International Compilation of Human Research Standards
2021 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

INTERNATIONAL ORGANIZATIONS

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)

PURPOSE

The International Compilation of Human Research Standards enumerates over 1,000 laws, regulations, and guidelines (collectively referred to as "standards") that govern human subject protections in 131 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 human subjects research protections around the world.

Collaborators from around the world, some who are acknowledged at the end of the Compilation, provided updates (or confirmations of prior listings), which are reflected in the hundreds of changes entered into this Edition. However, not all countries provided corroboration, so some of the information contain in this document may be outdated or incomplete (please see disclaimer below).

ORGANIZATION

This document only includes International Organizations. To access the complete International Compilation, please visit: https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html. You may jump to a specific country by clicking its name in the Table of Contents.

This document is organized by world region in alphabetical order: Africa, Asia/Pacific, Europe, Latin America and the Caribbean, Middle East/North Africa, and North America. Under each region, you will find the countries organized also in alphabetical order. For each country, 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 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 authorize an agency to promulgate human subjects standards, but do not direct the content of those regulations
3. Laws, regulations, or guidelines that are disease-specific or focus on research integrity, clinical bioethics, product liability, clinical trial inspection procedures, intellectual property, good manufacturing practice, bioequivalence testing, or informed consent in clinical practice
4. Ethics codes of academic, medical, or other professional organizations – see the Ethics Codes Collection: http://ethics.iit.edu/ecodes/about
5. Working papers, drafts, commentaries, or discussion papers

NEW STANDARDS, UPDATES, AND BROKEN LINKS

To request inclusion of a new standard in the Compilation, or to provide updated information or report broken links, please contact OHRP-Edu@hhs.gov.

If you would like to provide information for a country not currently included in the Compilation, we would love to hear from you. Please contact 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 opinions as to the current operative laws, regulations, or guidelines of any jurisdiction. In addition, because new standards are issued on a continuing basis, this Compilation is not an exhaustive source of all current applicable laws, regulations, and guidelines relating to human subject protections. The information contain in this Compilation may incomplete or outdated. While in-country persons have been requested to review listings to assure their accuracy and completeness, researchers and other individuals should check with local authorities and/or research ethics committees before commencing research activities.

TABLE OF CONTENTS

INTERNATIONAL ORGANIZATIONS

General

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

- International Ethical Guidelines for http://www.saveservices.org/wp-content/uploads/Analysis-of-113-Lawsuits-9.16.2019.xlsxResearch Involving Humans (2016): https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/

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

- Geneva Convention Relative to the Treatment of Prisoners of War, Articles 13 and 130 (1950): https://www.icrc.org/applic/ihl/ihl.nsf/7c4d08d9b287a42141256739003e636b/6fef854a3517b75ac125641e004a9e68
- Additional Protocol I Relating to the Protection of Victims of International Armed Conflicts, Article 11 (1977): http://www.icrc.org/ihl.nsf/7c4d08d9b287a42141256739003e636b/f6c8b9fee14a77fdc125641e0052b079

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

TRUST Project: http://www.globalcodeofconduct.org

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

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

- Good Participatory Practice: Guidelines for Biomedical HIV Prevention Trials (2011): http://www.unaids.org/sites/default/files/media_asset/JC1853_GPP_Guidelines_2011_en_0.pdf
- Ethical Considerations in Biomedical HIV Prevention Trials (2012): http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/jc1399_ethical_considerations_en.pdf

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/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html

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

- Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011): https://www.who.int/publications/i/item/9789241502948
- Ethical Issues in Patient Safety Research: Interpreting Existing Guidance (2013): https://www.who.int/publications/i/item/9789241505475

- 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
- Various: https://www.who.int/publications/i?healthtopics=487178c1-f124-4085-bf1f-564051f1cd63

World Medical Association: http://www.wma.net/e/

- 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): http://whqlibdoc.who.int/publications/2005/924159392X_eng.pdf
- Operational Guidance: Information Needed to Support Clinical Trials of Herbal Products (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/docs/imdrf/final/procedural/imdrf-proc-150326-statement-iso141552011.pdf
- 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: http://www.iso.org/iso/iso_catalogue/catalogue_ics/catalogue_detail_ics.htm?csnumber=45557

