

Table of Institutions

| Institution  | Documentation   | Link   |
|--|---|--|
| <b>CIOMS</b>   | – International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002) : Guidelines 21 & 7  | <a href="http://www.cioms.ch/publications/layout_guide2002.pdf">http://www.cioms.ch/publications/layout_guide2002.pdf</a>  |
| <b>WHO</b><br><br><b>WHO/IVR</b>   | – Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011)<br><br>– Ethical considerations arising from vaccine trials conducted in pediatric populations with high disease burden in developing countries, WHO/IVR ethics meeting (2002) | <a href="http://apps.who.int/iris/bitstream/10665/44783/1/9789241502948_eng.pdf">http://apps.who.int/iris/bitstream/10665/44783/1/9789241502948_eng.pdf</a><br><br><a href="http://www.who.int/ethics/topics/vaccinetrials_pediatric_ivr_en_2002.pdf">http://www.who.int/ethics/topics/vaccinetrials_pediatric_ivr_en_2002.pdf</a> |
| <b>World Medical Association</b>   | – Declaration of Helsinki (2008), Guideline B14   | <a href="http://www.wma.net/en/30publications/10policies/b3/17c.pdf">http://www.wma.net/en/30publications/10policies/b3/17c.pdf</a>  |
| <b>International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use</b> | – Guideline for Good Clinical Practice (1996)   | <a href="http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1_Guideline.pdf">http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1_Guideline.pdf</a>  |
| <b>UNAIDS</b>  | – Ethical   | <a href="http://www.who.int/ethics/topics/ethical">http://www.who.int/ethics/topics/ethical</a>  |

|  |  |   |
|--|--|---|
| <p><b>UNAIDS/ WHO</b></p> <p><b>UNAIDS/ AVAC</b></p> | <p>considerations in HIV preventive vaccine research (2000)</p> <ul style="list-style-type: none"> <li>– Meeting on care within the context of HIV/ AIDS-related research in developing countries (2002)</li> <li>– Ethical considerations in biomedical HIV prevention trials (2007): Guidance points 9 &amp; 12</li> <li>– Meeting report documented in paper titled “Ethical considerations related to the provision of care and treatment in vaccine trials” by Tarantola et al. (2007)</li> <li>– Revised GPP (2011): 3.12</li> </ul> | <p><a href="http://www.unaids.org/en/media/unaids/contentassets/dataimport/publications/irc-pub02/jc694-meetingoncare_en.pdf">_considerations_vaccine_research_unaids_en_2000.pdf</a></p> <p><a href="http://www.unaids.org/en/media/unaids/contentassets/dataimport/publications/irc-pub02/jc694-meetingoncare_en.pdf">http://www.unaids.org/en/media/unaids/contentassets/dataimport/publications/irc-pub02/jc694-meetingoncare_en.pdf</a></p> <p><a href="http://data.unaids.org/pub/Report/2007/jc1399_ethical_considerations_en.pdf">http://data.unaids.org/pub/Report/2007/jc1399_ethical_considerations_en.pdf</a></p> <p><a href="http://www.ncbi.nlm.nih.gov/pubmed/17466418">http://www.ncbi.nlm.nih.gov/pubmed/17466418</a></p> <p><a href="http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC1853_GPP_Guidelines_2011_en.pdf">http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC1853_GPP_Guidelines_2011_en.pdf</a></p> |
| <p><b>HPTN</b></p>                                   | <ul style="list-style-type: none"> <li>– HIV Prevention Trials Network Ethics Guidance for Research (2009)</li> </ul>  | <p><a href="http://www.hptn.org/web%20documents/EWG/HPTNEthicsGuidanceV10Jun2009.pdf">http://www.hptn.org/web%20documents/EWG/HPTNEthicsGuidanceV10Jun2009.pdf</a></p>  |
| <p><b>U.K. MRC</b></p>                               | <ul style="list-style-type: none"> <li>– Research involving human participants in developing societies (2004)</li> <li>– Policy on antiretroviral therapy for people infected with HIV and involved in research in developing countries (2003)</li> <li>– “Ethics and research guidance” tab on website</li> </ul>   | <p><a href="http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002461">http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002461</a></p> <p><a href="http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002455">http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002455</a></p> <p><a href="http://www.mrc.ac.uk/Ourresearch/Ethicsresearchguidance/index.htm">http://www.mrc.ac.uk/Ourresearch/Ethicsresearchguidance/index.htm</a></p>  |

