

| Country | Key Organizations | Legislation | Regulations | Guidelines |
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| AFRICA | | | | |
| Botswana | | | | |
| <i>General</i> | Ministry of Health, Research and Development Committee: http://www.moh.gov.bw/ | Anthropological Research Act 45 (1967) | | 1. Guide for a Consent Form (2005) 2. Guidelines for the Review of Research Proposals (2005) |
| <i>Drugs and Devices</i> | Ministry of Health, Drug Regulatory Unit: http://www.moh.gov.bw/ | | Drugs and Related Substances Regulations (1993) | SADC Guidelines for Regulating Clinical Trials in Human Subjects (2006) |
| Cameroon | | | | |
| For an overview of human subject protections in Cameroon, see the National Supplement by Training and Resources in Research Ethics Evaluation: http://elearning.trree.org/mod/resource/view.php?id=31&lang=en | | | | |
| <i>General</i> | | | Ministerial Order No. 079/A/MSP/DS of MINSANTE of October 22, 1987 | |
| Egypt | | | | |
| <i>General</i> | Medical Profession Union | Constitution of the Arab Republic of Egypt, Article 43: http://www.sis.gov.eg/En/Politics/Constitution/Text/040703000000000001.htm | Professional Ethics Regulations: Conducting Medical Research on Human Beings, Articles 52-61 (2003) | |
| <i>Drugs and Devices</i> | Egyptian Drug Authority: http://www.eda.mohp.gov.eg/ | | | |
| <i>Human Biological Materials</i> | | | Professional Ethics Regulations: Conducting Medical Research on Human Beings Articles 49-51 (2003) | |
| Ethiopia | | | | |
| <i>General</i> | Ethiopian Science and Technology Commission, Health Department | Proclamation 60/1999, Section 21 | | National Health Research Ethics Review Guideline, Fourth Edition (2005): www.most.gov.et/Ethics%20Guideline.pdf |
| <i>Drugs and Devices</i> | Drug Administration and Control Authority | | Drug Administration and Control Proclamation No. 176/1999, Article 21 | |
| <i>Human Biological Materials</i> | Ethiopian Science and Technology Commission, Health Department | | | National Health Research Ethics Review Guideline, Fourth Edition, Chapter 9 (2005): www.most.gov.et/Ethics%20Guideline.pdf |
| Gambia | | | | |
| <i>Genetic Research</i> | Medical Research Council (UK) The Gambia: http://www.mrc.gm/ | | | Guidelines of the National DNA Bank (2001) |

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| Kenya | | | | |
| <i>General</i> | 1. National Council for Science and Technology (NCST) 2. Ministry of Health (MOH) | 1. Science and Technology Act (2001) 2. HIV and AIDS Prevention and Control Act, Chapter 14 (2006) | NCST: Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya (2004): https://webapps.sph.harvard.edu/live/gremap/files/ke_NCST_guidelines.pdf | |
| <i>Drugs and Devices</i> | Pharmacy and Poisons Board: http://www.pharmacyboardkenya.org/ | Pharmacy and Poisons Act, Chapter 244 (2001): http://www.pharmacyboardkenya.org/assets/files/cap_244_revised_2002_Latest.pdf | MOH: Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines (2005) | |
| <i>Human Biological Materials</i> | Ministry of Health (MOH) | | Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines, page 44 (2005) | |
| Malawi | | | | |
| <i>General</i> | 1. National Commission for Science and Technology (NCST) 2. National Health Sciences Research Committee (NHSRC) 3. College of Medicine Research and Ethics Committee (COMREC): http://www.medcol.mw/ 4. Ministry of Health | 1. Presidential Decree on 30 th March 1974 2. Malawi Government Gazette, June 11, 1976, General Notice No. 398 3. Constitution of Malawi, Article 19(5) (1994) | | NCST: 1. The Framework of Guidelines for Research in the Social Sciences and Humanities in Malawi (2011) 2. Policy Requirements, Procedures and Guidelines for the Conduct and Review of Research (2012) 3. National Policy Measures and Requirements for the Improvement of Health Research Co-ordination in Malawi (2012) 4. National Policy Requirements and Guidance for the Provision of Insurance Cover for Research Participants in Clinical Trials in Malawi (2012) NHSRC: 1. Operational Guidelines (2001) 2. Summary Guidelines for Writing Research Proposals (2001) COMREC: Research Guidelines (2004): http://www.medcol.mw/comrec/researchguidelines.htm |

