

Country	Key Organizations	Legislation	Regulations	Guidelines
<b>INTERNATIONAL</b>				
<i>General</i>	<p>1. International Committee of the Red Cross (ICRC): <a href="http://www.icrc.org">www.icrc.org</a></p> <p>2. Office of the United Nations High Commissioner for Human Rights (OHCHR): <a href="http://www.ohchr.org/english/">http://www.ohchr.org/english/</a></p> <p>3. World Health Organization (WHO): <a href="http://www.who.int/en/">http://www.who.int/en/</a></p> <p>4. Council for International Organizations of Medical Sciences (CIOMS): <a href="http://www.cioms.ch/">http://www.cioms.ch/</a></p> <p>5. United Nations Educational, Scientific, and Cultural Organization, Bioethics Program (UNESCO): <a href="http://portal.unesco.org/shs/en/ev.php-URL_ID=1372&amp;URL_DO=DO_TOPIC&amp;URL_SECTION=201.html">http://portal.unesco.org/shs/en/ev.php-URL_ID=1372&amp;URL_DO=DO_TOPIC&amp;URL_SECTION=201.html</a></p> <p>6. UNAIDS: <a href="http://www.unaids.org/en/default.asp">http://www.unaids.org/en/default.asp</a></p> <p>7. World Medical Association (WMA): <a href="http://www.wma.net/e/">http://www.wma.net/e/</a></p>	<p>ICRC:</p> <p>1. Geneva Convention Relative to the Treatment of Prisoners of War, Articles 13 and 130 (1950): <a href="http://www.icrc.org/Web/Eng/siteeng0.nsf/html/genevaconventions#a1">http://www.icrc.org/Web/Eng/siteeng0.nsf/html/genevaconventions#a1</a></p> <p>2. Additional Protocol I Relating to the Protection of Victims of International Armed Conflicts, Article 11 (1977): <a href="http://www.icrc.org/ihl.nsf/7c4d08d9b287a42141256739003e636b/f6c8b9fee14a77fdc125641e0052b079">http://www.icrc.org/ihl.nsf/7c4d08d9b287a42141256739003e636b/f6c8b9fee14a77fdc125641e0052b079</a></p> <p>OHCHR:</p> <p>International Covenant on Civil and Political Rights, Article 7 (1976): <a href="http://www2.ohchr.org/english/law/ccpr.htm">http://www2.ohchr.org/english/law/ccpr.htm</a></p>		<p>WHO:</p> <p>1. Operational Guidelines for Ethics Committees that Review Biomedical Research (2000): <a href="http://whqlibdoc.who.int/hq/2000/TDR_PRD_ETHICS_2000.1.pdf">http://whqlibdoc.who.int/hq/2000/TDR_PRD_ETHICS_2000.1.pdf</a></p> <p>2. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants: <a href="http://whqlibdoc.who.int/publications/2011/9789241502948_eng.pdf">http://whqlibdoc.who.int/publications/2011/9789241502948_eng.pdf</a></p> <p>3. Ethical issues in Patient Safety Research: Interpreting Existing Guidance (2013): <a href="http://apps.who.int/iris/bitstream/10665/85371/1/9789241505475_eng.pdf">http://apps.who.int/iris/bitstream/10665/85371/1/9789241505475_eng.pdf</a></p> <p>CIOMS:</p> <p>1. International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002)</p> <p>2. International Guidelines for Ethical Review of Epidemiological Studies (2009)</p> <p>UNESCO:</p> <p>Universal Declaration on Bioethics and Human Rights (2005)</p> <p>UNAIDS:</p> <p>Ethical Considerations in Biomedical HIV Prevention Trials (2007): <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>WMA:</p> <p>Declaration of Helsinki (2013): <a href="http://www.wma.net/en/30publications/10policies/b3/index.html">http://www.wma.net/en/30publications/10policies/b3/index.html</a></p>
<i>Drugs and Devices</i>	<p><i>Drugs</i></p> <p>1. International Conference on Harmonization (ICH): <a href="http://www.ich.org/">http://www.ich.org/</a></p>			<p>ICH:</p> <p>E6 Good Clinical Practice: Consolidated</p>

