



Health
Canada

Santé
Canada

Health Products
and Food Branch

Direction générale des produits
de santé et des aliments

Tunney's Pasture
Address Locator # 0701A1
OTTAWA, Ontario
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03-104584-451

To: Canada's Research-Based Pharmaceutical Companies
Research Ethics Boards: members of the National Council on Ethics in Human Research (NCEHR), members of the Canadian Association of Research Ethics Board (CAREB), Ethics Committee of the Canadian Medical Association, Private Research Ethics Boards
Hospitals: Provincial Health Departments, Executive Director of the Royal College of Physicians and Surgeons of Canada, Registrars of Provincial Colleges of Physicians and Surgeons, Canadian College of Health Services Executives
Pharmacists: Canadian Pharmacists Association, Canadian Society of Hospital Pharmacists (CSHP), National Association of Pharmacy Regulatory Authorities (NAPRA), Ordres des Pharmaciens du Québec
Research Community: Canadian Institute of Health Research, Directors of Research Institutes, Association of Clinical Research Professionals (ACRP)- Canadian Chapter, Canadian Association of University Research Administrators (CAURA)
Universities: Faculties of Medicine, via Association of Canadian Faculties of Medicine, Vice-Presidents Research at Faculties of Medicine, Faculties of Nursing

Dear Stakeholders:

Subject: Reminder of regulatory requirements governing drugs for use in Clinical Trials in Canada

The purpose of this letter is to serve as a reminder that the use of drugs in clinical trials involving human subjects is subject to regulatory requirements in Canada. Health Canada is actively monitoring all regulated activities in this area.

On September 1, 2001, the *Food and Drug Regulations* were amended to introduce the addition of Division 5 "Drugs for clinical trials involving human

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subjects”. At that time, Health Canada communicated this amendment to a number of stakeholders. The Regulations apply to drugs for clinical trials involving human subjects, including trials which are not supported by commercial sponsors. This includes Phase I, II, and III clinical trials as well as trials with marketed products that are outside the parameters of the approved indication(s). The Regulations apply equally to all sponsors of clinical trials; individual investigators, research institutions and commercial sponsors.

We ask you to ensure that all of your clinical trials which are subject to Health Canada regulations are in compliance with the Regulations. Health Canada’s compliance monitoring activities, including inspections of clinical trial sites and sponsors, are currently underway based on the Health Products and Food Branch Compliance and Enforcement Policy. Also, to facilitate the administration of the Regulations, Health Canada has developed a Guidance document for clinical trial sponsors. These documents may be viewed at:

- for the Therapeutic Products Directorate
www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_e.html (english) [_f.html](http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_f.html) (french)

- for the Biologics and Genetic Therapies Directorate
[www.hc-sc.gc.ca/bgtd-dpbtg.index_e.html](http://www.hc-sc.gc.ca/bgtd-dpbtg/index_e.html) (english) [_f.html](http://www.hc-sc.gc.ca/bgtd-dpbtg/index_f.html) (french)

The Regulations require that clinical trial site information be submitted to Health Canada. This includes the title of the protocol, the drug, the sponsor of the clinical trial, a contact for the clinical trial, the clinical trial site, the qualified investigator, and the Research Ethics Board that approved the trial at that site. The above information is detailed in our “Clinical Trial Site Information” form, which is located on our website at the above addresses. Clinical trial site information must be submitted to Health Canada for all trials that are subject to *Food and Drug Regulations*, and that have commenced since September 1, 2001.

We invite you to contact us if you have any questions regarding clinical trials. For questions related to clinical trials with biologics, genetic therapies, or radiopharmaceuticals, please contact Dr. Norman Viner, Unit Head, Clinical Trial Applications at (613) 946-8045. For all other clinical trials, please contact Dr. Christine Nestruck, A/Manager, Clinical Trials, Therapeutic Products Directorate at (613) 941-0570. For questions related to compliance monitoring activities of clinical trials, please contact Mr. Jean Saint-Pierre, Good Clinical

Practices Coordinator, Health Products and Food Branch Inspectorate at (613) 952-8173. You will also find some useful web addresses and definitions attached to this letter (see Attachment 1).

Thank you for your diligent attention to this important health matter.

Yours sincerely,

A handwritten signature in blue ink, appearing to read "Diane C. Gorman". The signature is fluid and cursive, with the first name "Diane" being the most prominent part.

Diane C. Gorman
Assistant Deputy Minister

Attachment (1)

Attachment 1:

Definitions:

1. *Food and Drug Regulations*. Regulations Amending the *Food and Drug Regulations* (schedule 1024 – Drugs for Clinical trials Involving Human Subjects). Canada Gazette Part II. <http://canadagazette.gc.ca/partII/tempPdf/g2-13513.pdf>
SOR/DORS # 2001-203
2. “Clinical trial” means an investigation in respect of a drug for use in humans, that involves human subjects and that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of the drug, identify any adverse events in respect of the drug, study the absorption, distribution, metabolism and excretion of the drug, or ascertain the safety or efficacy of the drug (reference C.05.001).
3. “Good clinical practices” means generally accepted clinical practices that are designed to ensure the protection of the rights, safety and well-being of clinical trial subjects and other persons, and the good clinical practices referred to in section C.05.010 (reference C.05.001).

Related Health Canada Websites

4. Good Clinical Practices: Consolidated Guideline, International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use - Topic E6.
http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/goodclin_e.html
5. Inspection Strategy for Clinical Trials.
http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/insp_strat_clin_tria_e.pdf
6. Health Products and Food Branch Compliance and Enforcement Policy.
http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/compliance_enf_policy_e.pdf