|  |  |   |
|--|--|---|
| <p><b>Nuffield Council</b></p>   | <ul style="list-style-type: none"> <li>– The ethics of research related to healthcare in developing countries (2002)</li> <li>– A follow-up discussion paper (2005) 3.19 – 3.26</li> </ul>   | <p><a href="http://www.nuffieldbioethics.org/sites/default/files/Ethics%20of%20research%20related%20to%20healthcare%20in%20developing%20countries%20I.pdf">http://www.nuffieldbioethics.org/sites/default/files/Ethics%20of%20research%20related%20to%20healthcare%20in%20developing%20countries%20I.pdf</a></p> <p><a href="http://www.nuffieldbioethics.org/sites/default/files/HRRDC_Follow-up_Discussion_Paper.pdf">http://www.nuffieldbioethics.org/sites/default/files/HRRDC_Follow-up_Discussion_Paper.pdf</a></p> |
| <p><b>U.S. NIH</b></p>   | <ul style="list-style-type: none"> <li>– NIH Grants Policy Statement (2011)</li> <li>– Guidelines for Conduct of Research Involving Human Subjects at NIH (2004)</li> </ul>  | <p><a href="http://grants.nih.gov/grants/policy/nihgps_2011/index.htm">http://grants.nih.gov/grants/policy/nihgps_2011/index.htm</a></p> <p><a href="http://www.nccamwatch.org/research/human_guidelines.pdf">http://www.nccamwatch.org/research/human_guidelines.pdf</a></p>   |
| <p><b>USAID</b></p> <p><b>USAID/Global Campaign for Microbicides</b></p> | <ul style="list-style-type: none"> <li>– Procedures for Protection of Human Subjects In Research Supported by USAID</li> <li>– USAID Research: Policy Framework, Principles, and Operational Guidance</li> <li>– Mapping the Standards of Care at Microbicide Clinical Trial Sites (2008)</li> </ul> | <p><a href="http://transition.usaid.gov/policy/ads/200/humansub.pdf">http://transition.usaid.gov/policy/ads/200/humansub.pdf</a></p> <p><a href="http://transition.usaid.gov/policy/ads/200/poflframe.pdf">http://transition.usaid.gov/policy/ads/200/poflframe.pdf</a></p> <p><a href="http://www.global-campaign.org/clientfiles/SOC-ES.pdf">http://www.global-campaign.org/clientfiles/SOC-ES.pdf</a></p>  |
| <p><b>U.S. Department of Defense</b></p>                                 | <ul style="list-style-type: none"> <li>– No publically available guidance</li> </ul>   |   |
| <p><b>U.S. Ethical Advisory Bodies</b></p>                               | <ul style="list-style-type: none"> <li>– NBAC: Ethical and Policy Issues in International Research (2001)</li> <li>– Presidential Commission for the Study of Bioethical Issues: Research Across Borders: Proceedings of the International</li> </ul>  | <p><a href="http://bioethics.georgetown.edu/nbac/human/oversumm.html">http://bioethics.georgetown.edu/nbac/human/oversumm.html</a></p> <p><a href="http://bioethics.gov/cms/sites/default/files/IRP-%20Research%20Across%20Borders.pdf">http://bioethics.gov/cms/sites/default/files/IRP-%20Research%20Across%20Borders.pdf</a></p>   |