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| <i>Drugs and Devices</i> | Pharmacy, Medicines, and Poisons Board of Malawi | 1. Pharmacy, Medicines, and Poisons Act, Act 15 of 1988) 2. Section 42(1) of PMPB Act, 2003 Supplement | | |
| <i>Genetic Research</i> | National Research Council of Malawi (NRCM) | | Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi (2002) | |
| Mozambique | | | | |
| For an overview of human subject protections in Mozambique, see the National Supplement by Training and Resources in Research Ethics Evaluation: http://elearning.trree.org/mod/resource/view.php?id=61&lang=en | | | | |
| <i>General</i> | | | | Science and Technology Ethics Code (2007) |
| Nigeria | | | | |
| For an overview of human subject protections in Nigeria, see the National Supplement by Training and Resources in Research Ethics Evaluation: http://elearning.trree.org/mod/resource/view.php?id=57&lang=en | | | | |
| <i>General</i> | National Health Research Ethics Committee: http://nhrec.net/ | National Health Bill 2009 | | National Code of Health Research Ethics (2007): http://www.nhrec.net/nhrec/NCHRE_10.pdf |
| <i>Drugs and Devices</i> | National Agency for Food, Drug Administration and Control (NAFDAC): http://www.nafdac.gov.ng/ | Decree No. 15 of 1993 | Good Clinical Practice Regulations (2009): http://apps.who.int/medicinedocs/documents/s17103e/s17103e.pdf | |
| Rwanda | | | | |
| <i>General</i> | Ministry of Health, National Ethics Committee | | | Standard Operating Procedures (2009): http://www.moh.gov.rw/index.php?option=com_docman&task=doc_download&gid=126&Itemid=81 |
| South Africa | | | | |
| <i>General</i> | 1. Department of Health (DH): http://www.doh.gov.za 2. National Health Research Ethics Council: http://www.nhrec.org.za/ 3. Medical Research Council of South Africa (MRC): http://www.mrc.ac.za 4. Human Sciences Research Council (HSRC): http://www.hsrc.ac.za/index.phtml | 1. Constitution of South Africa, Section 12 (2) (1996) 2. National Health Act No. 61, Chapter 9 (2003): www.info.gov.za/view/DownloadFileAction?id=68039 3. MRC Act: http://www.mrc.ac.za/about/MRCAct.pdf 4. HSRC Act: www.hsrc.ac.za/en/about/hsrc-act | | DH: Ethics in Health Research: Principles, Structures, and Processes (2004): www.health.uct.ac.za/usr/health/research/hrec/links/Department_of_Health-Ethics_in_Health_Research_Principles_Structures_and_Processes_2004.pdf MRC: 1. Guidelines on Ethics in Medical Research: General Principles (2002) 2. Guidelines on Ethics in the Use of Biohazards and Radiation (2003) 3. Guidelines on Ethics in HIV Vaccine Trials (2003) |

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| | | | | <i>Access:</i> http://www.sahealthinfo.org/ethics/index.htm |
| <i>Drugs and Devices</i> | 1. Department of Health (DH): http://www.doh.gov.za 2. Medicines Control Council: http://www.mccza.com | Medicines and Related Substances Control Act, 101 of 1965 http://www.info.gov.za/view/DownloadFileAction?id=68096 | General Regulations Made in Terms of the Medicines and Related Substances Act, 1965 (2003): http://www.info.gov.za/view/DownloadFileAction?id=68096 | DH: Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa (2006): http://www.doh.gov.za/nhrec/norms/gcp.pdf |
| <i>Human Biological Materials</i> | Department of Health (DH): http://www.doh.gov.za | National Health Act No. 61, Chapter 8, Sections 53-68 (2003): http://www.doh.gov.za/docs/legislation-f.html | 1. Regulations Relating to the Use of Human Biological Material, 2 March 2012: http://www.doh.gov.za/docs/regulations/2012/regr177.pdf 2. Regulations Regarding General Control of Human Bodies, Tissues, Blood Products and Gametes, 2 March 2012 3. Regulations Relating to Blood and Blood Products, 2 March 2012: http://www.doh.gov.za/docs/regulations/2012/regr179.pdf 4. Regulations Relating to Artificial Insemination of Persons, 2 March 2012: http://www.doh.gov.za/docs/regulations/2012/regr175.pdf | |
| <i>Genetic Research</i> | Medical Research Council of South Africa (MRC): http://www.mrc.ac.za | | | MRC: Guidelines on Ethics in Reproductive Biology and Genetic Research (2002): http://www.sahealthinfo.org/ethics/book2.htm |
| <i>Embryos, Stem Cells, and Cloning</i> | Medical Research Council of South Africa (MRC): http://www.mrc.ac.za | National Health Act No. 61, Chapter 8, Section 57 (2003): http://www.doh.gov.za/docs/legislation-f.html | Regulations relating to Stem Cell Banks, 2 March 2012: http://www.doh.gov.za/docs/regulations/2012/regr183.pdf | MRC: Guidelines on Ethics in Reproductive Biology and Genetic Research (2002): http://www.sahealthinfo.org/ethics/book2.htm |
| Sudan | | | | |
| <i>General</i> | Federal Ministry of Health: http://www.fmoh.gov.sd/English/index.php | | | National Guidelines for Ethical Conduct of Research Involving Human Subjects (2008): http://sites.google.com/site/healthresearchlibrary/national-guidelines |
| <i>Drugs and Devices</i> | Federal Ministry of Health: http://www.fmoh.gov.sd/English/index.php | Act on Pharmaceuticals and Poisons (2001) | | |

