INTERNATIONAL GUIDELINES FOR BIOMEDICAL RESEARCH

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Main International Guidelines:

- The World Medical Association (WMA) Declaration of Helsinki - 1964. (Most recent update – 2013.)


THE WMA’s DECLARATION OF HELSINKI
The World Medical Association (WMA) Declaration of Helsinki – 1964:

• The World Medical Association’s Declaration of Helsinki is a set of ethical principles regarding human experimentation.

• It is probably the most influential document governing research worldwide, and is widely regarded as the cornerstone document on human research ethics.
The World Medical Association (WMA) Declaration of Helsinki:

• The Declaration was originally adopted in 1964 in Helsinki, Finland, and has undergone seven revisions since then, the latest in 2013. A commemorative publication this year was entitled: “50 Years of evolution of medical research ethics.”

• This document emphasizes the requirement that patients’ participation in research should not put them at a disadvantage with respect to medical care.
The World Medical Association (WMA) Declaration of Helsinki:

• The Declaration provides ‘dictates’ on:
  - Risks, Burdens, & Benefits
  - Vulnerable Groups & Individuals
  - Scientific Requirements and Research Protocols
  - Research Ethics Committees
  - Privacy and Confidentiality
  - Informed Consent
The World Medical Association (WMA) Declaration of Helsinki:

- **The Declaration provides ‘dictates’ on:**
  - The Use of Placebo
  - Post-Trial Provisions
  - Research Registration and Publication & Dissemination of Results
  - Unproven interventions in Clinical Practice
The Belmont Report:

• In the aftermath of the embarrassing revelations about the Tuskegee Study, the National Research Act of the USA was signed into law in 1974, thereby creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research.
The Belmont Report:

• The Commission was charged with identifying the basic ethical principles that should underlie the conduct of biomedical and behavioural research involving human subjects, and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles.
The Belmont Report:

The Commission was charged to consider:

- The boundaries between biomedical & behavioural research, and the accepted and routine practice of medicine;
- The role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects;
- Appropriate guidelines for the selection of human subjects for participation in such research, and
- The nature and definition of informed consent in various research settings.
The Belmont Report:

- The resulting **Belmont Report** summarizes the basic ethical principles identified by the Commission in the course of its deliberations.
- It is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human participants.
- The Report was published in the Federal Register, with re-prints readily made available to scientists, members of Institutional Review Boards, and Federal employees.
- The Belmont Report was adopted in its entirety as a statement of the policy of the Department for Health, Education, and Welfare in the USA.
The Belmont Report:

The Report - (1979) - addresses the following issues:

- Ethical Principles & Guidelines for Research involving Human Subjects
- Boundaries between Practice & Research
- The four (4) Basic Ethical Principles
- Applications – such as Informed Consent, Risk/Benefit Assessment, and the selection of subjects of research
The ‘Common Rule’:

The current U.S. system of protection of human research participants is heavily influenced by the Belmont Report. In 1981, with the Report as the foundational background, the Dept. of Health and Human Services and the Food and Drug Administration began revising and made compatible - their respective statutory regulations.

And so – in 1991 – the “Common Rule” or ‘Federal Policy for the Protection of Human Subjects” – was published and codified in separate regulations by 15 Federal Departments & Agencies. The HHS regulations – 45 CFR part 46 – has 4 subparts, with sub-part A being known as the Federal Policy or the “Common Rule.”
The ‘Common Rule’: 

The “Common Rule” outlines the Policy for the Protection of Human Research Subjects.

It requires compliance by all research and researchers supported by any Federal Department or Agency.

It outlines details for IRB functioning, the requirements and documentation of Informed Consent, and the early termination of research, and the evaluation of applications and proposals.

Sub-part B – addresses the additional protections needed for research with Pregnant women, Human foetuses, and Neonates.

Sub-part C – addresses the protections needed for research involving Prisoners, and Sub-part D – for research involving Children.
CIOMS
The Council of the International Organization of Medical Sciences (CIOMS):

- **CIOMS** - is an international, non-governmental, non-profit organization established jointly by WHO and UNESCO in 1949.

