X	X	X	X	X	X	X
ICH E8(R1) Introductory Overview video	X	X	N/A	N/A	N/A	N/A	N/A	N/A
HC Div 5	X	X	X	X	X	X	X	X
TDG	N/A	X	X	N/A	N/A	N/A	N/A	N/A
RESEARCH POLICY	X	X	X	X	X	X	X	X
25.3 RESEARCH INTEGRITY	X	X	X	X	X	X	X	X
SOP 705 RESEARCH FINANCE	X	N/A	N/A	N/A	N/A	N/A	N/A	N/A
BIG POINTS PRESENTATION	X	X	N/A	N/A	N/A	N/A	N/A	N/A
ACRP'S INVESITIGATOR RESPONSIBLITIES	X	N/A	N/A	N/A	N/A	N/A	N/A	N/A
POWERCHART TRAINING FOR RESEARCHERS (Learning Hub)	N/A	*	N/A	N/A	N/A	N/A	N/A	N/A

NONREGULATED PROJECTS – REQUIRED RESEARCH TRAINING							
	INVESTIGATOR/ PRECEPTOR	SC	LAB	IMAGING	PHARMACY	VOLUNTEER	STUDENT
TCPS2	X	X				X	X
CIM	X	X				X	X
RESEARCH POLICY	X	X				X	X
25.3 RESEARCH INTEGRITY	X	X				X	X
POWERCHART TRAINING FOR RESEARCHERS (Learning Hub)	*	X	N/A	N/A	N/A	N/A	N/A

TCPS2	Tri Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2)
CIM	Confidential Information Management
GCP	Good Clinical Practice
HC DIV 5	Health Canada, Part C Division 5 of the Food and Drug Regulations
TDG	Transportation of Dangerous Goods
ACRP	Association of Clinical Research Professionals
QI	Qualified Investigator
SC	Study Coordinator

*Click here to email Manager, Research Ethics, Compliance and Business Unit to review potential need

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