- **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 janet.gallant@nshealth.ca or julia.enikeeva@nshealth.ca

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.

Still not sure?

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.

Where can I get assistance?

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

Janet Gallant, Program Manager
Research Education
NSHA Research Services
janet.gallant@nshealth.ca
902-473-2118

nova scotia health authority

Supports for Investigator-Sponsored Clinical Trials

nova scotia health authority

Importance 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. In these situations the researcher assumes sponsor responsibilities.

It is essential to be aware of these requirements; otherwise, in the event of a regulatory inspection or an internal quality audit, the researcher 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 such a late stage. This can be a frustrating experience which may dissuade a researcher from pursuing future research. It is imperative that investigators make themselves aware of 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. The staff have the expertise to support investigators and their teams with education, training and/or consultations. We can offer you the assistance you need quickly and effectively.

How do I know if I need assistance?

Please take a moment to review the following to assist you in identifying if you need to know more about regulatory requirements and support. This brochure applies to clinical trials involving a drug or natural health product, including those products that have been approved for use by Health Canada.

Who is a sponsor?

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.

When is an investigator a sponsor?

If the investigator initiates and manages the trial, the investigator is acting as the sponsor.

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 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 the investigator and funder to ensure all parties are protected. Funding applications and research agreements must be reviewed and approved by Research Services. Please contact the Contract and Grant Facilitation team for assistance.

What are the responsibilities of a sponsor?

Below is a sample of responsibilities:

- 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

Supports available to the investigator

There are a number of resources available to support investigators who will be acting as sponsors. 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:

- provide education, advice and expertise related to contracts, budgets and applicable regulations
- facilitate the development of tools, templates, guidance documents to facilitate regulatory compliance
- asssist in 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 and should be sought as early as possible, before the protocol and funding proposal is submitted. This ensures that investigators:

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

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 the 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 Janet.Gallant@nshealth.ca for more information on training.

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 quality. We also offer consultation on the development of these documents and processes including:

- **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.