|  |   |  |
|--|---|--|
|  | Research Panel (2011)   |  |
| <b>Institute of Medicine</b>   | – Ethical Considerations for Research on Housing-Related Health Hazards Involving Children (2005)   | <a href="http://www.iom.edu/Reports/2005/Ethical-Considerations-for-Research-on-Housing-Related-Health-Hazards-Involving-Children.aspx">http://www.iom.edu/Reports/2005/Ethical-Considerations-for-Research-on-Housing-Related-Health-Hazards-Involving-Children.aspx</a>  |
| <b>U.S. Food and Drug Administration</b>   | – No publically available guidance  |  |
| <b>U.S. Office of Human Research Protections – Department of Health and Human Services</b>                         | – No publically available guidance  |  |
| <b>European Commission</b>   | – Ethics for Researchers (2007)<br><br>– Ethics in research and international cooperation (2009)  | <a href="ftp://ftp.cordis.europa.eu/pub/fp7/docs/ethics-for-researchers.pdf">ftp://ftp.cordis.europa.eu/pub/fp7/docs/ethics-for-researchers.pdf</a><br><br><a href="ftp://ftp.cordis.europa.eu/pub/fp7/docs/developing-countries_en.pdf">ftp://ftp.cordis.europa.eu/pub/fp7/docs/developing-countries_en.pdf</a> |
| <b>U.K. Department for International Development</b>   | – DFID Ethics Principles for Research and Evaluation (2011)   | <a href="http://www.dfid.gov.uk/Documents/publications1/evaluation/dfid-ethics-prepls-rsrch-eval.pdf">http://www.dfid.gov.uk/Documents/publications1/evaluation/dfid-ethics-prepls-rsrch-eval.pdf</a>  |
| <b>Inserm</b>  | – No publically available guidance  |  |
| <b>Wellcome Trust</b>  | – Research involving people living in low and middle income countries   | <a href="http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTD015295.htm">http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTD015295.htm</a>  |
| <b>Gates Foundation</b>  | – No publically available guidance  |  |
| <b>Institut Pasteur</b>  | – The Ethics Charter of the Institut Pasteur (2009), Chapter 2: Research on human subjects  | <a href="http://www.pasteur.fr/ip/resource/filecenter/document/01s-00003f-09u/charte-ethique-en.pdf">http://www.pasteur.fr/ip/resource/filecenter/document/01s-00003f-09u/charte-ethique-en.pdf</a>  |
| <b>Democratic Republic of Congo: Groupe Interproject de Reflexion et d’Intervention en Ethique (GIRIE)/ Centre</b> | – Workshop documented in paper titled “Engaging with research ethics in central francophone Africa: reflections on a workshop about ancillary | <a href="http://www.ncbi.nlm.nih.gov/pubmed/22866822">http://www.ncbi.nlm.nih.gov/pubmed/22866822</a>  |

|  |  |   |
|--|--|---|
| <b>Interdisciplinaire de Bioethique pour L’Afrique Francophone (CIBAF)/Kinshasa School of Public Health (KSPH)</b> | care” by Tshikala et al. (2012)  |   |
| <b>Eastern and Southern Africa (10 research centers in Kenya, Rwanda, Uganda, Zambia, and South Africa)</b>        | – Group discussions and interviews conducted by IAVI, documented in paper titled “Developing standards of care for HIV prevention research in developing countries—a case study of 10 research centers in Eastern and Southern Africa” by Ngongo et al. (2012) | <a href="http://www.ncbi.nlm.nih.gov/pubmed/22452384">http://www.ncbi.nlm.nih.gov/pubmed/22452384</a>   |
| <b>Ethiopian Science &amp; Technology Commission</b>   | – Ethiopian National Health Research Ethics Review Guideline (2005)  |   |
| <b>Indian Council of Medical Research</b>  | – Ethical Guidelines for Biomedical Research on Human Participants (2006)  | <a href="http://icmr.nic.in/ethical_guidelines.pdf">http://icmr.nic.in/ethical_guidelines.pdf</a>   |
| <b>Medical Research Council of Zimbabwe</b>  | – Conducting Health Research in Zimbabwe: What researchers need to know (2004)   | <a href="https://www.daidscrss.com/partners/Page_Regulatory_Management/Docs_Regulatory_Management/Docs_Flag_Forms/Zimbabwe_conducting_health_research_in_zim.pdf">https://www.daidscrss.com/partners/Page_Regulatory_Management/Docs_Regulatory_Management/Docs_Flag_Forms/Zimbabwe_conducting_health_research_in_zim.pdf</a> |
| <b>National Council for Science and Technology (Kenya)</b>   | – Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya (2004)   | <a href="https://webapps.sph.harvard.edu/live/gremp/files/ke_NCST_guidelines.pdf">https://webapps.sph.harvard.edu/live/gremp/files/ke_NCST_guidelines.pdf</a>   |
| <b>National Ministry of Health (Sudan)</b>   | – National Guidelines for Ethical Conduct of Research Involving Human Subjects (2008)  | <a href="https://sites.google.com/site/healthresearchlibrary/national-guidelines">https://sites.google.com/site/healthresearchlibrary/national-guidelines</a>   |
| <b>Nepal Health Research Council</b>   | – National Ethical Guidelines for  | <a href="http://www.nhrc.org.np/guidelines/National_Ethical_Guidelines.pdf">http://www.nhrc.org.np/guidelines/National_Ethical_Guidelines.pdf</a>   |

