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)

Africa

OASH | Office for Human Research Protections

AFRICA

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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.

TABLE OF CONTENTS

AFRICA – Regionwide

Clinical Trial Registries

Pan African Clinical Trials Registry: https://pactr.samrc.ac.za/

- PACTR, Terms and Conditions: https://pactr.samrc.ac.za/TermsAndConditions.aspx
- PACTR, FAQs: https://pactr.samrc.ac.za/FAQ.aspx
- African Clinical Trials Community: https://ctc.africa/

AFRICA – Angola

General

Key Organizations

- National Institute for Health Research (INIS): https://inis.gov.ao/
- INIS Ethics Committee (CEINIS): https://inis.gov.ao/comite-de-etica/

Relevant Standards

- INIS/CEINIS, Documents and Forms Required for Submitting Protocols: https://inis.gov.ao/comite-de-etica/

AFRICA – Benin

General

Key Organizations

- Ministry of Health: http://www.sante.gouv.bj/

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: https://www.moh.gov.bw/

Relevant Standards

- Anthropological Research Act 45 (1967): https://botswanalaws.com/consolidated-statutes/principle-legislation/anthropological-research
- Botswana National Drug (Medicine) Policy, Section 15 (2002, First Edition published 2005): www.moh.gov.bw/nationalmedicinepolicy/2002/2005
- Guidelines for Application for Research Permit: https://www.gov.bw/learning-and-teaching/application-research-permit
- National Health Quality Standards (2013): https://www.moh.gov.bw/Publications/standards/Volume_1_ED.pdf

Drugs, Biologics, and Devices

Key Organizations

- Ministry of Health and Wellness: https://www.moh.gov.bw/

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)

AFRICA – Burkina Faso

General

Key Organizations

- Ministry of Health and Public Hygiene: https://www.sante.gov.bf/accueil
- Technical Directorate of the National Institute of Public Health (INSP), The MURAZ Center: https://www.centre-muraz.bf/le-centre-muraz/
- Ministry of Health and Public Hygiene, Fundamental Texts: https://www.sante.gov.bf/ressources/textes-fondamentaux

AFRICA – Cameroon

General

Key Organizations

- Cameroon Bioethics Initiative: www.cambin.org
- Republic of Cameroon, Presidency of the Republic: https://www.prc.cm/en/

Relevant Standards

- Ministerial Order No. 079/A/MSP/DS of MINSANTE (1987): https://www.prc.cm/79/A/MSP/DS/1987
- Law on Medical Research Involving Humans (2022): https://perma.cc/DV9U-JZZQ

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

General

Key Organizations

- Ministry of Health: https://sante.gouv.cd/

Relevant Standards

- Order No. 1250 on the Organization of the National System of Pharmacovigilance in the Democratic Republic of Congo (2015): https://www.leganet.cd/1250/2015/
- Guidelines for the Ethical Evaluation of Research Involving Human Subjects in the Democratic Republic of Congo (2011) (French): https://clinregs.niaid.nih.gov/sites/default/files/documents/DRC/G-EthicalEval.pdf

AFRICA – Côte-d'Ivoire

General

Key Organizations

- Ministry of Health, Public Hygiene and Universal Health Coverage: https://guce.gouv.ci/health

Drugs, Biologics, and Devices

Key Organizations

- Ivorian Authority for Pharmaceutical Regulation (AIRP): https://www.airp.ci/

Relevant Standards

- Decree No. 2020-407 of April 22, 2020, Regulating Clinical Trials
- Order Relating to the Organization and Operation of the National Committee for Ethics in Life Sciences and Health (2018): https://api.airpdigital.com/nationalcommitteeethicslifesciencesandhealth/order/2018/
- Decision No. 03, Regulation of Medical Devices (2022): https://api.airpdigital.com/regulationofmedicaldevices/03/2022

AFRICA – Ethiopia

General

Key Organizations

- Ministry of Health: https://www.moh.gov.et/
- Ethiopian Science and Technology Commission, Health Department

Relevant Standards

- Proclamation 60/1999, Section 21
- National Health Research Ethics Review Guideline (2020): https://learning.ahri.gov.et/nationalhealthresearchethicsreview/guideline/2020

