Capital Health

Supports for Investigator-Initiated Clinical Trials

Research Education Program

Regulatory Requirements

Investigator-initiated clinical trials represent an important component of the research conducted at Capital Health. When investigator-initiated trials involve a drug or natural health product, compliance with certain regulations and guidelines is mandatory. In these situations the researcher assumes the responsibilities of the sponsor.

It is essential for the researcher 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-Initiated Clinical Trials

The good news is that there are supports available to researchers through Capital Health 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 would an investigator be 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.

For example, 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 authorization from Health Canada 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
- and more…

Supports available to the investigator

There are a number of resources and educational opportunities available, including study consultation. What does a study consultation entail?

- a one-hour meeting with the investigator and/or research team to gather information about the proposed research study
- provision of some preliminary information on the responsibilities of a sponsor-investigator during the meeting
- follow up after the initial meeting with recommendations and regulatory considerations for the investigator and/or team

Additional support and direction is also available to assist you in implementing recommendations.

Education sessions for investigator-initiated clinical trials

In addition to study consultations, there are a number of one-hour education sessions for investigators and teams who are interested in pursuing investigator-initiated clinical trials involving drugs and natural health products research. These sessions provide an overview of the various regulations and responsibilities of the sponsor-investigator, allowing investigators and teams to familiarize themselves with the requirements before they begin to develop their research plan.

The sessions listed and described on the reverse can be offered in any combination at any time that is convenient for research team members. Sessions can be tailored or developed in response to the suggestions or needs of the research team.

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.

Regulatory Requirements for Research

- provides an overview of regulations that pertain to drugs, medical devices and natural health products
- assists investigators and teams in identifying which regulations apply to various types of investigational products reviews Health Canada's approval process for different investigational products

ICH-GCP Investigator Responsibilities

- discusses the responsibilities of the principal investigator according to ICH-GCP
- meets Health Canada's requirement for ICH-GCP training of investigators, sub-investigators and applicable research team members

Division 5 Regulations

Health Canada requires all investigators, sub-investigators and research staff who are working on clinical trials involving drugs to be trained on Division 5 regulations. This session:

- reviews these regulations and compares the regulations to ICH-GCP
- focuses on sponsor obligations with regard to Health Canada's submission and reporting processes

Sponsor-Investigator Responsibilities for ICH-GCP Compliant Research

- essential for all research team members who will be involved in the conduct of an investigator-initiated clinical trial
- reviews the additional responsibilities of an investigator who is also acting as a sponsor, giving team members an opportunity to consider the infrastructure and planning required to conduct a ICH-GCP compliant trial

Investigator-Initiated Research Agreements

- reviews agreements, e.g., participating sites, confidentiality and non-disclosure agreements
- discusses liability, insurance and registration of clinical trials

Financial Management

- reviews opening research accounts, paying bills, transferring funds and closing accounts
- discusses salary allocation

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:

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