

International Compilation of Human Research Standards

2014 Edition

Compiled By:
Office for Human Research Protections
U.S. Department of Health and Human Services

PURPOSE

The International Compilation of Human Research Standards enumerates over 1,000 laws, regulations, and guidelines that govern human subjects research in 107 countries, as well as the standards from a number of international and regional organizations. This Compilation was developed for use by researchers, IRBs/Research Ethics Committees, sponsors, and others who are involved in human subjects research around the world.

Content experts, listed on page 128, provided listing updates (or confirmations of accuracy of prior listings), which are reflected in the hundreds of changes to the Compilation. Major changes in human subject standards were reported for Brazil, France, Kyrgyzstan, Switzerland, Taiwan, and Turkey. Three new countries are featured in the 2014 edition: Cameroon, Mozambique, and Zambia.

ORGANIZATION

The Table of Contents is found on page 3. For each country, the standards are categorized by row as:

1. General, i.e., applicable to most or all types of human subjects research
2. Drugs and Devices
3. Research Injury
4. Privacy/Data Protection (also see Privacy International reports: <https://www.privacyinternational.org/reports>)
5. Human Biological Materials
6. Genetic (also see the HumGen International database: <http://www.humgen.umontreal.ca/int/>)
7. Embryos, Stem Cells, and Cloning

These seven categories often overlap, so it may be necessary to review all standards to obtain a full understanding of the country's requirements.

The information is then organized into four columns:

1. Key Organizations – include those groups that issue regulations or guidelines, or serve in a national oversight role for human subjects research.
2. Legislation – encompasses statutes, statutory instruments, and legislative decrees, as well as any pertinent constitutional provisions.
3. Regulations – refer to instruments that are created and issued in the name of governmental administrative bodies.
4. Guidelines – pertain to non-binding instruments.

The year of the document's most recent version (or date of initial approval, if never amended) is indicated in parenthesis when that information is available, unless the date is part of the document's title, e.g., Act 46/2012.

HOW TO ACCESS A DESIRED DOCUMENT

Documents can be accessed in four possible ways:

1. Link to the web address (URL).
2. Search for document at the website of the agency listed in the Key Organizations column.
3. Perform an Internet search on the document title.
4. Request a local research ethics committee to provide the document.

In many cases the documents are available in English. Sometimes the English translation is a non-official version. When the citation links to a non-English document, the language is indicated in parenthesis, e.g., (Spanish).

TOPICS NOT COVERED

In order to focus its scope, the International Compilation of Human Research Standards does not include standards from the state or local levels. Nor does the Compilation cover:

1. Laws, regulations, or guidelines specific to research integrity, clinical bioethics, product liability, clinical trial inspection procedures, intellectual property, or informed consent in clinical practice.
2. Enabling legislation, i.e., laws that authorize an agency to promulgate human subjects regulations, but do not direct the content of those regulations.
3. Ethics codes of academic, medical, or other professional organizations.
4. Working papers, drafts, commentaries, or discussion papers.

UPDATES AND BROKEN LINKS

Updates and broken links should be reported to the attention of Edward E. Bartlett, PhD, International Human Research Liaison, Office for Human Research Protections, U.S. Department of Health and Human Services: edward.bartlett@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. 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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