Drugs, Biologics, and Devices

Key Organizations

- Ethiopian Food and Drug Authority (EFDA): http://www.efda.gov.et/

Relevant Standards

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

- Pharmacovigilance and Clinical Trial Lead Executive Office Guideline for Clinical Trial Authorization: http://www.efda.gov.et/wp-content/uploads/2023/10/Clinical-Trial-Authorization-Guideline-4th-edition.pdf
- Proclamations, various: http://www.fmhaca.gov.et/doc-category/policies-legislation-and-regulation/proclamations/
- Regulations, various: http://www.fmhaca.gov.et/doc-category/policies-legislation-and-regulation/regulations/
- Policies, various: http://www.fmhaca.gov.et/doc-category/policies-legislation-and-regulation/policies/

AFRICA – Gambia

General

Key Organizations

- MRC: The Gambia Unit (London School of Hygiene & Tropical Medicine): http://www.mrc.gm/
- Gambia Research Ethics and Methodology Training Initiative (GamREMTI): https://gamremti.gm/

Relevant Standards

- MRC, Research Governance & Integrity: https://www.lshtm.ac.uk/research/research-governance-integrity
- 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/

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

- Act 851, Public Health Act, 2012: https://bcp.gov.gh/publichealthact/851/2012
- Applications for Clinical Trials as Defined Under Section 150-166 (Part 8) of the Public Health Act 2012, Act 851: http://www.fdaghana.gov.gh/applicationsforclinicaltrials/publichealthact/851/2012
- Clinical Trials, Biological Products, Devices, and More, Guidelines and Forms, various: http://www.fdaghana.gov.gh/operational-guide.php
- Clinical Trials, Biological Products, Devices, and More, Operational Guidelines, various: http://www.fdaghana.gov.gh/application-form.php

AFRICA – Guinea

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

General

Key Organizations

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

Relevant Standards

- Public Health Code, Articles 237-316 (1997): http://www.verti.org/media/National%20Legislation/Guinea/GN_Code_Sante_Publique.pdf
- Decree No. D/218/PRG/SGG: On the Establishment, Functions and Organization of the National Ethics Committee for Research in Health (CNERS), Chapters I and II (1998): https://cners-guinee.org/CNERS/D/218/1998
- CNERS, Frequently Asked Questions: http://cners-guinee.org/faq/

Research Injury

Key Organizations

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

Relevant Standards

- Public Health Code, Articles 301-302 (1997): http://www.vertic.org/publichealthcode/301-302/1997

AFRICA – Kenya

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

General

Key Organizations

- National Council for Science and Technology (NCST): http://www.nacosti.go.ke/
- Ministry of Health (MOH): www.health.go.ke/

Relevant Standards

- Science and Technology Act (2001)
- HIV and AIDS Prevention and Control Act, Chapter 14 (2006)
- MOH, National Guidelines for Ethical Conduct of Research Involving Human Subjects (2008): https://healthresearchweb.org/nationalguidelinesethicalconductofresearchhumansubjects/2008

Drugs, Biologics, and Devices

Key Organizations

- Pharmacy and Poisons Board: http://www.pharmacyboardkenya.org/

Relevant Standards

- MOH, Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines (2005)
- Guidelines for the Conduct of Clinical Trials in Kenya (2022): https://pharmacyboardkenya.org/guidelines-for-the-conduct-of-clinical-trials-in-kenya/
- Guidelines for the conduct of clinical trials during public health emergencies and pandemics in Kenya (2022): https://pharmacyboardkenya.org/guidelines-for-the-conduct-of-clinical-trials-during-public-health-emergencies-and-pandemics-in-kenya/

Human Biological Materials

Key Organizations

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

Relevant Standards

- Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines, page 44 (2005): https://www.globalgiving.org/pfil/1108/projdoc.pdf

AFRICA – Liberia

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

General

Key Organizations

- Ministry of Health and Social Welfare: https://moh.gov.lr/

Relevant Standards

- Institutional Review Board (IRB) Policies and Procedures Handbook (2020): https://clinregs.niaid.nih.gov/IRBpoliciesprocedures/2020
- Ethics Committee Guidelines: Procedures for Researchers, Section 1 (2011): http://clinregs.niaid.nih.gov/ethicscommitteeguidelines/researchers/2011
- Operational Guidelines of the National Research Ethics Board (2019): https://clinregs.niaid.nih.gov/operationalguidelines/nationalresearchethicsboard/2019
- Guideline for Application to Conduct Clinical Trials in Liberia (2014): https://clinregs.niaid.nih.gov/documents/liberia/G-LibClinTrial.pdf