|  |  |  |
|--|--|--|
|  | Health Research in Nepal and Standard Operating Procedures (2011): 5.3.5   |  |
| <b>National Health Research Ethics Committee of Nigeria</b>    | – National Code of Health Research Ethics (2007)   | <a href="http://www.nhrec.net/nhrec/code.html">http://www.nhrec.net/nhrec/code.html</a>  |
| <b>Singapore Bioethics Advisory Committee</b>                  | – Ethics Guidelines for Human Biomedical Research (2012)   | <a href="http://www.bioethics-singapore.org/uploadfile/32914%20PM2012-06-20%20-%20BAC%20Ethics%20Guidelines%20(for%20comments)%20F.pdf">http://www.bioethics-singapore.org/uploadfile/32914%20PM2012-06-20%20-%20BAC%20Ethics%20Guidelines%20(for%20comments)%20F.pdf</a>  |
| <b>Australian National Health and Medical Research Council</b> | – Challenging Ethical Issues in Contemporary Research on Human Beings (2006)<br>– National Statement on Ethical Conduct in Human Research (2007)                 | <a href="http://www.nhmrc.gov.au/files_nhmrc/publications/attachments/e73.pdf">http://www.nhmrc.gov.au/files_nhmrc/publications/attachments/e73.pdf</a><br><br><a href="http://www.nhmrc.gov.au/files_nhmrc/publications/attachments/e72.pdf">http://www.nhmrc.gov.au/files_nhmrc/publications/attachments/e72.pdf</a>   |
| <b>South African MRC</b>                                       | – Guidelines on Ethics in Medical Research: General Principles (2002)<br><br>– Guidelines on Ethics for Medical Research: HIV Preventive Vaccine Research (2003) | <a href="http://www.mrc.ac.za/ethics/ethicsbook1.pdf">http://www.mrc.ac.za/ethics/ethicsbook1.pdf</a><br><br><a href="http://www.mrc.ac.za/ethics/ethicsbook5.pdf">http://www.mrc.ac.za/ethics/ethicsbook5.pdf</a>   |
| <b>Tanzania National Institute for Medical Research</b>        | – Standard Operating Procedures for the National Health Research Ethics Review Committee (2007)  | <a href="http://www.nimr.or.tz/wp-content/uploads/2012/08/SOPs- NIMR.pdf">http://www.nimr.or.tz/wp-content/uploads/2012/08/SOPs- NIMR.pdf</a>  |
| <b>Uganda National Council for Science &amp; Technology</b>    | – National Guidelines for Research Involving Humans as Research Participants (2007)  | <a href="http://www.uncst.go.ug/dmdocuments/Guideline.%20Human%20Subjects%20Guidelines%20Marc.pdf">http://www.uncst.go.ug/dmdocuments/Guideline.%20Human%20Subjects%20Guidelines%20Marc.pdf</a>  |
| <b>AstraZeneca PLC</b>   | – “Research Ethics” page on website<br>– AstraZeneca Global Policy: Bioethics  | <a href="http://www.astrazeneca.com/Responsibility/Research-ethics">http://www.astrazeneca.com/Responsibility/Research-ethics</a><br><a href="http://www.astrazeneca.com/cs/Satellite?blobcol=urldata&amp;blobheader=application%20Fpdf&amp;blobheadername1=Content-Disposition&amp;blobheadername2=MDT-">http://www.astrazeneca.com/cs/Satellite?blobcol=urldata&amp;blobheader=application%20Fpdf&amp;blobheadername1=Content-Disposition&amp;blobheadername2=MDT-</a> |

