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)

Africa
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 However, not all countries provided corroboration, so some of the information contain in this document may be outdated or incomplete (please see disclaimer below).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 Africa. 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.
# International Compilation of Human Research Standards
## 2021 Edition

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Last Updated: November 2021
AFRICA – Regionwide

Clinical Trial Registries

Pan African Clinical Trials Registry: http://www.pactr.org/
- PACTR, Terms and Conditions: https://pactr.samrc.ac.za/TermsAndConditions.aspx
- PACTR, FAQs: https://pactr.samrc.ac.za/FAQ.aspx

AFRICA – Algeria

Drugs, Biologics, and Devices

Key Organizations
- Directorate of Pharmacy and Medicine

Relevant Standards
- Order No. 387 of 31 July 2006 Relating to Clinical Trials
- Order No. 00200 of 25 July 2009 Amending Order No. 112 of 22 October 1995 Setting the Rules of Good Clinical Practice

AFRICA – Benin

General

Relevant Standards
- Law No. 2010-40 of 8 December 2010 Regarding the Ethical Code and Duties in Health Research in the Republic of Benin

AFRICA – Botswana

General

Key Organizations
- Ministry of Health and Wellness

Relevant Standards
- Guide for a Consent Form (2005)

Drugs, Biologics, and Devices

Key Organizations
- Ministry of Health and Wellness
Relevant Standards

- Drugs and Related Substances Regulations (1993)
- SADC Guidelines for Regulating Clinical Trials in Human Subjects (2006)
- Guideline for Regulating the Conduct of Clinical Trials Using Medicines in Human Participants (2012)

Social-Behavioral Research

Key Organizations

- Ministry of Health and Wellness

Relevant Standards

- Anthropological Research Act 45 (1967):
  c/f723732/25889598/1422112465653/ch59-02%2BANTHROPOLOGICAL%2BRESEARCH.pdf%3Ftoken%3DTS
  JMnYdWU7ijPvm7Qkzk4uU%253D+&cd=1&hl=en&ct=clnk&gl=us

AFRICA – Burkina Faso

General

Key Organizations

- Ethics Committee for Health Research

Relevant Standards

- Joint Order 2004-147 / MS / MESSE of 11 May 2004 on the Organization and Functioning of the Ethics Committee for Health Research in Burkina Faso

Drugs, Biologics, and Devices

Relevant Standards

- Joint Order 2004-147 / MS / MESSE of 11 May 2004 on the Organization and Functioning of the Ethics Committee for Health Research in Burkina Faso

AFRICA – Cameroon

General

Key Organizations

- Cameroon Bioethics Initiative: www.cambin.org

Relevant Standards

- Ministerial Order No. 079/A/MSP/DS of MINSANTE (1987):
  http://elearning.trree.org/pluginfile.php/34735/mod_folder/content/0/cm-arrete-079-MSP-Crea
  tionComiteEthique-1987.pdf?forcedownload=1
- Operational Guidelines for Ethics Committees in Charge of the Evaluation of Biomedical Research
AFRICA – Congo, Democratic Republic of

**NOTE:** For an overview of clinical research regulations in the Democratic Republic of the Congo, see the ClinRegs report: [https://clinregs.niaid.nih.gov/country/DRC](https://clinregs.niaid.nih.gov/country/DRC)

### General

**Relevant Standards**

- Decree-Law Framework on Public Health, Title VII: Regarding the National Medical Ethics Committee, Biomedical Research, Transplantation of Organs and Tissues, Genetic Treatment, and Cloning: [https://www.mindbank.info/item/2543](https://www.mindbank.info/item/2543)
- Proposal for Ministerial Order No. 1250 Establishing the National Advisory Committee on Ethics Health (2004): [https://healthresearchweb.org/?action=download&file=DRCPOlicy.pdf](https://healthresearchweb.org/?action=download&file=DRCPOlicy.pdf)

AFRICA – Côte-d’Ivoire

### Drugs, Biologics, and Devices

**Key Organizations**

- National Committee on Ethics and Research

**Relevant Standards**


AFRICA – Ethiopia

### General

**Key Organizations**

- Ethiopian Science and Technology Commission, Health Department

**Relevant Standards**

- Proclamation 60/1999, Section 21

### Drugs, Biologics, and Devices

**Key Organizations**

- Food, Medicine, and Health Administration and Control Authority: [www.fmhaca.gov.et](http://www.fmhaca.gov.et)

**Relevant Standards**

- Drug Administration and Control Proclamation No. 176/1999, Article 21
Human Biological Materials

