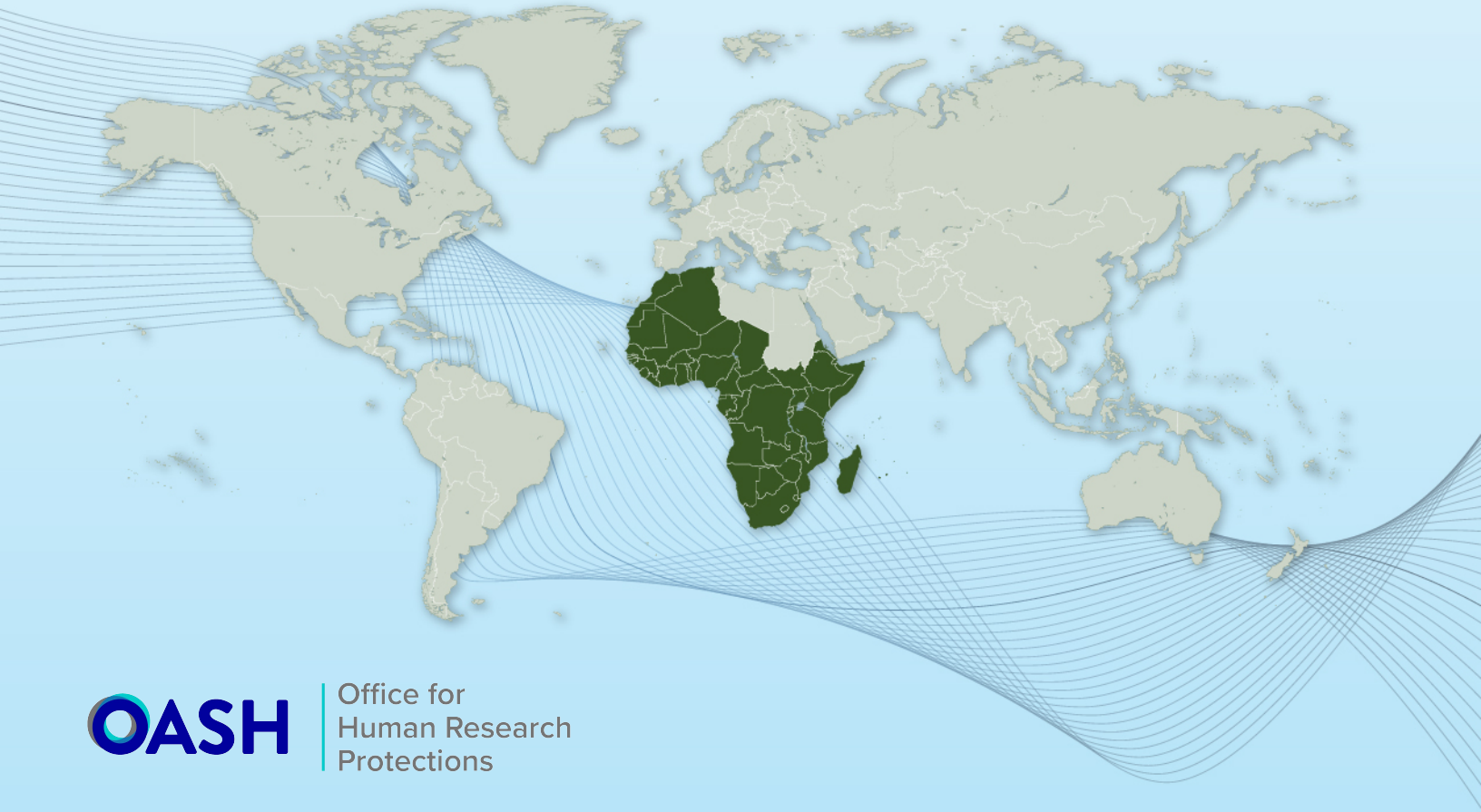
International Compilation of Human Research Standards
2021 Edition

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



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 However, not all countries provided corroboration, so some of the information contain in this document may be outdated or incomplete (please see disclaimer below).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

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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