|                              |   |   |
|------------------------------|---|---|
|                              |   | <a href="#">Type&amp;blobheadervalue1=inline%3B+filena<br/>me%3DBioethics.pdf&amp;blobheadervalue2=a<br/>binary%3B+charset%3DUTF-<br/>8&amp;blobkey=id&amp;blohtable=MungoBlobs&amp;b<br/>lobwhere=1285620406458&amp;ssbinary=true</a>  |
| <b>Eisai Co. Ltd.</b>        | – No publically available guidance  |   |
| <b>Gilead Sciences</b>       | – No publically available guidance  |   |
| <b>GlaxoSmithKline</b>       | – No publically available guidance  |   |
| <b>Johnson &amp; Johnson</b> | – Our Ethical Code for the Conduct of Research and Development  | <a href="http://www.jnj.com/wps/wcm/connect/1f0f21804f5567c99f42bf1bb31559c7/ethical-code-for-the-conduct-of-rd.pdf?MOD=AJPERES">http://www.jnj.com/wps/wcm/connect/1f0f21804f5567c99f42bf1bb31559c7/ethical-code-for-the-conduct-of-rd.pdf?MOD=AJPERES</a>   |
| <b>Merck &amp; Co. Inc.</b>  | – Public Policy Statement: Clinical Trial Ethics (2012)   | <a href="http://www.merck.com/about/views-and-positions/clinical_trial_ethics_march2012.pdf">http://www.merck.com/about/views-and-positions/clinical_trial_ethics_march2012.pdf</a>   |
| <b>Novartis AG</b>           | – Clinical trials in developing countries   | <a href="http://www.novartis.com/downloads/corporate-responsibility/resources/positions/clinical-trials-developing-markets.pdf">http://www.novartis.com/downloads/corporate-responsibility/resources/positions/clinical-trials-developing-markets.pdf</a>   |
| <b>Pfizer, Inc.</b>          | <ul style="list-style-type: none"> <li>– Compensation to Human Research Subjects in Clinical Studies</li> <li>– Global Standards for Interventional Clinical Studies</li> <li>– Statement on the Declaration of Helsinki and the Ethical Conduct of Clinical Studies (2008)</li> <li>– The Globalization of Clinical Trials (2009)</li> <li>– MRCT Project Report (2010)</li> </ul> | <a href="http://www.pfizer.com/research/research_clinical_trials/compensation_trial_participant_s.jsp">http://www.pfizer.com/research/research_clinical_trials/compensation_trial_participant_s.jsp</a><br><a href="http://www.pfizer.com/research/research_clinical_trials/global_clinical_trial_standards.jsp">http://www.pfizer.com/research/research_clinical_trials/global_clinical_trial_standards.jsp</a><br><a href="http://www.pfizer.com/files/research/Helsinki_statement_5_08.pdf">http://www.pfizer.com/files/research/Helsinki_statement_5_08.pdf</a><br><a href="http://www.pfizer.com/files/research/nejm_paper_globalization_of_trials.pdf">http://www.pfizer.com/files/research/nejm_paper_globalization_of_trials.pdf</a><br><a href="http://www.pfizer.com/files/research/research_clinical_trials/mrct.pdf">http://www.pfizer.com/files/research/research_clinical_trials/mrct.pdf</a> |
| <b>Roche Holdings Ltd.</b>   | <ul style="list-style-type: none"> <li>– Roche Position on Clinical Research (2012)</li> <li>– Roche Clinical Trials Policy in Low and Middle Income Developing</li> </ul>  | <a href="http://www.roche.com/roche_position_on_clinical_research.pdf">www.roche.com/roche_position_on_clinical_research.pdf</a><br><a href="http://www.roche.com/clinical_trials_policy_in_low_and_middle_income_developing_countries.pdf">www.roche.com/clinical_trials_policy_in_low_and_middle_income_developing_countries.pdf</a>  |

|                       |   |   |
|-----------------------|---|---|
|                       | Countries (2008)<br>– Roche Global<br>Position on Human<br>Subject Research<br>(2004) | <a href="http://www.roche.com/pages/downloads/sustain/pdf/poshumsubres.pdf">http://www.roche.com/pages/downloads/sustain/pdf/poshumsubres.pdf</a> |
| <b>Sanofi-Aventis</b> | – No publically<br>available guidance   |   |