Key Organizations
- Ethiopian Science and Technology Commission, Health Department

Relevant Standards

AFRICA – Gambia

Genetic Research

Key Organizations
- MRC: Gambia Unit: http://www.mrc.gm/

Relevant Standards
- Guidelines of the National DNA Bank (2001)

AFRICA – Ghana

NOTE: For an overview of the clinical trial information in Ghana, see: http://www.fdaghana.gov.gh/index.php?option=com_content&view=article&id=71&Itemid=55

Drugs, Biologics, and Devices

Key Organizations
- Food and Drugs Authority: http://www.fdaghana.gov.gh

Relevant Standards
AFRICA – Guinea

NOTE: For an overview of the clinical research regulations in Guinea, see the ClinReg report: https://clinregs.niaid.nih.gov/single_country.php?c_id=90

General

Key Organizations
- National Ethics Committee on Health Research (CNERS): http://cners-guinee.org/

Relevant Standards

Research Injury

Key Organizations
- National Ethics Committee on Health Research: http://cners-guinee.org/

Relevant Standards

AFRICA – Kenya


General

Key Organizations
- Ministry of Health (MOH): www.health.go.ke/

Relevant Standards
- Science and Technology Act (2001)

Drugs, Biologics, and Devices

Key Organizations
- Pharmacy and Poisons Board: http://www.pharmacyboardkenya.org/
Relevant Standards


Human Biological Materials

Key Organizations
- Ministry of Health (MOH): www.health.go.ke/

Relevant Standards

AFRICA – Liberia

NOTE: For an overview of the clinical research regulations in Liberia, see the ClinRegs report: https://clinregs.niaid.nih.gov/single_country.php?c_id=122

General

Key Organizations

Relevant Standards

Drugs, Biologics, and Devices

Key Organizations
- Liberia Medicines and Health Products Regulatory Authority

Relevant Standards

AFRICA – Madagascar

Drugs, Biologics, and Devices

Relevant Standards
AFRICA – Malawi

NOTE: For an overview of the clinical research regulations in Malawi, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=129

General

Key Organizations
- National Health Sciences Research Committee (NHSRC): http://www.ncst.mw/national-health-science-research-committee-nhsrc/
- College of Medicine Research and Ethics Committee (COMREC): http://www.medcol.mw/
- Ministry of Health: www.malawi.gov.mw

Relevant Standards
- Presidential Decree on 30th March 1974
- Malawi Government Gazette, June 11, 1976, General Notice No. 398
- NCST, National Policy Measures and Requirements for the Improvement of Health Research Coordination in Malawi (2012)
- NHSRC, Operational Guidelines (2001)
- NHSRC, Summary Guidelines for Writing Research Proposals (2001)

Drugs, Biologics, and Devices

Key Organizations
- Pharmacy, Medicines, and Poisons Board of Malawi

Relevant Standards
Social-Behavioral Research

Key Organizations
- National Committee on Research in the Social Sciences and Humanities

Relevant Standards

Human Biological Materials

Key Organizations
- National Commission for Science and Technology: www.ncst.mw

Relevant Standards

Genetic Research

Key Organizations

Relevant Standards
- Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi (2002)

AFRICA – Mali

NOTE: For an overview of clinical research regulations in Mali, see the ClinRegs report: https://clinregs.niaid.nih.gov/country/mali

Drugs, Biologics, and Devices

Key Organizations
- Directorate of Pharmacy and Medicine

Relevant Standards
## AFRICA – Mozambique

### General

#### Relevant Standards

- Science and Technology Ethics Code (2007):
  [http://elearning.trree.org/pluginfile.php/34764/mod_folder/content/0/02-CodigoDeEtica.pdf?forcedownload=1](http://elearning.trree.org/pluginfile.php/34764/mod_folder/content/0/02-CodigoDeEtica.pdf?forcedownload=1)

## AFRICA – Nigeria

### General

#### Key Organizations

- National Health Research Ethics Committee: [https://nhrec.net/](https://nhrec.net/)

#### Relevant Standards

- Guides and Forms, various: [https://nhrec.net/download-guides-and-forms/](https://nhrec.net/download-guides-and-forms/)

### Drugs, Biologics, and Devices

#### Key Organizations


#### Relevant Standards

- Decree No. 15 of 1993

### Clinical Trial Registries

#### Key Organizations

- National Health Research Ethics Committee: [http://nhrec.net/](http://nhrec.net/)

#### Relevant Standards

- Frequently Asked Questions: [http://nctr.nhrec.net](http://nctr.nhrec.net)
Social-Behavioral Research