- Anthropological Research Act 45 (1967): http://webcache.googleusercontent.com/search?q=cache:A7aea2ZEMhkJ:static1.1.sqspcdn.com/static/f/723732/25889598/1422112465653/ch59-02%2BANTHROPOLOGICAL%2BRESEARCH.pdf%3Ftoken%3DTSMJNydkWHdUJ7iPvvm7Qkzk4uU%253D+&cd=1&hl=en&ct=clnk&gl=us
- Guidelines for Application for Research Permit (2004)
- Guide for a Consent Form (2005)
- Guidelines for the Review of Research Proposals (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): http://webcache.googleusercontent.com/search?q=cache:A7aea2ZEMhkJ:static1.1.sqspcdn.com/static/f/723732/25889598/1422112465653/ch59-02%2BANTHROPOLOGICAL%2BRESEARCH.pdf%3Ftoken%3DTSMJNydkWHdUJ7iPvvm7Qkzk4uU%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-CreationComiteEthique-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

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
- Proposal for Ministerial Order No. 1250 Establishing the National Advisory Committee on Ethics Health (2004): https://healthresearchweb.org/?action=download&file=DRCPOlicy.pdf
- 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

Drugs, Biologics, and Devices

Key Organizations

- National Committee on Ethics and Research

Relevant Standards

- Decree No. 317 / SP / DSPH of 14 July 1987 on the Regulation of Drugs Before and After Marketing in Ivory Coast: http://elearning.trree.org/pluginfile.php/34816/mod_folder/content/0/20_Arrete_Regl_exp_clinique_des_substances_med.pdf?forcedownload=1

AFRICA – Ethiopia

General

Key Organizations

- Ethiopian Science and Technology Commission, Health Department

Relevant Standards

- Proclamation 60/1999, Section 21
- National Health Research Ethics Review Guideline, Fourth Edition (2014): http://www.ccghr.ca/wp-content/uploads/2013/11/national-research-ethics-review-guidline.pdf

Drugs, Biologics, and Devices

Key Organizations

- Food, Medicine, and Health Administration and Control Authority: www.fmhaca.gov.et

Relevant Standards

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

- 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/

Human Biological Materials

Key Organizations

- Ethiopian Science and Technology Commission, Health Department

Relevant Standards

- National Health Research Ethics Review Guideline, Fourth Edition, Chapter 9 (2005): http://www.ccghr.ca/wp-content/uploads/2013/11/national-research-ethics-review-guidline.pdf

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

- Act 851, Public Health Act, 2012: https://bcp.gov.gh/acc/registry/docs/PUBLIC%20HEALTH%20ACT,%202012%20(ACT%20851).pdf
- 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/images/stories/pdfs/Clinical%20Trials/REGULATION%20OF%20CLINICAL%20TRIALS%20IN%20GHANA.pdf
- 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/single_country.php?c_id=90

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.vertic.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/wp-content/uploads/2020/07/De%CC%81cret-.pdf
- 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/media/National%20Legislation/Guinea/GN_Code_Sante_Publique.pdf

AFRICA – Kenya

NOTE: For an overview of the clinical research regulations in Kenya, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=111

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/?action=download&file=Final%20national%20ethical%20guidelines-last%20draft.pdf

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

- Pharmacy and Poisons Act, Chapter 244 (2009): http://apps.who.int/medicinedocs/documents/s18245en/s18245en.pdf
- MOH, Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines (2005)
- MOH, Guidelines for Applications to Conduct Clinical Trials in Kenya (2014): http://pharmacyboardkenya.org/downloads/?file=Clinical%20Trial%20Guidelines%202014.pdf

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)

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

- 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/sites/default/files/documents/liberia/G-UL-PIRE-IRB_2020.pdf
- Ethics Committee Guidelines: Procedures for Researchers, Section 1 (2011): http://clinregs.niaid.nih.gov/documents/liberia/G-LIBR-NHSREC.pdf
- Operational Guidelines of the National Research Ethics Board (2019): https://clinregs.niaid.nih.gov/sites/default/files/documents/liberia/G-NREB-revised.pdf

Drugs, Biologics, and Devices

Key Organizations

- Liberia Medicines and Health Products Regulatory Authority

Relevant Standards

- Guideline for Application to Conduct Clinical Trials in Liberia (2014): https://clinregs.niaid.nih.gov/documents/liberia/G-LibClinTrial.pdf

