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 However, not all countries provided corroboration, so some of the information contain in this document may be outdated or incomplete (please see disclaimer below).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].”

Last Updated: November 2021
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.
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GENERAL

INTERNATIONAL ORGANIZATIONS


International Committee of the Red Cross (ICRC): [www.icrc.org](http://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/6fe854a3517b75ac125641e004a9e68](https://www.icrc.org/applic/ihl/ihl.nsf/7c4d08d9b287a42141256739003e636b/6fe854a3517b75ac125641e004a9e68)
- Additional Protocol I Relating to the Protection of Victims of International Armed Conflicts, Article 11 (1977): [http://www.icrc.org/ihl.nsf/7c4d08d9b287a42141256739003e636b/f6c8b9fee14a77fdec125641e0052b079](http://www.icrc.org/ihl.nsf/7c4d08d9b287a42141256739003e636b/f6c8b9fee14a77fdec125641e0052b079)


TRUST Project: [http://www.globalcodeofconduct.org](http://www.globalcodeofconduct.org)


- Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011): [https://www.who.int/publications/i/item/9789241502948](https://www.who.int/publications/i/item/9789241502948)


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

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


### 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/


#### Devices

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

- 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 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](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/](http://www.wma.net/e/)

**Research Injury**

**Council for International Organizations of Medical Sciences:** [http://www.cioms.ch/](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/](https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/)

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

**World Medical Association:** [https://www.wma.net/](https://www.wma.net/)

**Social-Behavioral Research**

**UNESCO:** [http://www.unesco.org/](http://www.unesco.org/)

**Privacy/Data Protection**

**World Medical Association:** [http://www.wma.net/e/index.htm](http://www.wma.net/e/index.htm)

**Human Biological Materials**

**International Air Transport Association:** [http://www.iata.org/](http://www.iata.org/)
- Infectious Substances and Diagnostic Specimens Shipping Guidelines (2005)

**International Society for Biological and Environmental Repositories:** [https://www.isber.org/](https://www.isber.org/)

**World Health Organization:** [http://www.who.int/en/](http://www.who.int/en/)

World Medical Association

Genetic Research

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


Embryos, Stem Cells, and Cloning

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

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Comac Medical Ltd.
Pan American Health Organization
The European Council

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Zambia: Maureen Mupeta Kombe

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India: Dr. Nandini K. Kumar
Japan: Dr. Shimon Tashiro, Takashi Tsuchiya
Malaysia: Dr. Nishakanthi Gopalan, Kuenyei Chin
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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.