International Compilation of Human Research Standards
2024 Edition

Compiled By:
Office for Human Research Protections (OHRP)
Office of the Assistant Secretary for Health (OASH)
U.S. Department of Health and Human Services (HHS)

International Organizations

OASH | Office for Human Research Protections

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PURPOSE

The International Compilation of Human Research Standards enumerates over 1,000 laws, regulations, and guidelines (collectively referred to as "standards") that govern the protection of research participants in more than 130 countries, as well as standards from various international and regional organizations. First published in 2005, the Compilation is intended for use by researchers, IRBs/Research Ethics Committees, sponsors, and others who are involved in the conduct or oversight of research involving human participants around the world.

ORGANIZATION

You may jump to a specific country by clicking its name in the Table of Contents.

This document is organized by country in alphabetical order. Before the world regions, there is a section for standards provided by several international organizations. Under each section, you will find the countries or international organizations organized also in alphabetical order. For each country or international organization, the information is then categorized as it relates to:

1. General (i.e., applicable to most or all types of human subjects research)
2. Drugs, Biologics, and Devices
3. Clinical Trial Registries
4. Research Injury
5. Social-Behavioral Research
6. Privacy/Data Protection
7. Human Biological Materials
8. Genetic
9. Embryos, Stem Cells, and Cloning

These nine categories often overlap, so it may be necessary to review other categories for a more complete understanding of a country's standards. The information under these nine categories is divided into Key Organizations and Relevant Standards. Key Organizations may include governmental and non-governmental organizations. Relevant Standards may include laws, legislations, regulations, guidance, official opinions or positions, etc. Since the meaning of these terms often vary significantly by county, they all have been grouped together under Relevant Standards, regardless as to whether they include mandatory requirements or voluntary guidelines.

Where possible, a link has been provided to specific key organizations and relevant standards. In many cases, the documents and webpages are available in English. When the URL links to a non-English website or document, an online language translator usually can render an English version. Many operating systems may also be able to translate a document or webpage. For example, in Chrome, you may be able to right click a document or page and select "translate to [your native language]."

TOPICS NOT COVERED

In order to focus its scope to human research protections, the International Compilation of Human Research Standards attempts to not include:

1. Standards from the state, provincial, or local levels
2. Enabling legislation, i.e., laws that only authorize an agency to promulgate standards, but that they themselves do not include substantive standards
3. Laws, regulations, or guidelines that are disease-specific or focus on research integrity, clinical ethics, products liability, clinical trial inspection procedures, intellectual property, good manufacturing practice, bioequivalence testing, informed consent in clinical practice, radiation, or environmental safety, etc.
4. Ethics codes of academic, medical, or other professional organizations
5. Working papers, drafts, commentaries, or discussion papers

GENERAL REQUEST FOR PUBLIC INPUT AND COMMENTS

To request that we include a new standard or a new country in the International Compilation, or to let us know of changes to these standards or broken links, please email us at:
OHRP-Edu@hhs.gov.

DISCLAIMER

Although this Compilation contains information of a legal nature, it has been developed for informational purposes only and does not constitute legal advice or opinion. In addition, because the standards contained in this Compilation may be created, changed, or revoked on a continuing basis, this Compilation is not an exhaustive source of all current standards, and the information provided may be incomplete or outdated. Users of this compilation must not rely only on the information it provides but should also check with local authorities, legal counsel, and/or research ethics committees before commencing research activities.

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INTERNATIONAL ORGANIZATIONS

General

Council for International Organizations of Medical Sciences (CIOMS): http://www.cioms.ch/

- Research Involving Humans (2016): https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/

International Committee of the Red Cross (ICRC): http://www.icrc.org

Office of the United Nations High Commissioner for Human Rights (OHCHR): https://www.ohchr.org/EN/pages/home.aspx

- International Covenant on Civil and Political Rights, Article 7 (1976): http://www.ohchr.org/en/professionalinterest/pages/ccpr.aspx

The TRUST Code: http://www.globalcodeofconduct.org

- Global Code of Conduct for Research in Resource-Poor Settings (2018): http://www.globalcodeofconduct.org/2018/05/Global-Code-of-Conduct

UNAIDS: http://www.unaids.org/

- Good Participatory Practice: Guidelines for Biomedical HIV Prevention Trials (2011): http://www.unaids.org/JC1853_GPP_Guidelines/2011
- Ethical Considerations in Biomedical HIV Prevention Trials (2012): https://www.unaids.org/2012/jc1399_ethical_considerations

United Nations Educational, Scientific, and Cultural Organization, Bioethics Program (UNESCO): https://en.unesco.org/

- Universal Declaration on Bioethics and Human Rights (2005): http://portal.unesco.org/declataion/bioethicsandhumanrights/2005

World Health Organization: http://www.who.int/en/

- Research Ethics Review Committee (ERC): https://www.who.int/groups/research-ethics-review-committee
- Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011): https://www.who.int/guidance/ethicsreviewhealthresearchhumanparticipants/2011
- Ethical Issues in Patient Safety Research: Interpreting Existing Guidance (2013): https://www.who.int/ethicalissuespatientsafetyresearch/interpretingguidance/2013
- Managing Ethical Issues in Infectious Disease Outbreaks: Guidance Document (2016): https://www.who.int/publications/i/item/guidance-for-managing-ethical-issues-in-infectious-disease-outbreaks
- WHO Guidelines on Ethical Issues in Public Health Surveillance (2017): https://www.who.int/publications/i/item/who-guidelines-on-ethical-issues-in-public-health-surveillance
- WHO Expert Group on Ethics and Governance of Artificial Intelligence for Health: https://www.who.int/groups/who-expert-group-on-ethics-and-governance-of-artificial-intelligence-for-health