AFRICA – Madagascar

Drugs, Biologics, and Devices

Relevant Standards

- Law No. 2011-002, Article 122 Regarding Clinical Trials: https://www.ilo.org/dyn/natlex/docs/ELECTRONIC/97799/116199/F1071917999/MDG-97799.pdf

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 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: www.malawi.gov.mw

Relevant Standards

- Presidential Decree on 30th March 1974
- Malawi Government Gazette, June 11, 1976, General Notice No. 398
- Constitution of Malawi, Article 19(5) (1994): https://www.constituteproject.org/constitution/Malawi_2017.pdf?lang=en
- NCST, The Framework of Guidelines for Research in the Social Sciences and Humanities in Malawi (2011)
- NCST, Policy Requirements, Procedures and Guidelines for the Conduct and Review of Research (2012)
- NCST, National Policy Measures and Requirements for the Improvement of Health Research Co-ordination in Malawi (2012)
- NCST, National Policy Requirements and Guidance for the Provision of Insurance Cover for Research Participants in Clinical Trials in Malawi (2012)
- NHSRC, Operational Guidelines (2001)
- NHSRC, Summary Guidelines for Writing Research Proposals (2001)
- COMREC, General Guidelines on Health Research (2010): http://comrec.medcol.mw/wp-content/uploads/2014/07/comrec_guidelines.pdf
- 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, Act 15 of 1988: https://malawilii.org/mw/legislation/act/1988/15

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/wp-content/uploads/2014/03/NATIONAL-FRAMEWORK-OF-GUIDELINES-IN-SSH.pdf

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/sites/default/files/documents/malawi/CIRCULAR.ON_.SAMPLES.AND_.RECOMPENSE-RECs.pdf

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 (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

- Law No. 09-059 of 28 December 2009 Governing Biomedical Research on Humans: https://clinregs.niaid.nih.gov/documents/LawNo09-059.pdf
- Fixing the Terms of Application of Law No. 09-059 of December 28, 2009 Governing Biomedical Research on Humans (2017) (French): https://clinregs.niaid.nih.gov/sites/default/files/documents/mali/DecreeNo2017-0245.pdf

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

AFRICA – Nigeria

General

Key Organizations

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

Relevant Standards

- National Health Act (2014): https://nigeriahealthwatch.com/wp-content/uploads/bsk-pdf-manager/2018/07/01_-Official-Gazette-of-the-National-Health-Act-FGN.pdf
- Nigerian Code of Health Research Ethics (2007): http://www.nhrec.net/nhrec/NCHRE_Aug%2007.pdf
- Policy Statement Regarding Enrollment of Children in Research in Nigeria (2016): http://nhrec.net/nhrec/Final%20NHREC%20Policy%20Statement%20on%20Enrollment%20of%20Children%20in%20Research.pdf
- 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
- Good Clinical Practice Guidelines (2020): https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Guidelines/CTD_Guidelines/NAFDAC-Good-Clinical-Practices-Guidelines-2020.pdf

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/

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

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

NOTE: For an overview of the clinical research regulations in Sierra Leone, see the ClinRegs report: https://clinregs.niaid.nih.gov/single_country.php?c_id=193

General

Key Organizations

- Sierra Leone Ethics and Scientific Review Committee

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

- 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
- Guideline for Good Clinical Practice (GCP) in Sierra Leone, Sections 3.2 and 3.3 (2018): https://clinregs.niaid.nih.gov/sites/default/files/documents/sierra_leone/PBSL-GCP-Guideline-V2.pdf
- Guidelines, various: http://www.pharmacyboard.gov.sl/Resources/Guidelines.aspx
- Clinical Trials, various: http://www.pharmacyboard.gov.sl/Resources/ClinicalTrials.aspx
- Forms, various: http://www.pharmacyboard.gov.sl/Resources/Forms.aspx

AFRICA – South Africa

NOTE: For an overview of the clinical research regulations in South Africa, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=199

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://protect-za.mimecast.com/s/5WP2Cr07VKf1mK59tzNft9?domain=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): http://www.saflii.org/za/legis/consol_act/nha2003147.pdf
- Regulations Relating to Research with Human Participants No. R719 (2014): https://www.gov.za/sites/default/files/gcis_document/201409/38000rg10268gon719.pdf
- DH, Ethics in Health Research: Principles, Structures, and Processes (2015): https://www.sun.ac.za/english/research-innovation/Research-

