Procedures not recognized as standard of care and/or undertaken for research purposes may not be performed in a non-hospital facility unless:

- there is no opportunity for the clinical trial to be conducted in a hospital
- the procedure is conducted under a properly constituted clinical trial with ethical oversight
- the clinical trial is approved by the Non-Hospital Medical Surgical Facilities Program Committee

Examples of research include but are not limited to:

- testing (safety and/or efficacy) of drugs, biologics, medical devices and/or natural health products
- administering an investigational drug or a market-approved drug for a non-approved indication
- administering a natural health product for research rather than treatment (e.g. effect of vitamins on in vitro fertilization outcomes)
- performing a procedure (clinical, therapeutic or otherwise) for research rather than treatment (e.g. bone biopsy to evaluate the safety and efficacy of an investigational drug)

**Definitions**

**clinical trial/study**

Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamics effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms “clinical trial” and “clinical study” are synonymous. (Health Canada *ICH Guidance E6: Good Clinical Practice*)
independent ethics committee (IEC) An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favourable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects. (Health Canada ICH Guidance E6: Good Clinical Practice)

institutional review board (IRB) An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects. (Health Canada ICH Guidance E6: Good Clinical Practice)

investigational product A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

investigator’s brochure A compilation of the clinical and non-clinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects.

protocol A document that describes the objectives(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. (Health Canada ICH Guidance E6: Good Clinical Practice)

subject An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.

trial site The location(s) where trial-related activities are actually conducted.

Facility processes ensure the ethical conduct of all research involving human subjects

INDICATORS:
- All research involving human participants and/or human biological materials is reviewed and approved by the College before the trial is initiated
○ All research involving human participants and/or human biological materials is reviewed and approved by an IRB/IEC

○ The IRB/IEC complies with Health Canada’s membership requirements for a research ethics board and functions in a manner consistent with Good Clinical Practices

○ Informed consent is obtained from the research subject prior to any clinical trial participation

○ A copy of the written IRB/IEC-approved informed consent form, signed and dated by the research subject and by the person who conducted the informed consent discussion, is on file in the patient medical record

○ Facility written policy and procedures are in place to ensure that clinical trial procedures are conducted in compliance with the study protocol and only when the specified clinical trial has current approval from both an IRB/IEC and the College

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**Facility processes ensure that clinical trial documentation demonstrates compliance with local/provincial/federal statutory requirements and professional/regulatory standards**

**INDICATORS:**

○ A clinical trial application is submitted to the College for each clinical trial

○ Clinical trial documentation on file for each clinical trial includes:
  - IRB/IEC approval and renewals
  - protocol and amendments
  - investigator’s brochure, as appropriate
  - informed consent form (IRB/IEC approved)
  - Health Canada Research Ethics Board (REB) Attestation form, as appropriate
  - Health Canada Qualified Investigator Undertaking (QUI) form
  - Health Canada Clinical Trial Site Information (CTSI) form
  - Health Canada Letter of No Objection (drugs, devices, natural health products)
  - NHMSFP application to conduct a clinical trial
  - College approval and renewals
  - IRB/IEC acknowledgement of study closure, as appropriate

○ IRB/IEC renewal (approval) documentation is submitted to the College, as appropriate

○ Written notification of participation exodus is submitted to the College when the facility’s participation in the specified clinical trial procedure concludes, as appropriate

○ IRB/IEC acknowledgement of study closure is submitted to the College, as appropriate
References


University of Waterloo, Research. Research with human participants [Internet]. Waterloo: University of Waterloo. Clinical trials or studies involving a drug, medical device, or natural health product [cited 2015 Feb 19]; [about 3 screens]. Available from: https://uwaterloo.ca/research/office-research-ethics/research-human-participants/application-process/clinical-trials-or-studies-involving-drug-medical-device-or