- Various: https://www.who.int/healthtopics

World Medical Association: https://www.wma.net/

- Declaration of Helsinki (2013): https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

Drugs, Biologics, and Devices

Drugs

International Conference on Harmonization (ICH): http://www.ich.org/

- Various guidelines, including Guidelines for Good Clinical Practice E6 (and Integrated Addendums E6(R2)-(R3)): https://www.ich.org/page/efficacy-guidelines

World Health Organization (WHO): http://www.who.int/en/

- Handbook for Good Clinical Research Practice (GCP): Guidance for Implementation (2005): https://iris.who.int/GDP/guidanceforimplementation/2005
- Operational Guidance: Information Needed to Support Clinical Trials of Herbal Products (2005): https://iris.who.int/guidance/informationneedclinicaltrialsherbalproducts/2005

Devices

International Medical Device Regulators Forum (IMDRF): http://www.imdrf.org/

- IMDRF: Statement Regarding Use of ISO 14155:2011 "Clinical Investigation of Medical Devices for Human Subjects-Good Clinical Practice" (2015): http://www.imdrf.org/clinicalinvestigationmedicaldevices/humansubjects/GCP/2015/statement
- Various Archived Documents from the Global Harmonization Task Force (GHTF), replaced by the IMDRF in 2012: http://www.imdrf.org/ghtf/ghtf-archived-docs.asp

International Standards Organization: http://www.iso.org/iso/home.html

- Clinical Investigation of Medical Devices for Human Subjects -- Good Clinical Practice. Standard Number 14155:2011: https://www.iso.org/standard/83968.html

Clinical Trial Registries

International Committee of Medical Journal Editors: http://www.icmje.org/

- Clinical Trial Registration: http://icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html

United States, National Institutes of Health, ClinicalTrials.gov:
https://www.clinicaltrials.gov/ct2/home

World Health Organization, International Clinical Trials Registry Platform:
http://www.who.int/ictrp/en/

- Resolution WHA 58.34 (2005): https://who.int/resolution58.34/2005

World Medical Association: https://www.wma.net/

- Declaration of Helsinki, Article 35 (2013): https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

- European Medicines Agency, Clinical Trials Information System (CTIS): https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/clinical-trials-human-medicines/clinical-trials-information-system

Research Injury

Council for International Organizations of Medical Sciences: http://www.cioms.ch/

- International Ethical Guidelines for Health-related Research Involving Humans (2016), Guideline 14: https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/

International Conference on Harmonization (ICH): http://www.ich.org/

- Various guidelines, including Guidelines for Good Clinical Practice E6 (and Integrated Addendums E6 (R2)-(R3)): https://www.ich.org/page/efficacy-guidelines

World Medical Association: https://www.wma.net/

- Declaration of Helsinki, Paragraph 15 (2013): https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

Social-Behavioral Research

UNESCO: http://www.unesco.org/

- Code of Conduct and Ethical Guidelines for Social Science Research: https://unesdoc.unesco.org/codeofconduct/ethicalguidelines/socialscienceresearch

Privacy/Data Protection

World Medical Association: https://www.wma.net/

- Declaration of Helsinki, Paragraph 24 (2013): https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
- Declaration of Taipei (2016): https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/
- Global Repository on National Digital Health Strategies: https://www.who.int/teams/digital-health-and-innovation/global-repository-on-national-digital-health-strategies

Human Biological Materials

International Air Transport Association: http://www.iata.org/

- Infectious Substances Shipping Regulations (ISSR) (2005): https://www.iata.org/en/publications/store/infectious-substances-shipping-regulations/

International Society for Biological and Environmental Repositories: https://www.isber.org/

- ISBER Best Practices: Recommendations for Repositories (2019) and Addendums: https://www.isber.org/page/BPR

World Health Organization: http://www.who.int/en/

- Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens (1997): https://iris.who.int/guidelines/safetransportinfectioussubstances/diagnosticspecimens/1997

Genetic Research

World Medical Association

- Human Genome Editing, Recommendations: https://www.who.int/publications/i/item/9789240030381
- Human Genome Editing (HGE) Registry: https://www.who.int/groups/expert-advisory-committee-on-developing-global-standards-for-governance-and-oversight-of-human-genome-editing/registry

Human Genome Organization: http://www.hugo-international.org/

- Statement on the Principled Conduct of Genetic Research (1996): http://www.eubios.info/HUGO.htm
- Statement on DNA Sampling: Control and Access (1998): http://hrlibrary.umn.edu/instree/dnastatement.html
- Statement on Gene Therapy Research (2001): https://www.eubios.info/GENTHER.htm
- Statement on Human Genomic Databases (2002): https://www.cairn.info/revue-journal-international-de-bioethique-2003-3-page-207.htm

UNESCO Bioethics Program: https://www.unesco.org/en/ethics-science-technology?hub=387

- Universal Declaration on the Human Genome and Human Rights Section 16 of III Programme for 1998-1999 (1997): http://unesdoc.unesco.org/section16/1997
- International Declaration on Human Genetic Data: Section 22 of Major Programme III – Social and Human Sciences (2003): http://unesdoc.unesco.org/section22/2003

Embryos, Stem Cells, and Cloning

International Society for Stem Cell Research: http://www.isscr.org/

- Guidelines for the Conduct of Human Embryonic Stem Cell Research (2021): https://www.isscr.org/guidelines

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