- In 2013, the membership of CIOMS included 49 international, national, and associate member organizations, representing many of the biomedical disciplines, national academies of sciences, and medical research councils.
The Council of the International Organization of Medical Sciences (CIOMS):

The main objectives of CIOMS are:

➢ To facilitate and promote international activities in the field of biomedical sciences;

➢ To maintain collaborative relationships with the United Nations and its specialized agencies, in particular WHO and UNESCO;

➢ To serve the scientific interests of the international biomedical community in general.
The Council of the International Organization of Medical Sciences (CIOMS):

The **CIOMS Guidelines** (The Council for International Organizations of Medical Sciences) recommend **standards** for the application of the Helsinki guidelines in **developing countries**. This includes stipulations that research products be made reasonably available to the inhabitants of any host developing country.
The Council of the International Organization of Medical Sciences (CIOMS) - cont’d:

The CIOMS Guidelines also recommend sensitivity to issues such as the local standards of health care and culture, influences of the local language on the informed consent process, and respect for privacy and confidentiality in research.
TRI-COUNCIL POLICY STATEMENT
Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans:

- Issued by the Canadian Institutes of Health Research.

- Addresses the topics: ‘Ethics Framework’, Research Ethics Board review, the Consent Process, Fairness and Equity in Research Participation, Privacy & Confidentiality, Conflicts of Interest, Multi-Jurisdictional Research, Qualitative Research, Clinical Trials, Human Biological Materials, and Human Genetics Research.

- Provides a benchmark for the ethical conduct of research involving humans.
Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (cont’d):

- Is used as a condition of funding, by all Agencies in Canada – for all researchers and their institutions.

- All Organizations and related entities are welcome to adopt the Policies enunciated therein – to guide the ethical aspects of the design, review, and conduct of research involving humans.

- The Document serves as a model and guide for all persons involved in the research endeavour.
THE INTERNATIONAL CONFERENCE ON HARMONIZATION
**ICH Harmonized Tripartite Guideline: Good Clinical Practice**

**International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use:**

- Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human beings.

- Compliance with this standard provides public assurance that the rights, safety, and well-being of trial participants are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

- The ICH GCP Guidance Document provides a unified standard for the European Union (EU), Japan, and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.

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The Guidance Document was developed with consideration of the current good clinical practices of the EU, Japan, the USA, as well as of Canada, Australia, the Nordic Countries, and the World Health Organization (WHO).

This Guidance Document should be followed when generating clinical trial data that are intended to be submitted to regulating authorities.

The principles established in this Guidance Document may also be applied to other clinical investigations that may have an impact on the safety and well-being of human participants.
THE BIOETHICS SOCIETY OF THE ENGLISH-SPEAKING CARIBBEAN (BSEC)
The Bioethics Society of the English-Speaking Caribbean (BSEC):


• The Guidelines outlines:
  ➢ The principles and fundamental considerations necessary for research with human participants
  ➢ The ethical requirements to be met
The Bioethics Society of the English-Speaking Caribbean (BSEC):

- The Guidelines outlines (cont’d):
  
  ➢ The details to be included in a research proposal
  
  ➢ How to determine the various levels of risks
  
  ➢ The steps recommended to obtain informed consent, and
  
  ➢ The composition, mandate, and terms of reference for

Research Ethics Committees.
Summary
Summary:

• The World Medical Association’s Declaration of Helsinki - is widely regarded as the cornerstone document on human research ethics.

• It stresses that patients’ participation in research should not put them at a disadvantage with respect to medical care.

• The Belmont Report - is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human participants.
Summary:

- The **CIOMS Guidelines** (The Council for International Organizations of Medical Sciences) recommend **standards** for the application of the Helsinki guidelines in **developing countries**.

- The **Tri-Council Policy Statement** – is issued by the Canadian Institutes of Health Research, and **provides a benchmark** for the ethical conduct of research involving humans.
Summary:

• The International Conference on Harmonization (ICH) stipulates good clinical practice, and is a Guidance Document that should be followed when generating clinical trial data that are intended to be submitted to regulating authorities.

• The Bioethics Society of the English-speaking Caribbean (BSEC) Guidelines outlines:
  ➢ The principles and fundamental considerations necessary for research with human participants in the Caribbean setting, and
  ➢ The details to be included in a research proposal.
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