

**The following is a brief excerpt of some important principles from the Canadian regulations on Clinical Trials. Click on the link below to see all of the regulations.**

[Regulations Amending the Food and Drug Regulations \(1024 - Clinical Trials\)](#)

### **New Regulatory Framework**

These Regulations have been developed to recognize the generally accepted principles of good clinical practice and internationally competitive submission review time lines. They reflect extensive consultation with stakeholders. A brief summary of the elements contained in the Regulations follows.

### **Good Clinical Practices (GCP)**

Sponsors of clinical trials conducted in Canada must be able to demonstrate that the trials are conducted according to generally accepted principles of good clinical practice. These principles include:

- clinical trials must be conducted in accordance with good clinical practices and the applicable regulatory requirement(s).
- before a trial is initiated, foreseeable risks and inconveniences must be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.
- the rights, safety, and well-being of the trial subjects are the most important considerations and must prevail over interests of science and society.
- the available non-clinical and clinical information on an investigational drug must be adequate to support the proposed clinical trial.
- clinical trials must be scientifically sound, and described in a clear, detailed protocol.
- a trial must be conducted in compliance with a protocol that has received REB approval prior to initiation.
- the medical care given to, and medical decisions made on behalf of, subjects must always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.
- each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).
- freely given informed consent must be obtained from every subject prior to clinical trial participation.
- all clinical trial information must be recorded, handled, and stored in a way that enables its accurate reporting, interpretation and verification.

— the confidentiality of records that could identify subjects must be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).

— investigational drugs must be fabricated, handled, and stored in accordance with applicable good manufacturing practices (GMP). They must be used in accordance with the approved protocol.

— systems with procedures that assure the quality of every aspect of the trial must be implemented.