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| <i>Human Biological Materials</i> | Federal Ministry of Health: http://www.fmoh.gov.sd/English/index.php | Human Organs and Tissues Transplant Legislation, Chapter 2, Articles 3 and 4 (1978) | | |
| <i>Genetic Research</i> | University of Khartoum, Institute of Endemic Diseases | | | Guidelines for Genetics Research on Sudanese Subjects (2005) |
| Tanzania | | | | |
| For an overview of human subject protections in Tanzania, see the National Supplement by Training and Resources in Research Ethics Evaluation: http://elearning.trree.org/mod/resource/view.php?id=41&lang=en | | | | |
| <i>General</i> | 1. Ministry of Health (MOH) 2. National Institute for Medical Research (NIMR), National Health Research Ethics Committee (NHREC): http://www.nimr.or.tz/ethical_guidelines.html 3. Tanzania Commission for Science and Technology (COSTECH): www.costech.or.tz | 1. National Institute for Medical Research, Act of Parliament No. 23, of 1979: http://www.parliament.go.tz/Polis/PAMS/Docs/23-1979.pdf 2. Tanzania Commission for Science and Technology, Act No. 7 of 1986 3. Amendment of NIMR Act 1997, Tanzania Government Gazette, No. 675 | NIMR: 1. Coordination of Health Research in Tanzania 2. Coordination of Formation of Institutional Health Research Committees to Formally Approve for Local Health Research 3. Coordination of Research in Tanzania | NHREC: 1. Guidelines on Ethics for Health Research in Tanzania (2001): https://webapps.sph.harvard.edu/live/gremap/files/Guidelines-2001-TZ-full.pdf 2. Brochure for Health Researchers in Tanzania (2006) COSTECH: COSTECH Guidelines on Research Permits and Clearance (2006) |
| <i>Drugs and Devices</i> | <i>Drugs</i> Tanzania Food and Drugs Authority: http://www.tfda.or.tz/ | Tanzania Food, Drugs, and Cosmetics Act, Sections 61, 66, 67, and 69 (2003): http://www.tfda.or.tz/tfdaact.pdf | | |
| | <i>Devices</i> Tanzania Food and Drugs Authority: http://www.tfda.or.tz/ | Medical Device Act (1988) | | |
| Tunisia | | | | |
| <i>Drugs and Devices</i> | Ministry of Public Health, Institut Pasteur: www.pasteur.tn | | Conditions of Contract and Specifications Related to Medical or Scientific Experimentation of Medicines Intended for Humans | Disposals and Director's Principles Related to Good Practices in Clinical Trials |
| Uganda | | | | |
| <i>General</i> | Uganda National Council for Science and Technology (UNCST): http://www.uncst.go.ug/ | Uganda National Council for Science and Technology Act (CAP 209) | | National Guidelines for Research Involving Humans as Research Participants (2007): http://uncst.go.ug/site/documents/rihp_guide.pdf |
| <i>Drugs and Devices</i> | National Drug Authority: http://www.nda.or.ug/ | National Drug Policy and Authority Act (CAP 206) (1993) | | |

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| Zambia | | | | |
| <i>General</i> | Ministry of Health: http://www.moh.gov.zm/ | National Health Research Act (2013) | | |
| Zimbabwe | | | | |
| <i>General</i> | Medical Research Council of Zimbabwe: http://www.mrcz.org.zw | 1. Government Notice Act (1974) 2. Research Act (1986) | | Ethics Guidelines for Health Research Involving Human Participants in Zimbabwe |
| <i>Drugs and Devices</i> | <i>Drugs</i> | | | |
| | Medicines Control Authority of Zimbabwe: http://www.mcaz.co.zw/ | Medicines and Allied Substances Control Act, Chapter 15:03 (1997) | 1. Medicines and Allied Substances Control Act, General Regulations (1991) 2. Statutory Instrument 150 of 1991 | Guidelines for Good Clinical Practice (2010): http://www.mcaz.co.zw/trials/GUIDELINES%20FOR%20GCP%202010%20Zimbabwe.pdf |
| | <i>Devices</i> | | | |
| | Medicines Control Authority of Zimbabwe: http://www.mcaz.co.zw/devices.html | | Medicines and Allied Substances Control (Condom) Regulations (2005): http://www.mcaz.co.zw/Condom%20Regulations.pdf | |
| <i>Human Biological Materials</i> | Research Council of Zimbabwe: www.rcz.ac.zw | | | 1. Foreign Researcher Application 2. Specimen Shipment Guidelines 3. Material Transfer Agreements |