Key Organizations
- National Health Research Ethics Committee: [http://nhrec.net/](http://nhrec.net/)

Relevant Standards

Human Biological Materials

Key Organizations
- National Health Research Ethics Committee: [http://nhrec.net/](http://nhrec.net/)

Relevant Standards

AFRICA – Rwanda

General

Key Organizations
- Ministry of Health: [https://www.moh.gov.rw/](https://www.moh.gov.rw/)
- National Ethics Committee: [http://www.rnecrwanda.org/](http://www.rnecrwanda.org/)

Relevant Standards
- Laws, various: [https://www.moh.gov.rw/publications?tx_filelist_filelist%5Baction%5D=list&tx_filelist_filelist%5Bcontroller%5D=File&tx_filelist_filelist%5Bpath%5D=2Fuser_upload%2FMoh%2FPublications%2FLaws%2F&cHash=7954b6ed1a3eebee62f86b8f124eab94](https://www.moh.gov.rw/publications?tx_filelist_filelist%5Baction%5D=list&tx_filelist_filelist%5Bcontroller%5D=File&tx_filelist_filelist%5Bpath%5D=2Fuser_upload%2FMoh%2FPublications%2FLaws%2F&cHash=7954b6ed1a3eebee62f86b8f124eab94)

AFRICA – Senegal

General

Key Organizations
- National Committee on Health Research Ethics

Relevant Standards
- Law Supporting the Code of Ethics for Health Research (2009)

AFRICA – Sierra Leone


General

Key Organizations
- Sierra Leone Ethics and Scientific Review Committee
Relevant Standards


Drugs, Biologics, and Devices

Key Organizations

- Ministry of Health: http://www.sante.gov.bf/
- Pharmacy Board of Sierra Leone: http://www.pharmacyboard.gov.sl/

Relevant Standards

- Guidelines for Conducting Clinical Trials of Medicines, Food Supplements, Vaccines, and Medical Devices in Sierra Leone, Sections: 3.1.7 and 3.2 (2014): https://www.medbox.org/pdf/5e148832db60a2044c2d399a
- Clinical Trials, various: http://www.pharmacyboard.gov.sl/Resources/ClinicalTrials.aspx

AFRICA – South Africa


General

Key Organizations

- Medical Research Council of South Africa (MRC): https://www.samrc.ac.za/
- Human Sciences Research Council (HSRC): http://www.hsrc.ac.za/en/about/research-ethics
- South African Health Products Regulatory Authority: https://protect-za.mimecast.com/s/5WP2Cr07VKf1mK59tzNft9?domain=sahpra.org.za/

Relevant Standards

Drugs, Biologics, and Devices

Key Organizations
- Health Products Regulatory Authority: https://www.sahpra.org.za/

Relevant Standards

Clinical Trials Registry

Key Organizations
- South African National Clinical Trials Register: https://sanctr.samrc.ac.za/

Relevant Standards
- FAQs: https://sanctr.samrc.ac.za/FAQ.aspx

Social-Behavioral Research

Key Organizations

Relevant Standards

Human Biological Materials

Key Organizations

Relevant Standards
Genetic Research

Key Organizations
- Medical Research Council of South Africa (MRC): https://www.samrc.ac.za/

Relevant Standards

Embryos, Stem Cells, and Cloning

Key Organizations
- Medical Research Council of South Africa (MRC): https://www.samrc.ac.za/

Relevant Standards

AFRICA – Tanzania

NOTE: For an overview of the clinical research regulations in Tanzania, see the ClinReg report: http://clinregs.niaid.nih.gov/single_country.php?c_id=212

General

Key Organizations
- Ministry of Health (MOH)
- National Institute for Medical Research (NIMR): http://www.nimr.or.tz/
- National Health Research Ethics Committee (NHREC):
- Tanzania Commission for Science and Technology (COSTECH): https://www.costech.or.tz/

Relevant Standards
### International Compilation of Human Research Standards  
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- Tanzania Commission for Science and Technology, Act No. 7 of 1986:  
  [https://www.costech.or.tz/storage/uploads/mSre0zVqCMimUglsnKrOrRlqHPgNxwwF1rpnkjX0.pdf](https://www.costech.or.tz/storage/uploads/mSre0zVqCMimUglsnKrOrRlqHPgNxwwF1rpnkjX0.pdf)
- NIMR, Research Policies, Guidelines, and Regulations:  
- COSTECH, Various, including Guidelines on Research Permits and Clearance (2006): Various:  
  [https://www.costech.or.tz/documents-and-publications](https://www.costech.or.tz/documents-and-publications)