Development/Documents/Integrity%20and%20Ethics/DoH%202015%20Ethics%20in%20Health%20Research%20-%20Principles,%20Processes%20and%20Structures%202nd%20Ed.pdf

- 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/english/research-innovation/Research-Development/Documents/Integrity%20and%20Ethics/DoH%202015%20Ethics%20in%20Health%20Research%20-%20Principles,%20Processes%20and%20Structures%202nd%20Ed.pdf

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.hpcsa.co.za/Uploads/Legal/legislation/NATIONAL_HEALTH_ACT%C2%A061_OF_2003.pdf
- 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 Regarding General Control of Human Bodies, Tissues, Blood Products and Gametes, 2 March 2012
- 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): https://www.hpcsa.co.za/Uploads/Legal/legislation/NATIONAL_HEALTH_ACT%C2%A061_OF_2003.pdf
- 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: 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

- National Institute for Medical Research, Act of Parliament No. 23, of 1979: https://www.nimr.or.tz/wp-content/uploads/2020/08/NIMR-Act.pdf

- Tanzania Commission for Science and Technology, Act No. 7 of 1986: https://www.costech.or.tz/storage/uploads/mSre0zVqCMimUgIsnKrOrRIqHPgNxwwFIrpnkjX0.pdf
- NIMR, Research Policies, Guidelines, and Regulations: https://www.nimr.or.tz/wp-content/uploads/2018/11/NIMR_RESEARCH_POLICY_REGULATIONS_2015.pdf
- Guidelines on Ethics for Health Research in Tanzania (2009): https://clinregs.niaid.nih.gov/documents/tanzania/G-EthicsHR.pdf
- COSTECH, Various, including Guidelines on Research Permits and Clearance (2006): Various: 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/

Relevant Standards

- Tanzania Food, Drugs, and Cosmetics Act, Sections 61, 66, 67, and 69 (2003): https://www.tmda.go.tz/uploads/publications/en1545477980-GN%20-%20THE%20TANZANIA%20FOOD,%20DRUGS%20AND%20COSMETICS%20(CLINICAL%20TRIALS%20CONTROL)%20REGULATIONS,%202013.pdf

Devices

Key Organizations

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

Relevant Standards

- Medical devices, various: https://www.tmda.go.tz/publications/39

Clinical Trials Registry

Key Organizations

- Tanzania Commission for Science and Technology (COSTECH): https://www.costech.or.tz/

Relevant Standards

- COSTECH, Database, Funded Projects: https://www.costech.or.tz/funded-projects
- Various: https://www.costech.or.tz/documents-and-publications

AFRICA – Uganda

NOTE: For an overview of the clinical research regulations in Uganda, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=223

General

Key Organizations

- Uganda National Council for Science and Technology (UNCST): http://www.uncst.go.ug/

Relevant Standards

- Uganda National Council for Science and Technology Act of 1990 (CAP 209): https://old.ulii.org/ug/legislation/consolidated-act/209
- 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: https://uncst.go.ug/main/wp-content/uploads/download-manager-files/National%20Guidelines.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/

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/sites/default/files/documents/acts/Health%20%20Research%20%20Act%202013.pdf

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.zamra.co.zm/wp-content/uploads/2021/01/MASA-No-3-2013.pdf
- Guidelines on Regulating the Conduct of Clinical Trials in Human Participants: https://www.who.int/medicines/areas/coordination/zambia_clinical_trials.pdf

Human Biological Materials

Relevant Standards

- National Health Research Act, Part VI (2013): http://www.parliament.gov.zm/sites/default/files/documents/acts/Health%20%20Research%20%20Act%202013.pdf

AFRICA – Zimbabwe

General

Key Organizations

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

Relevant Standards

- Medical Research Government Notice Act (1974)
- 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/

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
- Pharmacovigilance and Clinical Trials, Various Guidelines: https://www.mcaz.co.zw/index.php/downloads/category/15-guidelines

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.mcaz.co.zw/index.php/downloads/category/8-acts
- Medicines and Allied Substances Control Act, Various 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

- 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/node/240#:~:text=An%20Act%20to%20provide%20members,or%20disclosure%20of%20personal%20information

Human Biological Materials

Key Organizations

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

Relevant Standards

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

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.nba.ac.zw/books/national_biotechnolgy_act.pdf

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