Guidance for Clinical Research Training Requirements

All types of research require some form of training on conduct and compliance. Clinical research, which is different from *clinical medicine*, requires specific knowledge about regulations and required guidelines.

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.

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 Compliance Facilitator at Tracy.Wong@viha.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.

SUMMARY FOR THOSE NEW TO CLINICAL RESEARCH:

- Step 1: Contact Sheilah.Frost@viha.ca – discussion of planned research
- Step 2: Introduced to Tracy.Wong@viha.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 Compliance Facilitator: Tracy.Wong@viha.ca
E. Sarah Bennett, Manager, Research Ethics & Compliance: Elizabeth.Bennett@viha.ca

For questions around clinical research support and "hands on" training:
Sheilah Frost, Manager, Clinical Research: Sheilah.Frost@viha.ca

Table 1: KEY TRAINING PIECES FOR CLINICAL RESEARCH AT ISLAND HEALTH

TYPE OF TRAINING	TYPE OF RESEARCH	TIME TO COMPLETE	COMPLETION REQUIRED BY	OTHER
TCPS2 CORE Tutorial (on-line)	All Health Research	2-3 hours	Prior to start of study	Must be the most recent version (after 2014)
Confidentiality Information Management (CIM) Code of Practice (on-line)	Registries or trials requiring access to health records or use/viewing of personal health information	Up to 1 hour	Prior to start of study	Valid for 1 year *All Island Health staff, physicians and agents are required to take foundational privacy education.*
Island Health Standard Operating Procedures (SOPs) (read and Q&A)	Health Canada regulated clinical trials only **some SOPs may be recommended for other types of research (ie. registries, observational studies, Biobanks)*	10 - 15 minutes per SOP	Prior to start of study	(ie. informed consent, management of investigational products…)
Health Canada Division 5 (on-line)	Health Canada regulated clinical trials only	3-4 hours	Prior to start of study	Valid for 10 years Mandatory for Lead Investigator and Study Coordinator at site
Good Clinical Practice (on-line)	Health Canada regulated clinical trials only	3-4 hours	Prior to start of study	Valid for 3 years Mandatory for Lead Investigator and Study Coordinator at site

Note: A copy of this guidance document should be placed into the Investigative Study File.