AFRICA – Madagascar

General

Key Organizations

- Ministry of Public Health (MSANP): http://www.sante.gov.mg/ministere-sante-publique/

Relevant Standards

- National Health Policy (2016): http://www.sante.gov.mg/nationalhealthpolicy/2016
- National Health Research Policy (2016)

AFRICA – Malawi

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

General

Key Organizations

- National Commission for Science and Technology (NCST): http://www.ncst.mw/
- 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: https://www.health.gov.mw/

Relevant Standards

- Constitution of Malawi, Article 19(5) (1994): https://www.constituteproject.org/constitution/Malawi_2017
- NCST, Research Policies and Guidelines: https://www.ncst.mw/policies-and-guidelines/
- NCST, National Committee on Research In The Social Sciences And Humanities: https://www.ncst.mw/national-committee-on-research-in-the-social-sciences-and-humanities/
- COMREC, Research Policies and Procedures: https://www.medcol.mw/research-policies-and-procedures/

Drugs, Biologics, and Devices

Key Organizations

- Pharmacy, Medicines, and Poisons Board of Malawi

Relevant Standards

- Pharmacy, Medicines, and Poisons Act (2014): https://malawilii.org/pharmacymedicinesandpoisonsact/2014

Social-Behavioral Research

Key Organizations

- National Committee on Research in the Social Sciences and Humanities

Relevant Standards

- Framework of Guidelines for Research in the Social Sciences and Humanities in Malawi (2011): http://www.ncst.mw/framework/guidelines/researchinssh/2011

Human Biological Materials

Key Organizations

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

Relevant Standards

- National Regulatory Requirement and Position on Accessing, Collection, Storage, and Use of Human Biological Specimens for Research (2014): https://www.ncst.mw/wp-content/uploads/2014/03/National-regulatory-requirement-on-human-samples.pdf
- Circular on Human Biological Samples and Participants Recompense in Research Involving Human Subjects (2019): https://clinregs.niaid.nih.gov/circular/humanbiologicalsamples/participantsrecompense/researchhumansubjects/2019

Genetic Research

Key Organizations

- National Research Council of Malawi (NRCM): www.sdnp.org.mw/nrcm/

Relevant Standards

- Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi (2003): https://www.future-agricultures.org/procedures/guidelines/geneticresources/2003

AFRICA – Mali

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

Relevant Standards

- Law No. 09-059 of 28 December 2009 Governing Biomedical Research on Humans: https://clinregs.niaid.nih.gov/documents/LawNo09-059.pdf

AFRICA – Namibia

General

Key Organizations

- Ministry of Health and Social Services: https://mhss.gov.na/

Drugs, Biologics, and Devices

Key Organizations

- Namibia Medicines Regulatory Council (NMRC): https://nmrc.gov.na/

Relevant Standards

- Namibia Medicines and Related Substances Control Act 2003 Act No 13 of 2003Namibia Medicines Regulatory Council Guideline for Section 27 Applications: https://nmrc.gov.na/downloads/-/document_library/fWrwrqO3yOpJ/view_file/81842

- NMRC, National Guidelines for Medicine Safety Surveillance (2011): https://nmrc.gov.na/downloads/-/document_library/fWrwrqO3yOpJ/view_file/410136

AFRICA – Nigeria

General

Key Organizations

- National Health Research Ethics Committee: https://nhrec.net/
- Ministry of Health: http://site.health.gov.ng/

Relevant Standards

- National Health Act (2014): https://nigeriahealthwatch.com/nationalhealthact/2014
- Nigerian Code of Health Research Ethics (2007): http://www.nhrec.net/codeofhealthresearchethics/2007
- Policy Statement Regarding Enrollment of Children in Research in Nigeria (2016): http://nhrec.net/childreninresearch/2016
- Guides and Forms, various: https://nhrec.net/download-guides-and-forms/

Drugs, Biologics, and Devices

Key Organizations

- National Agency for Food, Drug Administration and Control (NAFDAC): http://www.nafdac.gov.ng/

