Education

ICH-GCP training is required by Health Canada for investigators and research team members who are working on clinical trials involving drugs or natural health products. In addition to this, Health Canada also expects investigators and research teams to be trained on all applicable regulations. In the event of an audit or inspection, evidence of this training is expected.

There are several training options available to ensure that training is easily accessible, including face to face sessions and on-line training. It is mandatory that sponsor-investigators engage in this training, understand the implications, comply with the regulations and fulfill their responsibilities.

Please contact andrea.dean@nshealth.ca for more information on training.

Other Supports

Research Services can also assist with other requirements such as:

- setting up agreements; e.g., participating sites, confidentiality, non-disclosure, data transfers, intellectual property
- issues relating to liability, insurance and registration of clinical trials
- developing job descriptions, recruiting staff, salary allocation
- opening research accounts, transferring funds, paying bills, etc.

Where can I get assistance?

Understanding the complex set of regulatory requirements of sponsor-investigator research can be a daunting task. To get started, please contact:

Andrea Dean, Research Education Program Manager
NSHA Research Services
andrea.dean@nshealth.ca 902-473-2118

Michele Chappell, Research Quality Program Manager
NSHA Research Services
michele.chappell@nshealth.ca 902-473-8549

Investigator-Sponsored Clinical Trials

nova scotia health authority
Research Services

What is a sponsor? When is it an investigator-sponsored clinical trial?

A sponsor is an individual, company, institution or organization that takes responsibility for the initiation (e.g., writes the research protocol), management and regulatory compliance for a clinical trial. There can be only one sponsor per trial.

If the investigator initiates and manages a clinical trial, the investigator is acting as the sponsor, then it is an Investigator-Sponsored Clinical Trial.

If, in addition to the above, the investigator is also conducting the trial **and** supervising the administration, dispensing, and/or use of the investigational product; then the investigator is acting as a **sponsor-investigator**. The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator. *Investigators who also act as sponsors can expect a higher level of preparation and responsibilities.*

What if the research will be financed by an external organization/ company or departmental funds?

The term "funder" is not synonymous with sponsor.

If the funder does not initiate, manage or have regulatory responsibility for the research, they are not acting as the sponsor.

If the investigator has initiated the research and plans to manage the research but receives funding from an external source (e.g., company, granting agency, institutional department), the investigator is still considered to be the sponsor. It is important to have an agreement in place between NSHA, the investigator and funder to ensure all parties are protected. Funding applications and all research agreements **must** be reviewed and approved by Research Services. Please contact the Contract and Grant Facilitation team for assistance.

Still not sure if you are the sponsor?

Please contact Research Services if you need clarification as to whether you are acting as a sponsor and for assistance in determining what your additional responsibilities entail to ensure regulatory compliance.

Responsibility of Regulatory Requirements

Investigator-sponsored clinical trials represent an important component of the research conducted at the Nova Scotia Health Authority (NSHA). When investigator-sponsored trials involve a drug or natural health product, compliance with certain regulations and guidelines is mandatory.

The sponsor is responsible for ensuring compliance with all applicable regulations and guidelines.

Sponsor Project Responsibilities

What are some of the responsibilities of a sponsor during the project?

- obtaining Health Canada authorization to conduct the trial (phase 1–3 trials)
- submitting safety reports to Health Canada
- designing the protocol, case report forms and other study documentation
- providing mechanisms for quality assurance and control systems with written standard operating procedures
- ensuring labeling requirements are met for investigational products
- maintaining records to establish trial has been conducted in accordance with the regulations, the protocol and ICH-GCP (Good Clinical Practices)
- developing a monitoring plan and associated standard operating procedures
- establishing a data safety and monitoring board
- securing facilities, services, equipment

It is essential to be aware of all of the responsibilities of a sponsor; otherwise, in the event of a regulatory inspection or an internal quality audit, the investigator could be cited for non-compliance, leading to suspension or termination of their research.

When an audit or inspection brings shortcomings to light, it is difficult to implement the infrastructure required to satisfy regulatory (e.g., Health Canada) requirements at later stages of the project. This can be a frustrating experience which may dissuade a researcher from pursuing future research.

It is imperative that investigators make themselves aware of all the requirements they must meet early in the planning process.

Support for Investigator-Sponsored Clinical Trials

The good news is that there are supports available to researchers through NSHA Research Services. Staff have the expertise to support investigators and their teams with education, training and/or consultations at all stages of the clinical trial.

It is essential that investigators take advantage of these services to ensure regulatory compliance and to ensure protection for themselves and the research participants.

These supports include:

- education, advice and expertise related to contracts, budgets, agreements and applicable regulations
- tools, templates and guidance documents to facilitate regulatory compliance
- the creation of a quality process specific to a trial and/or research team to protect participants and ensure the production of quality data

Study Consultation

A consultation is strongly encouraged as early as possible, as soon as the protocol is finalized.

This ensures that investigators:

- are adequately informed about all the responsibilities they will assume
- have realistic budgets
- have all necessary contracts and agreements in place
- understand the process and requirements for regulatory compliance

Quality Assurance

The sponsor-investigator must implement systems and processes that assure the quality and integrity of every aspect of the study. Research Services offers a number of guidance documents and templates to assist in the creation of essential documents to support research quality.

Consultation on the development of these documents and processes includes:

- **Protocol**
  A well written protocol is a recipe for success. Beyond the scientific merit of a protocol, the methodology and practicalities must be considered to ensure participants are protected, the methodology is feasible and the data generated is high quality. A guidance document and template are available to support protocol development.

- **Standard Operating Procedures**
  Health Canada expects written procedures to describe key processes at the research site (e.g., informed consent, recruitment, safety reporting, drug handling, drug storage). Consultation and templates are available.

- **Monitoring Plan**
  The sponsor-investigator must ensure that all trials are appropriately monitored to ensure participants are protected; protocol and regulatory compliance is assured; and the data is accurate, complete and verifiable. Monitor responsibilities, procedures and reporting must be detailed and documented in a monitoring plan. Templates and guidance are available.

- **Electronic System Validation**
  All electronic systems used during the course of a clinical trial must be validated. Health Canada has provided guidance on what this entails.
  For additional details, please contact michele.chappell@nshealth.ca