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	2. World Health Organization (WHO): <a href="http://www.who.int/en/">http://www.who.int/en/</a>			Guidance (1996): <a href="http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html">http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html</a>  WHO: 1. Handbook for Good Clinical Research Practice (GCP): Guidance for Implementation (2002): <a href="http://whqlibdoc.who.int/publications/2005/924159392X_eng.pdf">http://whqlibdoc.who.int/publications/2005/924159392X_eng.pdf</a> 2. Operational Guidance: Information Needed to Support Clinical Trials of Herbal Products (2005)
	<i>Devices</i>			
	1. Global Harmonization Task Force (GHTF): <a href="http://www.ghtf.org/">http://www.ghtf.org/</a> 2. International Standards Organization: <a href="http://www.iso.org/iso/home.html">http://www.iso.org/iso/home.html</a>			GHTF: 1. SG5/N2R8: 2007 Clinical Evaluation: <a href="http://www.ghtf.org/documents/sg5/sg5_n2r8_2007final.pdf">http://www.ghtf.org/documents/sg5/sg5_n2r8_2007final.pdf</a> 2. SG5(WD)/N3R6: 2007 Clinical Investigations: <a href="http://www.ghtf.org/documents/sg5/sg5_n3_2010.pdf">http://www.ghtf.org/documents/sg5/sg5_n3_2010.pdf</a> 3. GHTF SG5/N1R8: 2007 Clinical Evidence – Key Definitions and Concepts: <a href="http://www.ghtf.org/documents/sg5/sg5_n1r8_2007final.pdf">http://www.ghtf.org/documents/sg5/sg5_n1r8_2007final.pdf</a>  ISO: Clinical Investigation of Medical Devices for Human Subjects -- Good Clinical Practice. Standard Number 14155:2011: <a href="http://www.iso.org/iso/iso_catalogue/catalogue_ics/catalogue_detail_ics.htm?csnumber=45557">http://www.iso.org/iso/iso_catalogue/catalogue_ics/catalogue_detail_ics.htm?csnumber=45557</a>
<i>Research Injury</i>	1. International Conference on Harmonization (ICH): <a href="http://www.ich.org/">http://www.ich.org/</a> 2. Council for International Organizations of Medical Sciences: <a href="http://www.cioms.ch/">http://www.cioms.ch/</a>			ICH: E6 Good Clinical Practice: Consolidated Guidance, Section 5.8 (1996): <a href="http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html">http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html</a>  CIOMS: International Ethical Guidelines for Biomedical Research Involving Human Subjects, Guideline 19 (2002)
<i>Privacy/Data</i>	World Medical Association:			Declaration on Ethical Considerations

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<i>Protection</i>	<a href="http://www.wma.net/e/index.htm">http://www.wma.net/e/index.htm</a>			Regarding Health Databases (2002): <a href="http://www.wma.net/en/30publications/10policies/d1/index.html">http://www.wma.net/en/30publications/10policies/d1/index.html</a>
<i>Human Biological Materials</i>	1. World Health Organization: <a href="http://www.who.int/en/">http://www.who.int/en/</a> 2. International Air Transport Association (IATA): <a href="http://www.iata.org/">http://www.iata.org/</a> 3. International Society for Biological and Environmental Repositories (ISBER): <a href="http://www.isber.org">http://www.isber.org</a>			WHO: 1. Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens (1997): <a href="http://www.who.int/csr/emc97_3.pdf">www.who.int/csr/emc97_3.pdf</a> 2. Guideline for Obtaining Informed Consent for the Procurement and Use of Human Tissues, Cells, and Fluids in Research (2003): <a href="http://www.who.int/reproductive-health/hrp/tissue.pdf">http://www.who.int/reproductive-health/hrp/tissue.pdf</a>  IATA: Infectious Substances and Diagnostic Specimens Shipping Guidelines (2005)  ISBER: Best Practices for Repositories I: Collection, Storage and Retrieval of Human Biological Materials for Research (2005)
<i>Genetic Research</i>	1. Human Genome Organization (HUGO): <a href="http://www.hugo-international.org/">http://www.hugo-international.org/</a> 2. UNESCO Bioethics Program: <a href="http://portal.unesco.org/shs/en/ev.php-URL_ID=1372&amp;URL_DO=DO_TOPIC&amp;URL_SECTION=201.html">http://portal.unesco.org/shs/en/ev.php-URL_ID=1372&amp;URL_DO=DO_TOPIC&amp;URL_SECTION=201.html</a>			HUGO: 1. Statement on the Principled Conduct of Genetic Research (1996) 2. Statement on DNA Sampling: Control and Access (1998) 3. Statement on Gene Therapy Research (2001) 4. Statement on Human Genomic Databases (2002)  UNESCO: 1. Universal Declaration on the Human Genome and Human Rights (1997) 2. International Declaration on Human Genetic Data (2003)
<i>Embryos, Stem Cells, and Cloning</i>	International Society for Stem Cell Research: <a href="http://www.isscr.org/">http://www.isscr.org/</a>			Guidelines for the Conduct of Human Embryonic Stem Cell Research (2006): <a href="http://www.isscr.org/guidelines/ISSCRhESCguidelines2006.pdf">http://www.isscr.org/guidelines/ISSCRhESCguidelines2006.pdf</a>