Relevant Standards

- Decree No. 15 of 1993: https://faolex.fao.org/docs/pdf/nig48230.pdf
- Good Clinical Practice Guidelines (2020): https://www.nafdac.gov.ng/NAFDAC-Good-Clinical-Practices-Guidelines-2020
- NAFDAC, Various Guidelines (filter by product type): https://nafdac.gov.ng/regulatory-resources/guidelines/
- NAFDAC, Various Gazette Regulations (filter by product type): https://nafdac.gov.ng/regulatory-resources/nafdac-regulations/

Clinical Trial Registries

Key Organizations

- National Health Research Ethics Committee: http://nhrec.net/

Relevant Standards

- Frequently Asked Questions: http://nctr.nhrec.net

Social-Behavioral Research

Key Organizations

- National Health Research Ethics Committee: http://nhrec.net/

Relevant Standards

- Nigerian Code of Health Research Ethics (2007): http://www.nhrec.net/nhrec/NCHRE_Aug%2007.pdf

Human Biological Materials

Key Organizations

- National Health Research Ethics Committee: http://nhrec.net/

Relevant Standards

- Policy Statement on Storage of Human Samples in Biobanks and Biorepositories in Nigeria (2013): http://nhrec.net/nhrec/NHREC_Policy_Statement_on_Biobanks_FINAL.pdf

AFRICA – Rwanda

General

Key Organizations

- Ministry of Health: https://www.moh.gov.rw/
- National Ethics Committee: http://www.rnecrwanda.org/
- National Council for Science and Technology: https://www.ncst.gov.rw/

Relevant Standards

- Laws, various: https://www.moh.gov.rw/laws

AFRICA – Senegal

General

Key Organizations

- National Committee on Health Research Ethics (CNERS): https://www.cners.sn/

Relevant Standards

- For a comprehensive listing of research ethics standards in Senegal, visit https://www.cners.sn/, click on "About," then click on "Resources."

AFRICA – Sierra Leone

NOTE: For an overview of the clinical research regulations in Sierra Leone, see the ClinRegs report: https://clinregs.niaid.nih.gov/country/sierra-leone

Relevant Standards

- Application Guidelines (2017): https://mohs2017.files.wordpress.com/2017/03/guidelines-and-checklist-for-ethical-clearance-2017.pdf

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

- Clinical Trials, Various: http://www.pharmacyboard.gov.sl/ClinicalTrials.php
- Good Clinical Practice Guidelines (2021): https://pharmacyboard.gov.sl/gcpguidelines/2021
- Guidelines for the Application and Authorization of Clinical Trials of Medicines, Vaccines, and Medical Devices (2021): https://pharmacyboard.gov.sl/guidelines/clinicaltrials/2021
- Guidelines for the Inspection of Clinical Trials (2021): https://pharmacyboard.gov.sl/guidelines/inspectionofclinicaltrials/2021
- 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/guidelines/conductingclinicaltrials/2014
- Guideline for Good Clinical Practice (GCP) in Sierra Leone, Sections 3.2 and 3.3 (2018): https://clinregs.niaid.nih.gov/guideline/GCP/2018

AFRICA – South Africa

NOTE: For an overview of the clinical research regulations in South Africa, see the ClinRegs report: https://clinregs.niaid.nih.gov/country/south-africa

General

Key Organizations

- Department of Health (DH): http://www.health.gov.za/
- 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://sahpra.org.za/

Relevant Standards

- Constitution of South Africa, Section 12 (2) (1996): https://www.gov.za/documents/constitution/constitution-republic-south-africa-1996-1
- National Health Act No. 61, Chapter 9 (2003): https://www.gov.za/nationalhealthact/2003
- Regulations Relating to Research with Human Participants No. R719 (2014): https://www.gov.za/regulations/researchhumanparticipants/2014
- DH, Ethics in Health Research: Principles, Structures, and Processes (2015): https://www.sun.ac.za/ethicsinhealthresearch/2015
- MRC, Various Guideline Documents: https://www.samrc.ac.za/research/ethics/guideline-documents

Drugs, Biologics, and Devices

Key Organizations

- Department of Health (DH): http://www.health.gov.za/
- Health Products Regulatory Authority: https://www.sahpra.org.za/