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): http://www.wpro.who.int/health_research/policy_documents/ministerial_summit_on_health_research_may2005.pdf?ua=1

World Medical Association: http://www.wma.net/e/

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

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: http://www.unesco.org/new/fileadmin/MULTIMEDIA/HQ/SHS/pdf/Soc_Sci_Code.pdf

Privacy/Data Protection

World Medical Association: http://www.wma.net/e/index.htm

- 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/

Human Biological Materials

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

- Infectious Substances and Diagnostic Specimens Shipping Guidelines (2005)

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): www.who.int/csr/emc97_3.pdf

- Guideline for Obtaining Informed Consent for the Procurement and Use of Human Tissues, Cells, and Fluids in Research (2003): http://www.who.int/reproductivehealth/topics/ethics/human_tissue_use.pdf

World Medical Association

- Declaration of Taipei (2016): https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/

Genetic Research

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): http://www.hugo-international.org/img/gene_2001.pdf
- Statement on Human Genomic Databases (2002): https://www.cairn.info/revue-journal-international-de-bioethique-2003-3-page-207.htm

UNESCO Bioethics Program: http://portal.unesco.org/shs/en/ev.php-URL_ID=1372&URL_DO=DO_TOPIC&URL_SECTION=201.html

- Universal Declaration on the Human Genome and Human Rights Section 16 of III Programme for 1998-1999 (1997): http://unesdoc.unesco.org/images/0011/001102/110220e.pdf#page=47
- International Declaration on Human Genetic Data: Section 22 of Major Programme III – Social and Human Sciences (2003): http://unesdoc.unesco.org/images/0013/001331/133171e.pdf#page=45

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 (2006): https://www.isscr.org/docs/default-source/all-isscr-guidelines/hesc-guidelines/isscrhescguidelines2006.pdf?sfvrsn=91f5f996_0

ACKNOWLEDGEMENTS

The HHS Office for Human Research Protections thanks the following individuals for providing updates or confirmations of accuracy for the 2021 edition of the International Compilation of Human Research Standards. We are particularly grateful for the assistance provided by **Dr. Carla Saenz** of the Pan American Health Organization, **Dr. Barbara Sina** of the Fogarty Division of International Training and Research, and **Dr. Jonathan Kagan** of the U.S. National Institute of Allergies and Infectious Diseases.

Multinational Organizations:
Comac Medical Ltd.
Pan American Health Organization
The European Council

Africa:
South Africa: Prof. Douglas R Wassenaar
Zambia: Maureen Mupeta Kombe

Asia/Pacific:
Australia: Jeremy Kenner
India: Dr. Nandini K. Kumar
Japan: Dr. Shimon Tashiro, Takashi Tsuchiya
Malaysia: Dr. Nishakanthi Gopalan, Kuenyei Chin
South Korea: Byung-in (B.I.) Choe, Kyoungtae Park,Yoon-Joung Chang, Sang-Min Park, Jinyoung Jeong, Seoyun Hong

Europe:
Global Regulatory Affairs team at Comac Medical Ltd.
Finland: Marko Ahteensuu
Germany: Claudia Leuker
Macedonia: Marija Todorovska
Serbia: Slobodan Zabunovic
Switzerland: The International Society for Biological and Environmental Repositories (ISBER), Daniel Simeon-Dubach, Celeste Sandoval

Latin America and the Caribbean:
Brazil: Pan American Health Organization (PAHO) - Brazil
Chile: Dr. Juan Pablo Beca
Grenada: Cheryl Cox Macpherson
Mexico: M en C Ma. de los Dolores Delgado Ochoa
Panama: Dr. Claude Vergès
Peru: Dr. Carlos Zamudio Fuertes

Middle East/North Africa:
Jordan: Dr. Amal Al Omari and the King Hussein Cancer Center, Amman
Turkey: Dr. Hamdi Akan

OHRP would also like to thank other anonymous colleagues around the world for their invaluable contribution.