



**“The BIG PICTURE:
Policy & Regulatory
Framework for Research
Ethics”**

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ACTS, REGULATIONS & GUIDANCES

Act:

- is a means by which laws are made



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ACTS, REGULATIONS & GUIDANCES

Regulations:

- [referred to as delegated legislation or subordinate legislation] is a means of making laws as well
- viewed as the operational part of a law to define terms, explain procedures/processes or standards that must be met, etc. in order to comply with an Act



ACTS, REGULATIONS & GUIDANCES

Guidance documents:

- (sometimes called guidelines or directives) are important administrative documents which support laws and regulations.
- do not have the force of law
- set out how a department, regulatory authority or other body applies laws and regulations under their jurisdiction
- provide transparency & fill in details



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WHAT LAWS GOVERN RESEARCH ETHICS?

Canadian DRUG RESEARCH

1. Food and Drugs Act

<http://laws.justice.gc.ca/en/f-27/60010.html>

2. Regulations Amending the Food and Drug Act Regulations
(1024 - Clinical trials) : **Division 5 Drugs For Clinical Trials
Involving Human Subjects**

[http://www.hc-sc.gc.ca/hpfb-
dgpsa/inspectorate/food_drug_reg_amend_1024_gcp_entir
e_e.html](http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/food_drug_reg_amend_1024_gcp_entire_e.html)



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REGULATIONS AMENDING THE FOOD AND DRUG ACT REGULATIONS (1024 - CLINICAL TRIALS)

Who is governed by these regulations?

- Sponsors
 - individual, corporate body, institution or organization that conducts a clinical trial.
- Investigators
 - person responsible to the sponsor for the conduct of the clinical trial at a clinical trial site,
- Research Ethics Boards



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Sponsor's Obligations

- ***C.05.010.*** *Every sponsor shall ensure that a clinical trial is conducted in accordance with good clinical practices*

-refers to:

Good Clinical Practices [ICH: GCP 1997]



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Investigator's Obligations

- **Records**

C.05.012.

9(f) for each clinical trial site, an undertaking from the qualified investigator that is signed and dated by the qualified investigator prior to the commencement of his or her responsibilities in respect of the clinical trial, that states that

- (i) the qualified investigator will conduct the clinical trial in accordance with good clinical practices, and
- (ii) the qualified investigator will immediately, on discontinuance of the clinical trial by the sponsor, in its entirety or at a clinical trial site, inform both the clinical trial subjects and the research ethics board of the discontinuance, provide them with the reasons for the discontinuance and advise them in writing of any potential risks to the health of clinical trial subjects or other persons;



Research Ethics Board Obligations

(a) the principal mandate of which is to approve the initiation of, and conduct periodic reviews of, biomedical research involving human subjects in order to ensure the protection of their rights, safety and well-being



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ICH: Good Clinical Practice: Consolidated Guideline

<http://www.ncehr-cnerh.org/english/gcp/>

1.53 Sponsor:

“An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial



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ICH: Good Clinical Practice: Consolidated Guideline

1.34 Investigator

“A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator”.



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ICH: Good Clinical Practice: Consolidated Guideline

1.3.1 Institutional Review Board

[http://www.ncehr-
cnerh.org/english/gcp/review.html](http://www.ncehr-cnerh.org/english/gcp/review.html)



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WHAT LAWS GOVERN RESEARCH ETHICS?

Canadian DEVICE RESEARCH:

1. Food and Drugs Act
2. Medical devices for investigational testing involving human subjects

<http://laws.justice.gc.ca/en/f-27/sor-98-282/129684.html>



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Investigator's Obligations

- *k)* a written undertaking from each qualified investigator to
 - (i) conduct the investigational testing in accordance with the protocol provided by the manufacturer,
 - (ii) inform a patient who is to be diagnosed or treated using the device of any risks and benefits associated with its use, and obtain the patient's written consent for its use,...



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Sponsor's/REB's Obligations

(h) the name and address of each institution at which the investigational testing is proposed to be conducted and, in the case of a Class III or IV device, written approval from the institution indicating that the investigational testing may be carried out there;



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WHAT LAWS GOVERN RESEARCH ETHICS?

Canadian Natural Health Product Research:

1. Food and Drugs Act
2. Natural Health Product Regulations: Clinical Trials Involving Human Subjects: Part 4
http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/regs_cg2_tc_e.html



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HEALTH CANADA AUTHORITY

Role of the Health Products and Food Branch Inspectorate:

- To deliver a national compliance and enforcement program for products under the mandate of the Health Products and Food Branch.
- Applies to clinical drug, device & natural health product research



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HEALTH CANADA AUTHORITY

1. Voluntary Inspections:

http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/gcp_inspection_sum_rep_entire_e.html

2. Involuntary Inspections:

- **Compliance and Enforcement Policy**

http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/compliance_enf_policy_entire_e.html



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WHAT LAWS GOVERN RESEARCH ETHICS?

**U.S. Government Funded Studies:
Institutional Responsibilities:**

- 1. 45 CFR Part 46 for all U.S. federal government department/agency funded research**
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101>;
- 2. 21CFR Parts 50 and 54 for trials regulated by the Food and Drug Administration**
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm>



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WHAT POLICIES GOVERN RESEARCH ETHICS?

1. Tri-Council Policy on Research Involving Human Subjects

<http://www.ncehr-cnerh.org/english/home.php>

2. CIHR Policies:

- Stem Cells: stem cell investigators must have REB approval for their **non-clinical research**, in addition to approval from the UBC Animal Care Committee (when appropriate) and the UBC Biosafety Committee.

<http://www.cihr-irsc.gc.ca/e/15349.html>

- Non-Compliance <http://www.cihr-irsc.gc.ca/e/25178.html>



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WHAT OTHER LAWS AFFECT THE CONDUCT OF RESEARCH?

Public Entities:

1. Freedom of Information and Protection of Privacy Act of British Columbia (FIOPPA) enacted 04 October 1993

<http://www.oipcbc.org/>



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WHAT OTHER LAWS AFFECT THE CONDUCT OF RESEARCH?

Private Entities:

1. Personal Information Protection Act of British Columbia (PIPA) enacted 01 January 2004

http://www.legis.gov.bc.ca/37th4th/1st_read/gov38-1.htm#section6 ;

2. Personal Information Protection and Electronic Documents Act (PIPEDA) enacted 01 January 2001 and amended 01 January 2004.

http://www.privcom.gc.ca/legislation/02_06_01_e.asp



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Questions????

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