Relevant Standards

- Medicines and Related Substances Control Act, 101 of 1965: https://www.gov.za/documents/drugs-control-act-7-jul-1965-0000
- General Regulations Made in Terms of the Medicines and Related Substances Act, 1965 (2003)
- South African Good Clinical Practice: Clinical Trial Guidelines (2020): https://www.sahpra.org.za/wp-content/uploads/2021/06/SA-GCP-2020_Final.pdf

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

- Department of Health (DH): http://www.health.gov.za/

Relevant Standards

- Ethics in Health Research: Principles, Processes, and Structures, Section 3.3.7(i) (2015): https://www.sun.ac.za/ethicsinhealthresearch/2015

Human Biological Materials

Key Organizations

- Department of Health (DH): http://www.health.gov.za/

Relevant Standards

- National Health Act No. 61, Chapter 8, Sections 53-68 (2003): https://www.gov.za/nationalhealthact/2003
- Regulations Relating to the Use of Human Biological Material, 2 March 2012: https://www.gov.za/sites/default/files/gcis_document/201409/35099rg9699gon177.pdf
- Regulations Relating to Blood and Blood Products, 2 March 2012: https://www.gov.za/sites/default/files/gcis_document/201409/35099rg9699gon180.pdf
- Regulations Relating to Artificial Insemination of Persons (2016): https://www.gov.za/sites/default/files/gcis_document/201609/40312gon1165.pdf

Genetic Research

Key Organizations

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

Relevant Standards

- Guidelines on Ethics for Medical Research, Reproductive Biology and Genetic Research (2002): http://www.kznhealth.gov.za/research/ethics2.pdf

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

- National Health Act No. 61, Chapter 8, Section 57 (2003)
- Regulations relating to Stem Cell Banks, 2 March 2012: https://www.gov.za/sites/default/files/gcis_document/201409/35099rg9699gon183.pdf
- Guidelines on Ethics in Reproductive Biology and Genetic Research (2002): http://www.kznhealth.gov.za/research/ethics2.pdf

AFRICA – Tanzania

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

General

Key Organizations

- Ministry of Health (MOH): https://www.moh.go.tz/
- National Institute for Medical Research (NIMR): http://www.nimr.or.tz/
- National Health Research Ethics Committee (NHREC): https://www.health.gov.ng/Source/74/National-Health-Research-Ethics-Committee
- Tanzania Commission for Science and Technology (COSTECH): https://www.costech.or.tz/

Relevant Standards

- National Institute for Medical Research, Act of Parliament No. 23, of 1979: https://nimr.or.tz/wp-content/uploads/2022/01/NIMR_Act.pdf
- Tanzania Commission for Science and Technology, Act No. 7 of 1986: http://www.parliament.go.tz/commissionforscienceandtechnology/1986
- NIMR, Research Policies, Guidelines, and Regulations (1979): https://nimr.or.tz/wp-content/uploads/2022/03/NIMR-Research-Policy.pdf
- Guidelines on Ethics for Health Research in Tanzania (2009): https://clinregs.niaid.nih.gov/documents/tanzania/G-EthicsHR.pdf
- The Personal Data Protection (Personal Data Collection and Processing) Regulations, 2023: https://oagmis.agctz.go.tz/portal/legislation/1350

Drugs, Biologics, and Devices

Key Organizations

- Tanzania Medicines and Medical Devises Authority: https://www.tmda.go.tz/

Relevant Standards

- Tanzania Food, Drugs, and Cosmetics Act, Sections 61, 66, 67, and 69 (2003) : https://www.tmda.go.tz/fooddrugscosmeticsact/2003
- Medical devices, various: https://www.tmda.go.tz/publications/39
- Tanzania Commission for Science and Technology (COSTECH): https://www.costech.or.tz/

AFRICA – Uganda

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

General

Key Organizations

- Ministry of Health: https://www.health.go.ug/
- Uganda National Council for Science and Technology (UNCST): https://www.uncst.go.ug/