### Drugs, Biologics, and Devices

#### Drugs

**Key Organizations**
- Tanzania Medicines and Medical Devises Authority:  
  [https://www.tmda.go.tz/](https://www.tmda.go.tz/)

**Relevant Standards**
- Tanzania Food, Drugs, and Cosmetics Act, Sections 61, 66, 67, and 69 (2003):  

#### Devices

**Key Organizations**
- Tanzania Medicines and Medical Devises Authority:  
  [https://www.tmda.go.tz/](https://www.tmda.go.tz/)

**Relevant Standards**
- Medical devices, various:  

### Clinical Trials Registry

**Key Organizations**
- Tanzania Commission for Science and Technology (COSTECH):  
  [https://www.costech.or.tz/](https://www.costech.or.tz/)

**Relevant Standards**
- COSTECH, Database, Funded Projects:  
  [https://www.costech.or.tz/funded-projects](https://www.costech.or.tz/funded-projects)
- Various:  
  [https://www.costech.or.tz/documents-and-publications](https://www.costech.or.tz/documents-and-publications)

### AFRICA – Uganda

**NOTE:** For an overview of the clinical research regulations in Uganda, see the ClinReg report:  

### General

**Key Organizations**
- Uganda National Council for Science and Technology (UNCST):  
Relevant Standards


**Drugs, Biologics, and Devices**

### Key Organizations

- National Drug Authority: [http://www.nda.or.ug/](http://www.nda.or.ug/)

### Relevant Standards

- National Drug Policy and Authority Act Regulations: [https://www.nda.or.ug/ndpa-act-regulations/](https://www.nda.or.ug/ndpa-act-regulations/)
- Clinical Trial Application Forms: [https://www.nda.or.ug/application-forms/](https://www.nda.or.ug/application-forms/)

**AFRICA – Zambia**

### General

**Key Organizations**

- Ministry of Health: [https://www.moh.gov.zm/](https://www.moh.gov.zm/)

**Relevant Standards**


**Drugs, Biologics, and Devices**

**Key Organizations**

- Zambia Medicines Regulatory Authority: [http://www.zamra.co.zm/](http://www.zamra.co.zm/)

**Relevant Standards**

- Guidelines on Regulating the Conduct of Clinical Trials in Human Participants: [https://www.who.int/medicines/areas/coordination/zambia_clinical_trials.pdf](https://www.who.int/medicines/areas/coordination/zambia_clinical_trials.pdf)
Human Biological Materials

**Relevant Standards**

- National Health Research Act, Part VI (2013):

AFRICA – Zimbabwe

**General**

**Key Organizations**

- Medical Research Council of Zimbabwe: [http://www.mrcz.org.zw](http://www.mrcz.org.zw)

**Relevant Standards**

- Research Act (1986)
- Ethics Guidelines for Health Research Involving Human Participants in Zimbabwe

Drugs, Biologics, and Devices

**Drugs**

**Key Organizations**

- Medicines Control Authority of Zimbabwe: [http://www.mcaz.co.zw/](http://www.mcaz.co.zw/)

**Relevant Standards**

- Medicines and Allied Substances Control Act, Chapter 15:03 (1997)
- Medicines and Allied Substances Control Act, General Regulations (1991)
- Statutory Instrument 150 of 1991

**Devices**

**Key Organizations**

- Medicines Control Authority of Zimbabwe: [https://www.mcaz.co.zw/](https://www.mcaz.co.zw/)

**Relevant Standards**

- Medicines and Allied Substances Control Act, Various Regulations: [https://www.mcaz.co.zw/index.php/downloads/category/7-regulations](https://www.mcaz.co.zw/index.php/downloads/category/7-regulations)
Privacy/Data Protection

Key Organizations
- Registrar General: http://www.rg.gov.zw/
- Zimbabwe National Statistics Agency: http://www.zimstat.co.zw/

Relevant Standards
- Access to Information and Protection of Privacy Act, Chapter 10:27: http://www.veritaszim.net/node/240#:~:text=An%20Act%20to%20provide%20members,or%20discl osure%20of%20personal%20information

Human Biological Materials

Key Organizations
- Research Council of Zimbabwe: www.rcz.ac.zw

Relevant Standards
- Various: http://www.rcz.ac.zw/research-registration/

Genetic Research

Key Organizations
- National Biotechnology Authority of Zimbabwe: http://www.nba.ac.zw/

Relevant Standards
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