Relevant Standards

- Uganda National Council for Science and Technology Act of 1990 (CAP 209): https://faolex.fao.org/docs/pdf/uga96724.pdf
- National Guidelines for Research Involving Humans as Research Participants (2014): https://iuea.ac.ug/sitepad-data/uploads//2021/03/Human-Subjects-Protection-Guidelines-July-2014.pdf
- Research Registration and Clearance Policy and Guidelines (2016): https://clinregs.niaid.nih.gov/sites/default/files/documents/uganda/G-UNCSTreg.pdf
- National Guidelines for the Conduct of Research During the COVID-19 Pandemic (2020): https://www.uncst.go.ug/manage/files/downloads/National%20Guidelines(1).pdf

Drugs, Biologics, and Devices

Key Organizations

- National Drug Authority: http://www.nda.or.ug/

Relevant Standards

- Human Medicine Guidelines, including Guidelines for the Conduct of Drug Related Clinical Trials (2019): https://www.nda.or.ug/human-medicine-guidelines/
- National Drug Policy and Authority Act Regulations: https://www.nda.or.ug/ndpa-act-regulations/
- Human Medicine Guidelines: https://www.nda.or.ug/human-medicine-guidelines/
- Clinical Trial Application Forms: https://www.nda.or.ug/application-forms/

- National Research Biobanking Guidelines (2021): https://www.uncst.go.ug/manage/files/downloads/National_Biobanking_Gudelines(2).pdf

AFRICA – Zambia

General

Key Organizations

- Ministry of Health: https://www.moh.gov.zm/

Relevant Standards

- National Health Research Act (2013): http://www.parliament.gov.zm/nationalhealthresearchact/2013

Drugs, Biologics, and Devices

Key Organizations

- Zambia Medicines Regulatory: Authority: http://www.zamra.co.zm/

Relevant Standards

- Medicines and Allied Substances Act, Part VI: Regulation of Clinical Trials, 2013: https://www.parliament.gov.zm/medicinesalliedsubstancesact/2013
- Guidelines on Regulating the Conduct of Clinical Trials in Human Participants, First Edition: https://www.zamra.co.zm/wp-content/uploads/2023/05/Guidelines-on-Application-for-Clincal-Trial-Authorisation.pdf

Human Biological Materials

Relevant Standards

- National Health Research Act, Part VI (2013): http://www.parliament.gov.zm/nationalhealthresearchact/2013

AFRICA – Zimbabwe

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

General

Key Organizations

- Ministry of Health and Child Care: https://www.mohcc.gov.zw/
- Medical Research Council of Zimbabwe: http://www.mrcz.org.zw

Relevant Standards

- Research Act (1986): https://faolex.fao.org/docs/pdf/zim93551.pdf
- Medical Research Council of Zimbabwe, Various Protocol-related Forms: http://www.mrcz.org.zw/forms/

Drugs, Biologics, and Devices

Key Organizations

- Medicines Control Authority of Zimbabwe: https://www.mcaz.co.zw/

Relevant Standards

- Medicines and Allied Substances Control Act, Chapter 15:03 (1997): https://www.jsc.org.zw/upload/Acts/2016/1503updated.pdf
- Medicines and Allied Substances Control Act, General Regulations (1991): https://faolex.fao.org/docs/pdf/zim117614.pdf
- Statutory Instrument 150 of 1991: https://faolex.fao.org/docs/pdf/zim117614.pdf
- Pharmacovigilance and Clinical Trials, Various Guidelines: https://www.mcaz.co.zw/pharmacoviligance-and-clinical-trials/clinical-trials

Privacy/Data Protection

Key Organizations

- Zimbabwe National Statistics Agency: http://www.zimstat.co.zw/

Relevant Standards

- Constitution of Zimbabwe of 2013, Section 57: https://www.constituteproject.org/constitution/Zimbabwe_2013.pdf
- Access to Information and Protection of Privacy Act, Chapter 10:27: http://www.veritaszim.net/accessinformationandprotectionprivacyact/10/27

Human Biological Materials

Key Organizations

- Medical Research Council of Zimbabwe: http://www.mrcz.org.zw/

Relevant Standards

- Research Act (2001): http://faolex.fao.org/docs/pdf/zim93551.pdf
- Various: https://www.rcz.ac.zw/

Genetic Research

Key Organizations

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

Relevant Standards

- National Biotechnology Authority Act, Chapter 14:31 (2006): https://www.jsc.org.zw/upload/Acts/2011/1431post.pdf

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